Politechnika Wrocławska

DOCTORAL DISSERTATION

Methodology of assessing and reducing the risk of development of tooling in automotive industry

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1. Contents

List of important abbreviations

ACEA	European Automobile Manufacturers Association
AHP	Analytic Hierarchy Process
AIAG	Automotive Industry Action Group
ALARP	As Low As Reasonably Practicable
ANP	Analytic Network Process
AP	Action Priority
APQP	Advanced Product Quality Planning
AQ	Assessment Question
AS/EN 9100	Aerospace Quality Management Standard
BOM	Bill of Materials
C	Cost (limitation)
CAD	Computer-Aided Design
CAD/CAM	Computer-Aided Design / Computer-Aided Manufacturing
CE	Conformité Européenne (European Union conformity marking)
CI	Consistency Index
CR	Consistency Ratio
CW	Calendar Week
DEC	Development Center
DFA	Design for Assembling
DFM	Design for Manufacturing
DFMEA	Design Failure Mode and Effects Analysis
DOE	Design of Experiments
ERP	Enterprise Resource Planning
EU	European Union
FMEA	Failure Mode and Effects Analysis
FMEA - MSR	Monitoring and System Response
FMECA	Failure Mode, Effects and Criticality Analysis
FOT	First-Of-Tool
H	High
HACCP	Hazard Analysis and Critical Control Points
HAZOP	Hazard and Operability Study
HRA	Human Reliability Analysis
HY	Hybrid

IATF 16949	Automotive Quality Management Standard
ISO	International Organization for Standardization
ISO 13485	Medical Devices - Quality Management Systems
ISO 14971	Medical Devices - Risk Management
ISO 22301	Business Continuity Management
ISO 22400	KPIs for Manufacturing Operations
ISO 27005	Information Security Risk Management
ISO 31000	Risk Management - Guidelines
ISO 31010	Risk Assessment Techniques
ISO 9001	Quality Management Systems
ISO/TR 31004	Guidance for Implementation of ISO 31000
IT	Information Technology
KPI	Key Performance Indicator
L	Low
LOPA	Layer of Protection Analysis
M	Medium
MATLAB	Matrix Laboratory
MCA	Multi-Criteria Analysis
MCDM	Multi-Criteria Decision Making
MFMEA	Machine Failure Mode and Effects Analysis
MSR	Monitoring and System Response
NPD	New Product Development
O	Occurrence
OEM	Original Equipment Manufacturer
ORG	Organisational
PDCA	Plan Do Check Act
PFMEA	Process Failure Mode and Effects Analysis
PIA/DPIA	(Data) Privacy Impact Assessment
PLC	Product Life Cycle
PLM	Product Lifecycle Management
PM	Project Manager
PML	Project Manufacturing Leader
PP	Production Plant
PPAP	Production Part Approval Process
PPE	Product and Process Engineer

Q	Quality (limitation)
QL	Qualitative
QT	Quantitative
QFD	Quality Function Deployment
R&D	Research & Development
RC	Risk Category
RF	Risk Factor
RI	Input Risk
RL	Risk Limitation
RPN	Risk Priority Number
RSTG	Stage Risk
RT	Tooling Recovery Time
RTSTG	Total Stage Risk
S	Severity
STG	Stage
SWIFT	Structured What-If Technique
SWOT	Strengths, Weaknesses, Opportunities and Threats analysis
T	Timing (limitation)
TA	Tooling Availability
TAI	Tooling Auto Integration
TB	Tooling Buyer
TBT	Tooling Back to Toolmaker
TC	Tooling Cost
TCRR	Tooling Cost Revenue Ratio
TCTS	Tooling Commissioning at Tool Supplier
TD	Tool Design
TDA	Tooling Design Approval
TDFTR	Tooling Design First Time Right
TDRC	Tooling Design Compliance
TDRN	Tooling Design Reviews Number
TE	Tooling Engineer
TECH	Technical
TETPT	Tooling Entry to Production Time
TF	Tooling Flexibility
TFOT	Tooling First-Off-Tool Parts

TFTR	Tool First Time Right
TII	Tool Innovation Index
TLT	Tooling Lead Time
TM	Tooling Manufacturing
TMC	Tooling Maintenance Cost
TMP	Tooling Modifications Possibility
TPC	Tooling Process Consistency
TPM	Total Productive Maintenance
TPO	Tooling Purchase Order
TQ	Tooling Quality
TRfP	Tooling Readiness for Production
TRTP	Tooling Repair Time and Parts
TS	Tool Specification
TSASE	Tooling Supplier Aftersales Service Evaluation
TSC	Tooling Specification Clarity
TSDeE	Tooling Supplier Design Evaluation
TSDoE	Tooling Supplier Documentation Evaluation
TSFTR	Tooling Specification First Time Right
TSR	Tooling Specification Readiness
TSRN	Tooling Specification Reviews Number
TSTE	Tooling Supplier Timing Evaluation
TSTHE	Tooling Supplier Tool Handover Evaluation
TSU	Tooling Supplier
TSwDC	Tooling Specification with Design Compliance
TTR	Tooling Transport
TUS	Tooling User Satisfaction
VA/VE	Value Analysis / Value Engineering
VaR	Value at Risk
VDA	Verband der Automobilindustrie
VH	Very High
VL	Very Low

Glossary

Term	Definition
Advanced Product Quality Planning **(APQP)**	Automotive framework aligning phases and quality tools across product and process development
Aggregation	Combining normalized R_I and R_{STG} using a multiplicative operator to capture interaction between baseline and stage-specific exposure
Assessment Question **(AQ)**	A standardized prompt used by experts to evaluate a risk factor consistently within the RC/RL framework
Bill of Materials **(BOM)**	Structured list of components/materials defining the product/tooling build
Calendar Week **(CW)**	Time reference used in plans (e.g., CW7, CW9) to denote target weeks
Decision gate (**Gate**)	A formal review point where documented evidence is evaluated to authorize progression, deferment, or redesign
Decision thresholds **(L/M/H)**	Fixed bands for R_I, R_{STG}, R_{TSTG} that define go/hold/stop logic and required mitigation intensity
Dominance **(RC/RL)**	A materially higher contribution of a given RC or RL relative to alternatives, guiding focus of mitigation actions
Enterprise Resource Planning **(ERP)**	Integrated enterprise system used for planning and coordinating resources/data
Expert Group	Formally appointed panel of qualified, neutral experts providing linguistic ratings, validations and judgments for the methodology.
Fuzzification / Defuzzification	Conversion from linguistic to numeric values / from fuzzy to crisp scores for decision use
Fuzzy RPN	Defuzzified numerical summary derived from linguistic expert ratings and membership functions, used to prioritize R_I and R_{STG}.
IATF 16949	Automotive quality management system standard required across the supply chain
Input Risk **(RI)**	Fixed, project level exposure arising from baseline conditions; remains constant across stages
Linguistic scale	A qualitative verbal scale (e.g., Very Low, Low, Medium, High, Very High) used for expert ratings prior to numerical conversion
Linguistic scale level	A single verbal category within the linguistic scale (e.g., 'High').
Linguistic scale rating	An expert’s assignment of a linguistic scale level to a risk factor (e.g., 'Quality = High')
Membership function **(MF)**	The function mapping linguistic scale levels to numerical values (commonly triangular or trapezoidal) for fuzzification/defuzzification
Milestone	Measurable evidence confirming completion of a stage and readiness to proceed to the next one; milestones are assessed at gates
Normalization	Mapping heterogeneous risk scores to a common bounded scale prior to aggregation and thresholding.
Plan Do Check Act **(PDCA)**	Continuous improvement loop integrated with the development model and feedback to next iterations

Product and Process Engineer **(PPE)**	Owns product concept and process parameters relevant to tooling scope
Product Lifecycle Management **(PLM)**	System supporting product data, changes, and lifecycle governance
Production Part Approval Process **(PPAP)**	Formal approval of parts and processes for serial production
Production Plant **(PP)**	Site that validates, accepts, and operates the tool in serial production
Production Tooling	Specialized tools/fixtures (e.g., moulds, dies, jigs) used to manufacture components in serial production.
Production Tooling Development	Stage-based process: specification → design → manufacturing → commissioning → start-up; integrated with APQP/PDCA.
Project Manager **(PM)**	Manages schedule, budget, and cross functional coordination
Project Manufacturing Leader **(PML)**	Ensures industrialization at the target plant and coordinates plant side readiness
Risk	The effect of uncertainty on objectives, typically expressed through sources, events, likelihood, and consequences
Risk Category **(RC)**	An organizing group for risk factors sharing origin/mechanism (e.g., Technical, Organisational)
Risk Factor **(RF)**	Condition or dependency that may generate or intensify exposure within RC/RL boundaries; operationalized via AQ.
Risk Limitation **(RL)**	A boundary/constraint perspective used to evaluate exposure (e.g., Cost, Timing, Quality)
Stage Gate	A structured development model divided into stages, each separated by formal decision gates that control progression
Stage Risk **(RSTG)**	Variable, stage specific exposure that can change as the process progresses
Tooling Buyer **(TB)**	Manages sourcing and commercial negotiations for tooling
Tooling Commissioning at Tool Supplier **(TCTS)**	Verification, testing, and qualification of the tool at the supplier prior to shipment
Tooling Cost **(TC)**	Investment cost of tooling; ranked as highly important in AHP weighting
Tooling Design Approval **(TDA)**	Formal review/validation/sign off of the tool design prior to manufacturing
Tooling Engineer **(TE)**	Leads tooling from specification through supplier acceptance and handover to production
Tooling First Off Tool Parts **(TFOT)**	Initial conforming parts produced to confirm readiness before full ramp up
Tooling Lead Time **(TLT)**	End to end duration from nomination to production of first parts at the plant
Tooling Manufacturing **(TM)**	Activities between design approval and completion of the tool fit for production trials
Tooling Quality **(TQ)**	The tool's ability to deliver specification compliant, stable production performance
Tooling Supplier **(TSU)**	Designs and manufactures the tool; supports commissioning/start up
Tooling Transport **(TTR)**	Time from dispatch from supplier to arrival at the production plant, including logistics and customs
Total Stage Risk **(RTSTG)**	The decision indicator combining R_I and R_{STG} (normalized, multiplicative aggregation) used for gate decisions

Summary

The dissertation develops and validates a stage-based methodology of assessing and reducing the risk of development of tooling in automotive industry. The method answers gaps identified in literature and practice: the lack of unified definitions and a standardized, APQP/PDCA-aligned tooling-development model; the absence of tooling-specific metrics; and the limited operationality of generic risk tools such as FMEA in innovative, multi-dependency projects.

The contribution of the dissertation is the following.

First, the thesis introduces author's definitions of production tooling and the tooling-development process and proposes an integrated, stage-based model synchronized with product development (APQP/PDCA), distinguishing core tooling stages and supporting activities. Second, it establishes a measurement basis: experts selected 42 and then 8 critical metrics, with AHP-based weights confirming the dominance of Tooling Cost (TC), Tooling Lead Time (TLT) and Tooling Quality (TQ). Third, it presents a hybrid methodology of assessing and reducing the risk of development of tooling in automotive industry that structurally decomposes risk into Risk Categories (RC) and Risk Limitations (RL: cost, timing, quality), separates Input Risk (R_I) from Stage Risk (R_{STG}), and converts unified linguistic expert judgements into numbers via fuzzy logic, yielding a bounded Total Stage Risk (R_{TSTG}) with fixed L/M/H thresholds for gate decisions and clear ownership of mitigation. Fourth, it delivers operational artefacts (workflow, AQ templates, RC/RL matrices, thresholds, decision logic) enabling repeatable deployment.

The methodology of assessing and reducing the risk of development of tooling in automotive industry is demonstrated on a simple hand-press example and validated industrially at Autoneum Poland Sp. z o.o. on a representative project (Proj_1). Results show that Total Stage Risk (R_{TSTG}) supports comparable, decision-ready stage-level risk assessment; RC/RL distributions increase interpretability and guide proportionate actions; and the fixed thresholds enable transparent APQP gate decisions (go/hold/stop). The thesis discusses limitations (e.g., choice of multiplicative aggregation, expert-based threshold calibration) and outlines directions for future work (empirical threshold calibration, sensitivity analyses of membership functions, and IT integration with PLM/ERP). Overall, the approach provides a missing bridge between risk analysis and gate decisions in tooling development, improving prioritisation and aligning decisions with TC/TLT/TQ constraints.

Streszczenie

W rozprawie opracowano i zweryfikowano opartą na etapach metodykę oceny i redukcji ryzyka w rozwoju oprzyrządowania produkcyjnego w przemyśle motoryzacyjnym. Metodyka ta wypełnia luki zidentyfikowane w literaturze i praktyce: brak ujednoliconych definicji i znormalizowanego modelu rozwoju oprzyrządowania, zgodnego z metodami APQP/PDCA; brak specyficznych dla danego oprzyrządowania metryk; oraz ograniczoną operatywność ogólnych narzędzi do oceny ryzyka, takich jak FMEA, w innowacyjnych, wielowarstwowych projektach.

Wkład rozprawy jest następujący.

Po pierwsze, rozprawa przedstawia autorskie definicje oprzyrządowania produkcyjnego i procesu jego rozwoju oraz proponuje zintegrowany, oparty na etapach model zsynchronizowany z rozwojem produktu (APQP/PDCA), rozróżniając główne etapy oprzyrządowania i działania wspomagające. Po drugie, ustala podstawę pomiaru: eksperci wybrali 8 krytycznych metryk, z wagami opartymi na AHP potwierdzającymi dominację Kosztu Oprzyrządowania (TC), Czasu Przejścia Oprzyrządowania (TLT) i Jakości Oprzyrządowania (TQ). Po trzecie, prezentuje metodykę, która strukturalnie rozkłada ryzyko na kategorie ryzyka (RC) i ograniczenia ryzyka (RL), oddziela ryzyko wejściowe (R_I) od ryzyka etapu (R_{STG}) i przekształca zunifikowane lingwistyczne oceny eksperckie na liczby za pomocą logiki rozmytej, uzyskując ograniczone całkowite ryzyko etapu (R_{TSTG}) ze stałymi progami L/M/H dla decyzji bramkowych i jasną odpowiedzialnością za łagodzenie ryzyka. Po czwarte, dostarcza artefakty operacyjne (przepływ pracy, szablony AQ, macierze RC/RL, progi, logikę decyzyjną), umożliwiając powtarzalne wdrożenie.

Metodyka została zaprezentowana na dydaktycznym przykładzie prasy ręcznej, a następnie przetestowana przemysłowo w Autoneum Poland Sp. z o.o. w reprezentatywnym projekcie (Proj_1). Wyniki pokazują, że R_{TSTG} wspiera porównywalną, gotową do podjęcia decyzji ocenę ryzyka na poziomie etapu; rozkłady RC/RL zwiększają interpretowalność i kierują proporcjonalnymi działaniami; a stałe progi umożliwiają transparentne decyzje bramkowe APQP. W rozprawie omówiono ograniczenia (np. wybór agregacji multiplikatywnej, kalibrację progów opartą na ekspertach) i nakreślono kierunki dalszych prac (empiryczna kalibracja progów, analizy wrażliwości funkcji przynależności oraz integracja IT z systemami PLM/ERP). Podsumowując, podejście to stanowi brakujący pomost między analizą ryzyka a decyzjami dotyczącymi bramek w rozwoju narzędzi, usprawniając priorytetyzację i dostosowując decyzje do ograniczeń TC/TLT/TQ.

Introduction and scope of the dissertation

Risk is present in all facets of human existence, from routine daily choices to complex decisions made at operational or strategic levels within organizations and entire economies. It significantly influences the stability and outcomes for individual people as well as social groups. As an intrinsic part of actions and decision-making processes, risk permeates nearly every sphere of life, making it a subject of interest for researchers and experts across many disciplines, such as engineering, medicine, economics, law, and finance. Nevertheless, because of this diversity, risk is interpreted in various ways depending on the context, and its definitions often reflect domain-specific perspectives. This leads to a wide range of classifications, assessment methods, and measures used to quantify its impact. The fact that the term “risk” is so widely applied results in different understandings and often ambiguous interpretations.

In the literature, risk is often framed as the likelihood of unplanned events occurring at a given time and place with potentially adverse consequences. Risk cannot be eliminated, as it is inherent in life and business, especially in the context of uncertainty, variability of the environment, and the temporal constraints. Its incidence increases with the passage of time, the multiplicity of elements affecting the course of a risky event [1], [2]. In project execution, risk is a potential threat that can affect the achievement of project objectives, such as delays, budget overruns, failure to meet quality requirements or planning errors. A common assessment approach models risk as the product of consequence magnitude and probability of occurrence [3], [4]. This approach is insufficient for complex, dynamic, and multidimensional projects characterized by temporal variability, data uncertainty, interdependent risks, and cross-functional factors.

The global automotive industry faces intense competitive pressures that necessitate transformative initiatives. Regulatory targets - such as the EU phase-out of new internal-combustion-engine vehicle registrations by 2035 - together with advances by Asian manufacturers, are reshaping strategic alignments among OEMs and suppliers. Parts manufacturers operate in volatile markets that demand rapid delivery of innovative and cost-effective solutions. The proliferation of model variants, the shortened product development cycles, and the continuous introduction of facelifts, substantially contributes to the escalating complexity of new project implementation. Production tooling has grown increasingly sophisticated, requiring adaptation to multiple vehicle architectures, while simultaneously balancing the imperative for enhanced product quality against the need to minimize tooling development costs and cycle times. Such focus presents a critical challenge for research and development organizations tasked with the design and manufacturing of OEM specific tooling solutions. To survive in today's highly uncertain automotive industry market, where the number of cars produced is becoming difficult to forecast and potential profits are uncertain, every project is a competitive battle, and opportunities for new business are becoming increasingly difficult to predict. At the same time, development organizations require highly skilled human resources working under enormous time pressure and focused on cost reduction, while developing product concepts that have never existed before. All these innovative activities generate uncertainty and, consequently, increased risk, the ravages of which can affect the development project itself, and every stage of the product's lifecycle. In today's difficult development realities, the ability to assess the risk of undertaken activities by development companies is becoming not only a necessary condition but, at the same time, increasingly difficult.

The automotive industry has been a key sector of the EU economy for decades, contributing to its growth, innovation, and economic prosperity. Playing a significant role in industry, it generates 8% of the EU's added value, 6.1% of total employment for nearly 14 million people, and directly in the production of motor vehicles, nearly 2.6 million people (ACEA, 2025) [5]. The German automotive industry plays a particularly important role in this context, accounting for nearly 35% of EU car production in 2024, with 3.94 million cars (ACEA, 2025) [5].

The development of production tooling plays an important role in the automotive industry, in the value chain between product development and mass production, enabling the development of new products and their efficient, cost-effective production on a large scale. At the same time, the German industry related to the development of production tooling is struggling with the problems of profound market changes, which generate the need for significant investment in the area of research and development and its effective risk management [6].

Also, presented in the Figure 1, the analysis of data on the number of publications containing the terms "product development" and "risk management" found in the Web of Science environment shows a continuous interest in the topic of product development in the last decade and a growing trend in the literature on issues related to risk management.

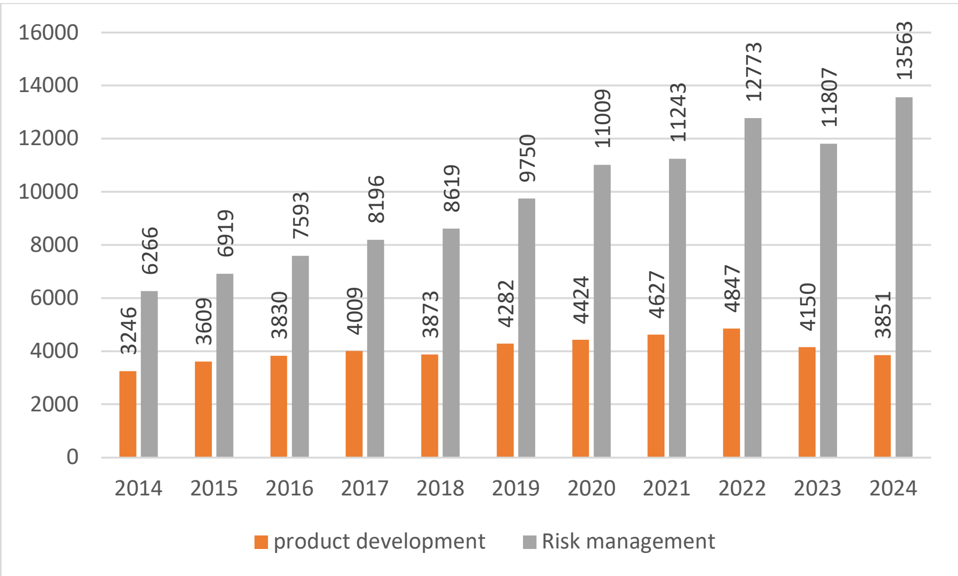


Figure 1 Number of publications in the Web of Science databases from 2014 to 2024 for the keywords "product development" and "risk management"

Organizations protect themselves against risk by implementing various strategies and management actions that aim to minimize the negative effects of potential threats. To this end, they implement standards aimed, among others, at assessing operational risk and require the same from their business partners. The most used for this purpose are

ISO standards and their variations, dedicated to specific environments. The ISO 9001:2015 standard introduces the key concept of risk-based thinking where risk management is the fundamental foundation for creating a quality management system [7].

The high level of interest in risk management methods by various organizations, as mandated by ISO 9001, does not reflect the availability of risk analysis methods. ISO 9001 emphasizes only the need to identify, assess, and control risk as an integral part of the quality management system. Organizations therefore have the freedom to choose appropriate methods and tools to implement these activities, ensuring that these processes are properly documented and effective. The following standards and guidelines are considered to be the most appropriate in order to tackle this problem [8]:

- ISO 31000:2018 Risk management – Guidelines.
- ISO Guide 73:2009 Risk management – Vocabulary.
- IEC/ISO 31010:2019 Risk management – Risk assessment techniques.
- ISO/TR 31004:2013 Risk management – Guidance for the implementation of ISO 31000.

The widely used Failure Mode and Effects Analysis (FMEA) method, first used in the USA in 1949, although today required by automotive suppliers meeting the requirements of the IATF 16949 standard, finds only fragmented application in risk assessment, for example, in product design assessment (DFMEA) or process assessment (PFMEA), but not in a comprehensive view of the entire product development process of automotive suppliers. At the same time, the FMEA method has numerous drawbacks, including time-consuming, subjective nature, inability to integrate with organisational knowledge bases, and the lack of a cost-based approach. Some improvements to the method presented in the AIAG & VDA manual published in 2019, while mitigating some of the drawbacks (e.g., the method for estimating the RPN risk priority number), still do not qualify it for use in complex development process systems of R&D companies. Other methods found in the literature, such as event tree analysis or the Ishikawa diagram, are usually limited to a single issue or are too mathematically complex, time-consuming, or require significant simplification to be used in more complex processes such as comprehensive product development or the development of production tooling without the ability to estimate risk for the entire development process and to address the value of this process caused by risk.

Meanwhile, automotive suppliers continue to grapple with challenges stemming from the COVID-19 pandemic, the semiconductor crisis, inflation, rising raw material costs, and the shift toward alternative propulsion systems and sustainable development. The current situation poses significant threats to suppliers who are slow to adopt the latest consumer trends and regulations [6]. All these events generate a significant need for risk management adopted to market realities. At the same time key general standards related to risk management as well as automotive industry-specific standards that are widely respected by automotive experts, were issued in a different context and do not meet the requirements of the automotive industry's current challenges.

The methodology of assessing and reducing the risk of development of tooling in automotive industry proposed in this dissertation enables risk consideration across key process elements, including organisational resources, product-design choices, materials and production technologies, tooling suppliers, and related dependencies. Furthermore, risk assessment at all stages of product development will reduce the uncertainty of decision-making, which will ultimately translate into faster implementation of new solutions. In the methodology of assessing and reducing the risk of development of tooling in automotive industry developed for the purposes of this doctoral thesis, the development process is divided into individual stages. Risk is operationalized in two layers: as a fixed, input risk that remained unchanged throughout the analysed process of production tooling development, and as a variable risk associated with an individual process stage, which could change during the process. Importantly, risk was categorized according to its category and constraints, significantly facilitating the identification of root causes and improving the ability to prevent risks by focusing activities on a given category. After collecting data on the analysed process of production tooling development, risk analysis activities were developed in the context of the time required for development activities carried out at each pre-defined stage of the production tooling development process. For the analysed process of production tooling development, risk was presented in terms of the additional time required to complete individual stages of the analysed process for selected product variants characterized by similar time resulting from the implementation of individual tasks within the stages.

The dissertation consists of the following parts:

Product and Tooling Development (Chapter 1)

The evolution of NPD models (Stage-Gate, V-model, PLC, Agile) is presented, along with the nature of APQP in automotive, and the role of tooling in industrialization. Production tooling is defined and a tooling development model integrated with APQP/PDCA is proposed (Figure 5), which distinguishes core and supporting stages and introduces an improvement loop (PDCA). Tooling development metrics are identified and systematized; weights are derived confirming the dominance of 3 of the metrics.

Risk and Risk Assessment Methods (Chapter 2)

Risk definitions and classifications are summarized, standards (ISO 31000/31010) and risk assessment techniques are discussed, highlighting the limitations of FMEA in innovative and multi-layered projects (subjectivity, effort, poor integration with time/cost). This necessitates a step-by-step, decision-making tool embedded in tool development metrics.

Problem, objective, questions/hypotheses, input, and justification (Chapter 3)

The problem was formulated: the lack of a dedicated, comparable methodology for assessing tool development risk synchronized with NPD/APQP. The objective, questions, and hypotheses were defined, and scientific and practical input was gathered. The methodology of assessing and reducing the risk of development of tooling in automotive industry was also justified and the gaps from Chapters 1 and Chapter 2 were closed.

Risk Assessment and Reduction Methodology (Chapter 4)

The original methodology of assessing and reducing the risk of development of tooling in automotive industry is presented in four phases:

- Process preparation.

Risk analysis preparation (RC/RL, R_I and R_{STG} identification, AQ construction).

- Calculation (linguistic scales, fuzzification/defuzzification, fuzzy-RPN for R_I and R_{STG}, R_{TSTG} determination).

- Analysis and minimization (RC/RL distribution matrices, L/M/H thresholds, action plan with ownership).

A flow chart for the implementation of the methodology of assessing and reducing the risk of development of tooling in automotive industry is shown (Figure 11). The example of a hand-press is used to illustrate the stages of the methodology.

Industrial validation (Chapter 5)

The methodology of assessing and reducing the risk of development of tooling in automotive industry was applied in the real-world environment of Autoneum Poland Sp. z o.o. decomposing the process into STG1–STG6 (specification, supplier nomination, design, manufacturing, supplier acceptance, and plant commissioning). A panel of experts and project data (Proj_1) were used. The resulting R_I, R_{STG}, and R_{TSTG} were classified according to thresholds, and the RC/RL matrices indicated dominance which was directly translated into corrective actions with owners and deadlines.

1. Product and production tooling development

This chapter presents the product development process and its integration with production tooling development. It discusses the most important models and methods for managing product development, such as Stage-Gate, V-model, APQP, and their application in the automotive industry. Key factors influencing process efficiency, including cost, lead time, and quality, are highlighted. Special attention is given to the role of tooling in product industrialization, its classification, technological trends, and the lack of a standardized model for production tooling development in the literature. The chapter concludes with an analysis of metrics for assessing the tooling development process and their significance for risk management.

Nowadays modern manufacturing and development organizations are experiencing intense pressure resulting from dynamic market changes, evolving consumer preferences, and the need to minimize costs and shorten the cycle of introducing innovative products [9], [10]. Customer expectations with their increasing purchasing power, legal regulations, emphasis on recycling combined with energy efficiency requirements, growing quality requirements, flexibility, and modularity of production tooling [11] are subjected to constant change [12]. End users demand new products' multifunctionality, competitive pricing, extended service life, and optimized energy consumption [13]. Ongoing globalization forces manufacturers to effectively implement better and cheaper products. Government organizations are raising their requirements for sustainability [14]. Such dynamically changing circumstances of introducing a new product to the market force alterations in the perspective on the product development process. Studies indicate that approximately 40% of newly developed products fail at the development stage, 1 in 7 products achieve commercial success, and 13% of organizations report that their new product commercialization efforts deliver the expected profits [15], [16], [17].

Interest in structured product development methodologies has steadily grown since the late 1960s [18], [19]. Foundational work by Booz, Allen & Hamilton (1968) initiated systematic analysis of the new product development process, identifying key stages, decision points and organisational challenges [20]. It was when the process of creating new products began to be systematically analysed, key stages and challenges associated with it were identified. Important events in upcoming years were among others, the introduction of project management methodologies, was extensive like the development of marketing research or the implementation of computer-aided design [21]. All of them contributed to the dynamic development of this field in the following decades. Despite the rich theoretical and practical achievements, the topic of shaping new products remains open and is an area of continuous adaptation to changing market, technological conditions and implementation of innovative solutions [22].

Literature trends also indicate a steady increase in publications related to sustainable development, reflecting its growing influence on product strategy, material selection and manufacturing technologies. Figure 2 illustrates the number of publications indexed in the Web of Science and Scopus databases that include the keyword "sustainable development," broken down by year.

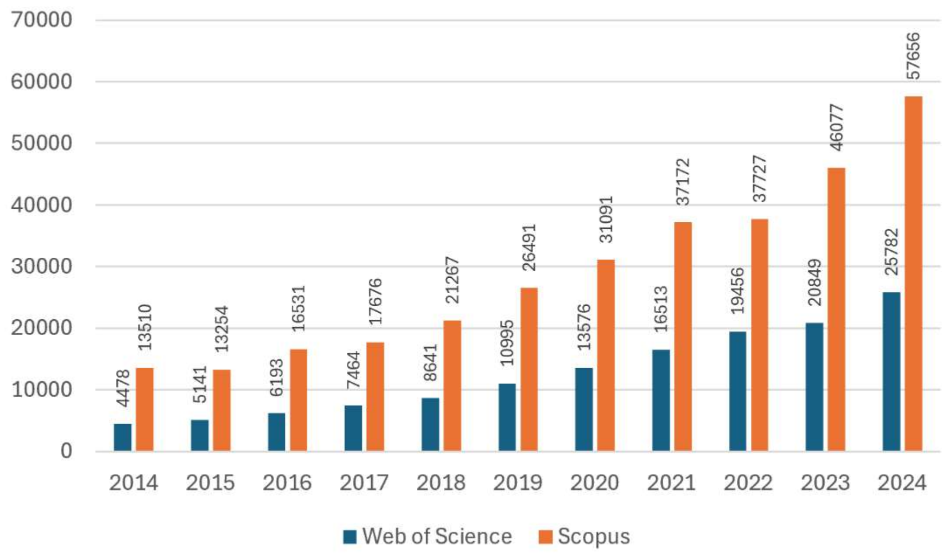


Figure 2 Number of publications in the Web of Science and Scopus databases from 2014 to 2024 for the keyword "Sustainable development"

Sustainable development, understood as a multidimensional concept integrating economic, environmental, and social objectives, originated in the 1970s and has since evolved into a central theme in contemporary manufacturing and product development strategies. Today, manufacturers increasingly focus on how new products can contribute to sustainability goals, resource efficiency and responsible consumption, which directly influences product design, material selection and production technologies.

1.1 Product development

The definition of product development covers a wide range of activities, from identifying and selecting new product opportunities, through concept development and evaluation, technical and marketing aspects, go-to-market strategies, to modifications and updates to existing products. It also involves strategic and organisational issues related to creating and managing teams, creating marketing plans, solving problems in the product development process, retiring the product, and evaluating the development process to ensure its success [23], [24].

The literature provides many definitions of the product development process as a comprehensive process of creating a product that has never been on the market before, but also the process of improving an existing product. In both cases, it aims to meet customer needs, increase the company's competitiveness, and achieve business sustainability [25], [26], [27], [28].

Numerous definitions of product development concept exist. Table 1 summarizes those found in the literature.

Table 1 Review of selected product development definitions

Definition of the concept of product development	Source
"a continuous process of evaluating the product and implementing the new solution, includes new product introduction based on the requirement of the market and consumers"	[29]
“process of taking a new idea and turning that idea into an actual product, available on the market”	[30]
“set of activities beginning with the perception of a market opportunity and ending in the production, sale, and delivery of a product “	[24]
“consists of the activities of the firm that lead to a stream of new or changed product market offerings over time. This includes the generation of opportunities, their selection and transformation into artifacts (manufactured products) and activities (services) offered to customers, and the institutionalization of improvements in the new product development activities themselves”	[31]
“process of creating new products with added or different characteristics in comparison with existing products for the sake of offering additional benefits to consumers and maintaining or increasing the probability of the product’s provider”	[32]
“a broad field of endeavor dealing with the planning, design, creation, and marketing of a new product”	[33]
“series of interrelated decisions, actions and activities carried out by an enterprise in which the need to develop a new product of an economic organization is satisfied by introducing a new product to the market”	[19]
“the development of new products is essential for a company, supported by technical progress, which enables the creation of products that meet customer needs to a greater extent than do current products”	[34]

Analysis of the definitions presented in Table 1 reveals several recurring characteristics of product development: its multidimensional and iterative nature, orientation toward customer value, dependence on cross-functional collaboration, and reliance on innovation. Notably, none of the definitions explicitly refer to the role of production tooling, despite its critical role in industries with complex, large-scale manufacturing, such as automotive.

According to the definitions presented in Table 1 and the conclusions presented, for the purposes of this work **product development can be defined as a complex, interdisciplinary process involving the creation of a new product or the improvement of an existing one that responds to market needs and customer preferences very often fostered with integrated production tooling development process**. This process involves generating and implementing innovative ideas related to the design, implementation, and commercialization of a product, integrates activities aimed at increasing a company's competitiveness, achieving business goals, and ensuring sustainable development underlining importance of the process of tooling development.

Thus, the product development process, despite the fact that it has gained a recognized place in the literature on the subject and since certain tendencies and general patterns can be observed, is not presented in a way that maintains full consistency with the way it proceeds and the possibility of its efficient and complete monitoring. However, its conceptual frameworks are undoubtedly very helpful in understanding and dealing with the specific features of this process [15], [16], [35], [36], [37], [38].

Given the diversity of product development definitions, organizations rarely follow identical development processes. Differences in product complexity, organisational culture, market environment and technological capabilities lead to the creation of customized - and often costly - development models [17]. Effective development frameworks must, therefore, account for innovation costs relative to the value added by the product [17] and remain aligned with the organization's strategic and operational context [39].

The evolution of product development models can be divided into six key stages, each corresponding to shifts in market expectations and technological progress, as presented in Table 2. Initially, simple linear models dominated the 1960s and 1970s. Subsequent developments introduced iterative cycles and process-improvement mechanisms. In the 1990s, the focus shifted toward cross-functional collaboration and reducing time-to-market. In the early 21st century, flexibility, adaptability to changing conditions, and the use of process simulations became increasingly important [40]. More recent approaches emphasize agility, continuous customer feedback, digital-technology integration, and the involvement of broader user communities in the product development process [37], [41].

The fundamental distinction among product development models divides them into sequential models, where stages follow one another in a linear order and integrated models, in which phases overlap. Sequential models offer strong process control but tend to be inflexible and difficult to modify. In contrast, integrated models rely on interdisciplinary collaboration, enabling faster responses to changing conditions. Although they are more adaptable and better aligned with today's dynamic market environment, they are also more challenging to manage [42], [43], [44].

Table 2 Classification of new product development models. Source: author's own work based on [45], [40], [46]

Generation of the Model	Type of Model	Triggering Factor	Nature of Model
First / Second (1960s until early 1970s)	Simple linear model	Technology and science, including: "push" models driven by technology and "pull" models driven by market	The supply-demand model aligns market needs with technological capabilities, ensuring innovations meet both technical feasibility and commercial appeal
Third (early 1990s)	Nonlinear combined model	Assumes interaction of various elements and feedback of information	Driven by rapid socio-economic changes, rising competitiveness, and shorter product life cycles, this model divides development into interconnected phases, leveraging all technological possibilities to meet evolving consumer needs

Fourth (21st century)	Parallel, integrated model	Successes and experiences of Japanese firms, and the development of marketing and sales departments for marketing communication needs	Emphasizes internal integration and collaboration with suppliers and customers through strategic alliances and partnerships
Fifth (current times)	Feedback model	Based on integrated network connections	Driven by IT development, modern management methods, and growing inter-enterprise agreements, this feedback model links successive innovation phases in a continuous cycle and promotes open innovation through knowledge sharing for rapid market adaptation
Sixths (upcoming model)	Open Innovation	Increasing globalization, technological advancement, user involvement, digital transformation	A dispersed model built on open collaboration, crowdsourcing, partnerships, and IP sharing, enabling rapid adaptation through external knowledge and networks while boosting innovation speed and diversity

In practice, hybrid models dominate, blending elements of both classifications to improve flexibility, adaptability, speed, and team-technology integration [37], [41].

Along with the evaluation of product development models, there was an evaluation of product development methods, the most common of which in the literature include:

- Total Design - Total Design - introduced by Stuart Pugh - emphasizes the holistic integration of all elements of the product development process, with a strong focus on the user perspective. The method incorporates comprehensive market analysis, conceptual development, engineering considerations, manufacturing aspects, and commercialization activities to ensure that the final product meets customer needs and achieves market success [37].
- Concurrent Engineering involves carrying out development activities in parallel to shorten lead times and reduce costs. It requires well-coordinated, interdisciplinary teams and emphasizes early identification of potential issues through effective communication among engineers, suppliers, and customers [47], [48].
- Integrated Product Development is a comprehensive method of managing the entire development process, emphasizing integration, collaboration, and the coordinated use of tools such as Concurrent Engineering, Value Analysis/Value Engineering (VA/VE), and Design for X (e.g., DFA, DFM) [49], [50].
- Dynamic Product Development method relies on continuous iteration, rapid feedback cycles, and active involvement of teams and management. This approach enables organizations to adapt quickly to changing market and technological conditions, enhancing innovation, effectiveness, and overall competitiveness [51], [52].
- The Stage-Gate method structures product development into a sequence of stages separated by decision gates. Each stage includes defined tasks and deliverables, while each gate functions as a formal review point where

decisions on continuation, modification, or termination of the project are made [47].

- Incremental Development, widely used in software engineering, divides the process into successive increments, each delivering a functional subset of the final system. This enables early testing, iterative improvements, and gradual refinement of the product, reducing the risk of major errors and enhancing flexibility in adapting requirements. The method is commonly applied within Agile and Scrum frameworks [53] [54].
- The Product Life Cycle (PLC) presents the entire lifespan of a product - from initial concept to market withdrawal - and can be applied as a product-development model. It provides a comprehensive structure that spans need analysis, concept generation, design, testing, production, and after-sales support [26].
- Quality Function Deployment (QFD), a method that translates customer requirements into specific design and process characteristics, supporting prioritization of development activities and ensuring alignment with customer expectations [55].
- The Spiral method structures product development into successive iterative cycles ("spirals") that include risk analysis, prototyping, and testing. Widely used in software engineering, it is well-suited for complex and highly innovative projects [56].

To select the most appropriate product development method for the implementation of this dissertation, they were evaluated according to key criteria that reflect important aspects of the development process as presented in Table 3. The selection of criteria was briefly justified as follows:

- Flexibility and adaptability – the ability to quickly respond to changing requirements and market conditions in a dynamic market, technological environment and market conditions is crucial. A flexible method allows for modifications at various stages of the project, minimizing the risk of the product not meeting customer or market needs but also enables the introduction of changes resulting from actions focused on risk reduction.
- Degree of control and risk – the ability to monitor and minimize project risks. In large, complex projects, especially in high-risk industries (e.g., automotive), it's important to monitor progress and manage potential risks. The method should enable effective process control and timely risk identification and mitigation.
- Implementation time and costs – the time and cost efficiency of the process, enabling its implementation in a way that is competitive with today's market requirements.
- Effectiveness in error detection and elimination – the ability to quickly detect errors allows for their early elimination and avoids unnecessary costs of fixing errors later.
- Suitable for innovative and complex projects – the ability to work on high-risk and technically advanced projects and effectively support the processes of experimentation, adaptation and gradual development, which are crucial in projects with high uncertainty and high technological complexity.

- Possibility of integration with the process of development of production tooling.

The evaluation scale used in Table 3 includes four levels of applicability:

- Very High – maximum applicability.
- High – strong performance.
- Medium – moderate effectiveness.
- Low – limited applicability.

Table 3 Evaluation of selected product development methods. Source: author's own work

Method	**Flexibility & Adaptability**	**Control & Risk Management**	**Time & Cost Efficiency**	**Error Detection & Prevention**	**Suitability for Innovation & Complex Projects**	**Tooling Development**
Total Design	Medium	High	High	High	Yes	High
Concurrent Engineering	High	High	Medium	Medium	Yes	High
Integrated Product Development	High	High	Medium	Medium	Yes	High
Dynamic Product Development	High	Medium	Low	High	Yes	High
Stage – Gate	**High**	**Very High**	**Medium**	**High**	**Yes**	**Very High**
Incremental Development	High	Medium	Low	Medium	Yes	High
Product Life Cycle (PLC)	High	High	Medium	Medium	Yes	Very High
Quality Function Deployment (QFD)	Medium	Medium	Low	Low	Yes	Medium
Spiral Method	High	High	Medium	High	Yes	Medium

The analysis presented in Table 3 indicates that the Stage-Gate method stands out as the most comprehensive and effective, particularly in relation to the objectives of this dissertation. It is characterized by a high degree of control and clearly defined decision points, which enable effective progress monitoring and risk minimization while maintaining flexibility in the execution of individual stages. A more detailed description of this method is provided in the following section.

Stage-Gate method was developed by Robert G. Cooper [57], [58], [59]. The term refers to a structured product development process divided into stages separated by decision gates that serve as key evaluation points. The method is particularly suitable for organizations that internally finance their product development projects.

Figure 3 illustrates the Stage-Gate approach, including the key stages of the method.

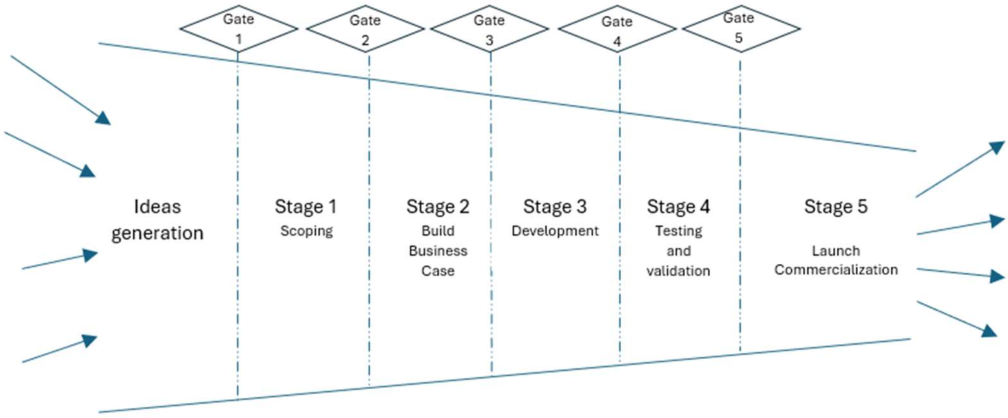


Figure 3 Stage – Gate product development approach. Source: author's own work based on [58]

The individual stages of the Stage-Gate method are described below:

- Idea generation focuses on collecting and visualizing concepts for new products using tools such as brainstorming, trend analysis, customer insights, employee suggestions, and partner feedback. The objective is to develop a portfolio of potential product ideas for further evaluation.
- Scoping develops an initial understanding of the product concept through preliminary analysis of market conditions, opportunities, and potential challenges.
- Business case assesses the product's profitability and commercial potential through detailed market, technical, technological, economic, and risk analyses.
- Development includes creating specifications, models, and documentation; selecting materials; conducting cost and logistics analyses; designing tooling; producing prototypes and initial series; and testing concepts.
- Testing and validation verify whether the product meets defined expectations and requirements through quality testing, user testing, and analysis of the resulting data.
- Launch involves final preparations for commercialization, production, marketing, and distribution.

After each stage, a decision is made whether the project should proceed, be modified, or be terminated.

A gate-based decision approach is also applied in the automotive industry; however, it is adapted to industry-specific requirements and supplemented with additional qualitative tools and guidelines. Automotive new product development processes are described in industry standards and manuals issued by major automotive manufacturer groups. The most significant among these are the VDA standards, primarily used by German manufacturers, and the AIAG manuals, widely applied by manufacturers in the United States and Japan. According to the AIAG manuals [60], the management system for developing new products and modifying existing ones is based on the Advanced Product Quality Planning (APQP) approach [63]. APQP, developed in the

1980s by General Motors, Ford, and Chrysler to meet the needs of the United States automotive industry, has since evolved into a core requirement of the IATF 16949 standard [61], which is required throughout the automotive supply chain and is typically implemented by suppliers in accordance with OEM Customer-Specific Requirements. IATF 16949 is an international automotive quality management standard that defines requirements for the development, production, and delivery of automotive products. A characteristic feature of automotive product development processes is the overlap of project phases and the extensive use of quality tools to assess progress. This approach enables proactive planning and assurance of product quality throughout the development process. Figure 4 presents the five main phases of the APQP approach used in automotive product development.

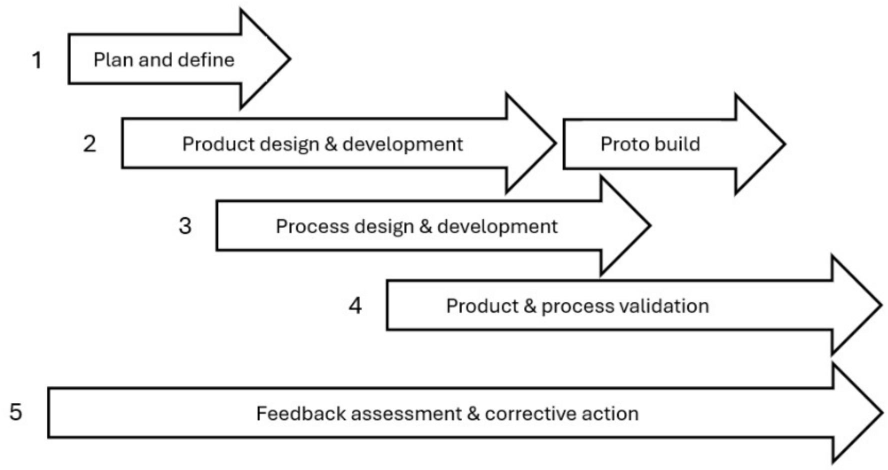


Figure 4 Model of APQP implementation. Source: author's own work based on [62]

The five phases of the APQP approach, illustrated in Figure 4, are described in detail below:

1. Plan and define.
   In this phase, project objectives, customer requirements, activity scope and required resources are defined. A project schedule is developed, and key quality and technical criteria are identified. The purpose of this phase is to establish the foundation for effective product and process development. Key activities include analysing customer and market requirements, determination of technical and quality requirements, identification of risks and potential problems, development of a project plan and schedule.

2. Product design and development including proto build.
   This phase focuses on developing and verifying the product design. It considers customer requirements, functionality, durability, safety, and regulatory compliance. Technical drawings, CAD models, specifications, and prototypes are created and tested in this phase. Key activities include design creation and approval, engineering analyses, requirements verification, prototype testing and validation, and documentation of technical specifications.

3. Process design development.
   This phase focuses on developing a production process capable of ensuring repeatability and quality compliance. Activities include creating production plans, selecting machines and tooling, defining control processes, and training personnel. Key activities include defining process flows, station layouts, and parameters; conducting process FMEA; planning process controls and training personnel.

4. Product and process validation.
   This phase verifies that the production process is capable of consistently producing parts that meet defined requirements. Validation activities include conducting P-FMEA, performing process trials, and producing initial verification batches. Key activities include conducting production trials (e.g., PPAP), analysing results, identifying potential issues, verifying and approving the control plan, and documenting outcomes and approvals.

5. Feedback assessment and corrective action.
   This phase comprises the evaluation of production performance, including full-scale production runs, process monitoring, and continuous improvement of both the product and the manufacturing process. Regular evaluations ensure that the product continues to meet customer requirements. Key elements of this stage include monitoring process and product quality, analysing control and inspection data, implementing corrective and preventive actions, and ensuring continuous improvement.

The APQP approach used in automotive new product development offers several benefits, including improved product quality, reduced delivery times, increased customer satisfaction, cost reduction, and enhanced process control. It provides a structured framework for systematic process management. Although APQP is widely used and recognized as an effective method for ensuring product quality in the automotive industry, it also presents several limitations, including [63], [64], [65]:

- High cost and labour intensity require substantial human, financial, and time resources, which poses a particular challenge for smaller organizations.
- Extensive documentation requirements may increase administrative burden and raise the likelihood of errors.
- Limited flexibility, which may restrict innovation during new product development.
- A tendency toward routine execution, leading to activities driven by established patterns rather than creative problem-solving.
- The requirement to provide master samples and the pressure to produce FOT (First-of-Tool) parts significantly earlier than required for the initial vehicle build.
- Time-consuming and outdated documentation preparation processes.
- The need for extensive coordination and communication between teams responsible for individual activities.

- Low effectiveness when risk analysis activities, such as FMEA, are performed inadequately.

When analysing the APQP approach in the context of production tooling development, each phase includes at least one task related to tooling, as summarised in Table 4.

Table 4 Tooling related tasks described in the APQP stages. Source: author's own work based on [63]

APQP Stage	Function	Tooling-related task
1. Plan and define	1.13 Capacity Planning	Organization capacity planning must include downtime related to completing required tooling, equipment and facility maintenance
2. Product design and development including proto build	2.10 New Equipment, Tooling and Facilities Requirements	The team should ensure that there is a process to determine that new equipment and tooling are capable and delivered on time. Facilities progress should be monitored to ensure completion prior to planned production tryout. Refer to the New Equipment, Tooling and Test Equipment Checklist in Appendix A-3
3.Product and process development	3.7 Process Instructions	The process instructions for standard operating procedures should be visible and should include set-up parameters such as machine speeds, feeds, cycle times, and tooling, and should be accessible to the operators and supervisors
4. Product and process validation.	4.1 Significant Production Run	The significant production run must be conducted using production tooling, production equipment, production environment (including production operators), production facility, production gages and production rate
5. Feedback assessment and corrective action	-	-

Each APQP stage is supplemented with an appendix in form of checklists which "are provided as a guide to assist the organization in verifying the APQP process to ensure completeness and accuracy" [63]. All tasks from the appendixes related to production tooling are presented in Table 5.

Table 5 Tooling related tasks described in the APQP appendixes. Source: author's own work based on [63]

APQP Stage	Appendix	Point in the appendix	Question
2. Product design and development including proto build	A-2 Design Information Checklist	1b	Does the design require special tooling?
		24	Is the method of checks/tooling/and testing equipment equivalent to the final processing location?
	A-3 New Equipment, Tooling, and Test Equipment Checklist	2b	Have lists been prepared identifying (Include all sub-tiers) new tooling?
		3b	Have acceptance criteria been agreed upon and documented per customer requirements for: (Include all sub-tiers) new tooling?
		4	Will a preliminary capability study be conducted at the tooling and/or equipment manufacturer?
		7a	Is a preventive maintenance plan complete for equipment and tooling? Critical tooling and machine parts need a min/max inventory level - long lead-time parts?
		9	Are setup instructions for new equipment and tooling complete, understandable, and in work instruction format?
		18	Has the PFMEA been comprehended and incorporated into tooling and equipment design?
	A-9 Sourcing Checklist	28	Are specialized tooling or fixtures required for this program?
		29	Does the supplier have in-house tooling/pattern-making capability?
		75	Does the supplier have all the necessary machinery, tooling and equipment for product realization?

The analysis of the APQP approach presented in Table 4 and Table 5 in the context of production tooling development highlights in each phase as follows:

- Phase 1 - considering downtime in capacity planning.
- Phase 2 - ensuring on-time delivery of new tooling and its monitoring.
- Phase 3 - ensuring tooling availability.
- Phase 4 - conducting tests using the target tooling.

At the same time, from the perspective of the production tooling development process, the APQP exhibits several limitations:

- Lack of a clearly defined production tooling development process and the absence of explicit control mechanisms.
- No formal division of the tooling development process into distinct stages, nor its alignment with corresponding product development phases.
- Absence of an iterative framework for development and validation of production tooling.
- Risk analysis for the tooling development process is performed only in Phase 3, which is too late to effectively mitigate early design-related risks.
- Lack of guidelines supporting cost and time optimisation during the tooling development process.
- No guidelines for assessing tooling performance throughout the development phase.
- Absence of tooling-related considerations within risk factors, DFMEA, and product/process quality-assessment checklists.

On this basis, it is possible to confirm the deficiencies in the literature on the subject in the context of the defined process of production tooling development. As the development of such a model is essential for the objectives of this dissertation, the following section (1.2) defines the production tooling development process and proposes a dedicated model integrated with the broader new product development framework.

1.2 Production tooling development

Production tooling comprises highly specialized, one-of-a-kind technical systems that fundamentally shape manufacturing performance; their innovation and maturity directly condition the capability of the entire production system [66]. In their common forms - moulds, dies, punches, casting tools and cutting dies - tooling constitutes the core of mass and large-scale production, especially in automotive, but also in medical, aerospace, pharmaceutical, electronics and textile industries [67]. By directly interacting with the workpiece, tooling determines the part's shape, stiffness, dimensional accuracy, and surface structure [68]. Tooling condition is pivotal for processes such as moulding, stamping, cutting, punching, cold/hot forming, casting, injection moulding, and spraying, among others. The development and fabrication of prototype and serial tooling are among the most time- and cost-intensive phases of new product development [69].

In serial production, the role of production tooling is critical: production readiness, engineering changes, cleaning, preventive maintenance and wear monitoring directly affect part quality. While maintenance traditionally conducts repairs and inspections, many firms establish dedicated tooling units for changeover and operational readiness. Some still underprioritize tooling despite its centrality to production stability and quality [70], [71].

Although one-piece tools exist, a typical tool consists of upper and lower halves whose working surfaces account for part shrinkage, operating temperature and technological tolerances. Key functional components include mounting interfaces; guidance systems, stop blocks; media connectors; transport and handling fixtures, fixation elements, thermal insulation, and tool-specific systems (ejectors, venting, part-transfer).

The literature provides few precise definitions of "tooling" in the mechanical engineering context. Dictionary and sectoral sources define tooling as:

- Set of equipment used for a particular purpose [72].
- Set of tools used to manufacture a particular component, part, or assembly [73].
- Different kinds of products: moulds used to form different materials from polymeric to metallic ones; dies used to shear, stamp or forge metallic materials and jigs and fixtures used to position and hold parts in their working process or to control their dimensional conformity. As specific manufacturing devices, tools are positioned between the equipment goods and intermediate products [66].

For the purposes of this dissertation, production tooling denotes **a tool or set of tools and devices used to produce specific components or assemblies. This set can include various products, such as moulds for shaping different materials, dies for cutting, stamping or forging, and devices for precisely positioning and fixing parts during the production process, ensuring their dimensional consistency.**

These tools operate at the interface between production machines and semi-finished products, playing an important role in the production of components or assemblies.

Given the broad diversity of production tooling, its multiple definitions and varied applications, considering the limited literature available, a structured classification is necessary. For the purposes of this dissertation, the following general divisions are proposed:

- Tooling division by type of production: serial / prototype:

  Serial tooling to produce parts in quantities exceeding several hundred pieces [74], operating in serial conditions exposed to complicated loading conditions such as long term mechanical loads, temperature, friction or the action of chemicals (lubricants, release agents), most often made as castings or milled from blocks, sometimes from resins. Proto tooling to produce a few or several dozen pieces after production, the continuation of which most often requires repairs of the produced parts, made of resins, aluminium, plastic blocks or using additive techniques.

- Tooling division by type used materials: soft tooling / hard tooling:

  Soft tooling refers to less durable parts of the tooling, manufactured often in additive manufacturing technology; composite elements enable prototype or small-series production batches [75], [76], [77]. Made of materials such as rubber, silicones, or plastics, mainly used for prototyping and small-scale production, are characterized by short lead times and lower costs, limited durability and are not suitable for serial production. Hard tooling - made of durable materials such as steel or other metals. Intended for large-scale serial production, are characterized by high durability, accuracy and long service life; are more expensive to produce, but profitable for large production runs.

- Tooling division due to the way the main elements of the equipment are made: casting / block milling:

  Castings are often intended for lower load and lower efficiency tools, and when a pair or more of the same tools are made. Block tools for single or high-load tools [78].

- Tooling division due to the basic operation performed by the tool:

  Forming (metal, textile, TPU, cast), injection (polypropylene, polyamide, polyurethane), cutting (metal, fibres, plastic components, assembling), and a mix of them like one-step forming and cutting tool.

- Tooling division due to the material from which the main components of the tools are made:

  Metal / plastic / ceramic / composite tools depending on the properties of the materials, their hardness, weight, strength, shrinkage, abrasion resistance, resistance to high temperatures, resistance to chemical agents, workability or thermal conductivity [79], [80], [81].

- Tooling division due to the number of nests:

  One cavity / multi cavity [82] where the decision on the number of nests depends on factors such as the size of the produced parts, technological possibilities, size of the machines and their parameters, production volume, production cycle time, level of automation, ergonomic factors, etc. [83], [84].

- Tooling division due to the way the geometry of the part is created:

Geometry specific tooling where the shape of the part is directly transpired from the shape of the tools / generic tooling – where shape of part is generated as a result of some operations of the tool which shape is different than the shape of the part [68].

- Tooling division due to the number of operations performed in the tool:

One step / multi-step [85].

- Tooling division due to the method of operation:

Manual or automatic – depends on the manufacturing concept, tooling cost, production volume, complexity of operation and its duration, production flexibility.

In recent years, production tooling has undergone significant technological advancement enabled by multi-axis machining, advanced computer-aided design systems, new high-performance materials, including composites, and additive manufacturing technologies. As tooling technologies evolve, the literature increasingly highlights several emerging development directions:

- Sustainable tooling - driven by green manufacturing principles, emphasizes the use of recyclable materials, reduced energy consumption, lower tool mass, higher functional versatility, compact form factors and improved material efficiency (reduced BOM usage and scrap) [86], [87], [88].
- Rapid tooling - used primarily for prototype and low-volume tooling - relies on additive manufacturing techniques using polymers, metals, ceramics, and composites. Its key advantage over conventional tooling lies in significantly shorter lead times, as it allows direct production from digital models without labour-intensive assembly or adjustment operations [89], [90], [91].
- Tooling Industry 4.0 - transforms traditional tools into digitally integrated, sensor-enabled and data-driven systems, enhancing process speed, flexibility and manufacturing quality [92], [93], [94].
- Flexible tooling - supported by rapid tooling advancements and modular design - enables quick adaptation to new product variants, dimensional changes or modular architectures. It supports quick-change systems, compatibility with variable machine environments and reduction of manufacturing disturbances [95], [96], [97].

At the same time, increasing part complexity and the growing specialization of tooling have led to higher expectations regarding cost, lead time and quality. For example, in metal forming process, tooling costs may account for up to 20% of the total manufacturing cost of a component, depending on technological and quality requirements [98]. Consequently, manufacturing companies increasingly emphasize optimizing the tooling development process to reduce cost, shorten lead time and meet the growing technical and quality requirements.

The development of production tooling encompasses defining, designing, manufacturing and implementing dedicated tools such as moulds, dies, matrices, forming tools and auxiliary production devices typically for serial production [96]. Its purpose is to enhance reliability, efficiency and product quality while reducing manufacturing costs [27]. The tooling development process plays a decisive role in determining the quality, precision and manufacturing cost of the produced components [81]. Tooling development is typically integrated with the product development process and governed by time-to-market requirements, representing a substantial share of overall new product development costs [99]. Tooling development is frequently carried out within one or multiple organizations and involves collaboration with external partners and sub-suppliers.

The literature does not provide a unified definition of the production tooling development process. It is most commonly described through three stages [100], [101]:

- Planning - identification of tooling requirements, definition of functional properties and performance criteria ensuring alignment with product specifications (dimensional accuracy, surface quality, stiffness, etc.).
- Design - translation of planning requirements into detailed technical designs, considering ergonomics, manufacturability, material selection, component assembly and long-term maintainability.
- Manufacturing - fabrication of tooling using machining, casting, additive manufacturing and assembly processes, followed by testing and validation to confirm functional and quality compliance.

Another perspective on tooling development is provided by the 4P model [102] which distinguishes four phases aligned with the product lifecycle:

- Proof of concept - ideation, roadmap definition, product research, tooling feasibility buy-in.
- Product development - preliminary design, product engineering, DOE, DFMEA research, tooling readiness assessment.
- Production - tooling buy-off, serial manufacturing ramp up, implementation of tooling TPM.
- Product retirement - idle tooling management, production shutdown, decommissioning activities.

All of them consist of activities and deliverables matrix, followed within standard procedures tailored to the specificity of the product.

In the literature, tooling development is often addressed primarily through the lens of tool construction or improvement, with emphasis on automation [103], [104], simulation based design [105] or new tooling materials [106]. In addition, the tooling development process is shifting from traditional, experience-based methods toward more industrialized, efficient and knowledge-driven approaches involving sub-suppliers and dedicated R&D departments [107].

The **literature review did not identify any standardized definition for production tooling development**. Existing publications focus on selected aspects - such as technology-specific tooling design, structural analysis or manufacturing - but do not propose an integrated framework. The available literature focuses primarily on selected procedures related to tooling development, such as technology-specific tool design (e.g., injection moulding or sheet-metal forming), structural strength analysis [47] and manufacturing aspects. Other publications address tooling development through CAD-based methods, including dedicated software add-ons (e.g., Autodesk

Inventor) [108] or through die and tool-design automation systems incorporating basic AI-based functionalities [109].

The very limited literature regarding guidelines and models for the production tooling development process results in significant negative implications for organizations involved in tooling design and industrialization. These consequences include, but are not limited to problems such as:

- Lack of clearly defined process boundaries for tooling development.
- Insufficient organisational awareness of the strategic importance of tooling development.
- Development of own ineffective models and methods.
- Reliance on subjective decision-making in critical stages of tooling development.
- Absence of standardized guidelines for key activities, including decision-making criteria (e.g., supplier selection).
- Limited understanding of how effective tooling development influences order acquisition, profitability, product quality, and production efficiency.
- Lack of performance indicators capable of measuring and improving the tooling development process.
- Barriers to process efficiency, innovation, and continuous improvement.
- Critically, and directly relevant to this dissertation, the absence of a standardized framework prevents effective risk analysis within the tooling development process.

At the same time, production tooling plays a critical role in product industrialization. A properly executed tooling implementation process - from concept definition, through specification, design, manufacturing, and initial testing, to pilot production - significantly influences the success of product industrialization and project execution. For the purposes of this dissertation, the production tooling development process is **defined as a structured, stage-based sequence of activities that translates product and process requirements into a validated production toolset, covering specification, design, manufacturing, supplier commissioning, and start-up at the target plant, aligned with APQP/PDCA governance.**

Given the absence of a standardized model in the literature, this dissertation proposes an original production tooling development model, grounded in the above definition of the production tooling development process. The model serves as the foundation for developing a methodology of assessing and reducing the risk of development of tooling in automotive industry for assessing and reducing risks associated with tooling development.

The original production tooling development model developed for this dissertation (Figure 5) consists of three main sections, each represented by a distinct colour.

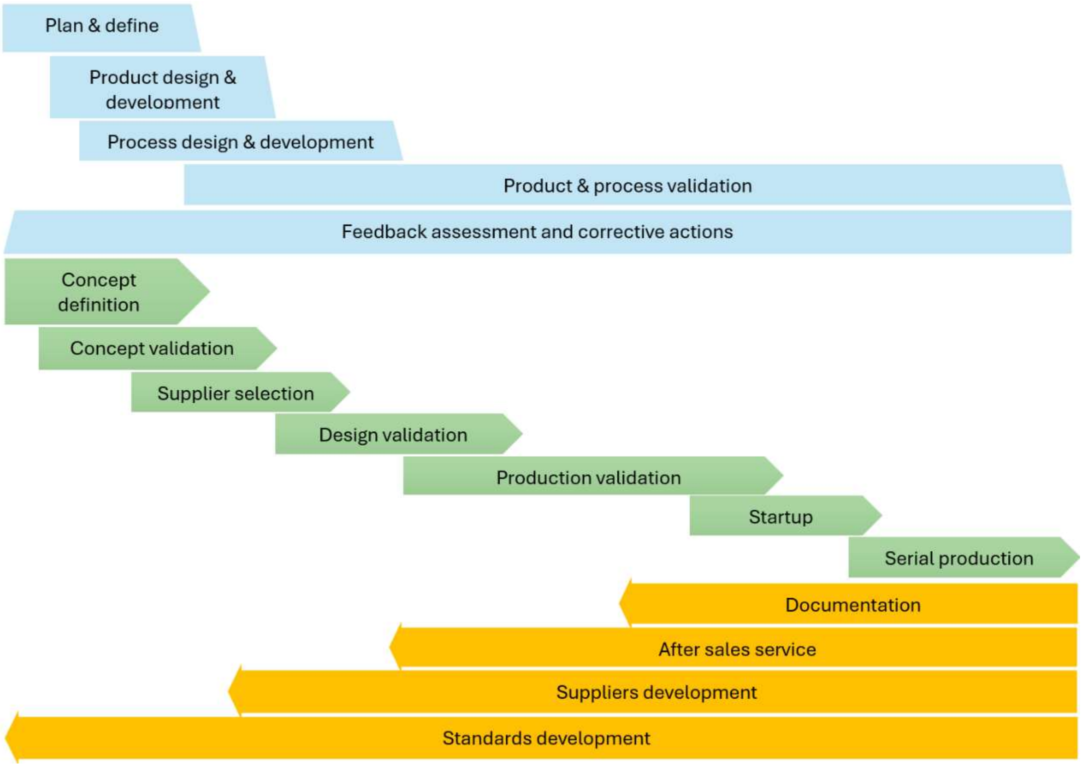


Figure 5 Production tooling development model. Source: author's own work

The blue section represents the new product development process based on the APQP approach, while the green section captures the core production tooling development process. The orange section illustrates the supporting activities that complement the core tooling development process. In this model, the new product development process - structured according to the Plan-Do-Check-Act (PDCA) cycle - acts as a reference framework for the tooling development process. Consequently, each phase of tooling development is synchronized with the corresponding stages of the new product development process. Additionally, the supporting activities and their outcomes can be incorporated throughout the tooling development sequence, with feedback integrated through a continuous improvement loop.

The proposed model integrates tooling development with APQP and PDCA in a manner not reflected in existing literature. It formalizes the relationship between product development stages, tooling-specific activities and supporting processes, addressing the current lack of standardization in tooling development workflows.

1.3 Production tooling development metrics and its assessment

In competitive manufacturing environments, effective implementation of production tooling is a decisive factor for project success and long-term performance throughout serial production. Organisational factors, management practices, planning effectiveness, team competence and, critically, tooling cost, delivery time and quality constitute key determinants of success [110], [107], [111].

The price of tooling is frequently a decisive criterion in supplier selection, representing a major competitive differentiator. In the automotive industry, tooling lead time is particularly critical, as it directly affects on-time delivery of initial production batches required for crash, climate, durability, and regulatory testing. Short lead times enable rapid responses to OEM design changes and delivery of additional parts in a short time, which is often the deciding factor in winning the project as OEM supplier. Although innovative technologies such as rapid tooling and additive manufacturing significantly accelerate tooling fabrication, their applicability in mass production remains limited due to durability and precision requirements. Consequently, serial tooling manufactured via conventional processes remains essential and irreplaceable for high-volume production [112].

Given its complexity, innovation intensity and importance for competitiveness, the tooling development process requires continuous monitoring and precise evaluation of progress. Each stage of tooling development requires detailed, specific information tailored to the customized nature of tooling processes, which is also essential for conducting effective risk analysis.

Literature on production process management highlights the importance of using measurable process metrics to capture the characteristics of production processes. These metrics enable effective assessment of efficiency, quality and maintenance performance, supporting process monitoring and optimization [113], [114], [115]. A properly configured set of metrics supports performance improvement by providing objective data for decision-making, deviation detection and prioritization of improvement actions, for example:

- Performance assessment - enables evaluation of how effectively production objectives are achieved by analysing performance indicators such as cycle time, output levels, and product quality, allowing early detection of deviations from the expected standards.
- Early problem detection and elimination - supports rapid identification of loss sources, such as high defect rates, machine downtime, or quality non-conformities, enabling timely corrective actions.
- Strategic and operational decision support - provides objective data for evidence-based decision-making regarding investments, process optimisation, and resource allocation, improving production efficiency and profitability.
- Targeted improvement actions - allows organisations to focus efforts and resources on the most critical areas, ensuring maximum added value and minimising waste.

ISO 22400 [116], [117] defines 34 fundamental KPIs that can be grouped into three main categories: production, quality, and maintenance. Examples of metrics include throughput rate, quality ratio, utilization efficiency, scrap ratio, finished goods rate, and equipment load ratio. ISO 22400 provides a comprehensive set of metrics for production performance assessment, but they require adaptation to industry-specific conditions and integration with modern IT systems to be fully effective [118]. Therefore, adapting production metrics to industry-specific conditions and validating their practical effectiveness is essential to ensure that they accurately reflect real manufacturing performance and support reliable decision-making.

Available studies do not show examples of indicators for the development of production tooling. In general, narrowing the issue to indicators accepted in production terminology with commonly used metrics such as availability, efficiency, productivity, capacity, and changeover times [119], which are insufficient from the point of view of dealing with the problem of risk analysis and reduction in tooling development processes. Therefore, for the purposes of this dissertation, it was found necessary to develop metrics for the production tooling development process, which in the next stage will be used to analyse the risk of this process.

To identify key metrics for the production tooling development process, a literature review was conducted to identify existing metrics in areas such as mass production, unit production, industrialization process, as well as new product development [116], [117], [118], [119], [120]. The review resulted in the identification of 91 relevant metrics. Although these metrics were not derived directly from tooling-specific literature, their process-oriented nature justified their inclusion in the initial assessment phase.

This expert selection and the entire evaluation process constitute the author's own original research conducted specifically for this dissertation. A total of 5 experts have been selected from a group of 55 people involved directly into process of product development in automotive industry. Three experts were engaged in the process of tooling development, while two had prior experience in tooling activities and were currently employed as product development engineers. All experts held higher technical degrees and possessed several years of professional experience and varying years of experience in different organizations. The list and basic information about the experts are presented in the Table 6.

Table 6 Experts list in the process of tooling development

Expert	**Education**	**Age**	**Professional experience in years**	**Number of years in the organization**	**Number of years in Tooling Engineer role**	**Number of toolsets followed**
Expert_1	higher technical	44	20	12	12	70
Expert_2	higher technical	41	16	8	8	50
Expert_3	higher technical	38	13	3	3	20
Expert_4	higher technical	36	10	4	2	15
Expert_5	higher technical	46	25	2	2	15

The initial list of 91 metrics was reviewed by the selected experts, who identified 42 metrics as directly relevant to the tooling development process. Subsequently, the experts evaluated the 42 metrics and selected 8 critical metrics considered essential for managing and assessing the risk within the tooling development process. The results of this selection are presented in the Table 7.

Table 7 Production tooling development metrics. Source: author's own work based on experts' evaluation and review of the literature [116], [117], [118], [119], [120]

No	Name	Code	Description	Critical
1	2	3	4	5
1	Operator Training	OT	Effectiveness of training of the tooling operators	No
2	Tool Innovation Index	TII	Application of innovative technical solutions	No
3	Tooling Flexibility	TF	Flexibility of the tool in the context of producing different product references	No
4	Tooling Readiness for Production	TRfP	Tool production readiness, including heating, cooling times and others	No
5	Tooling Auto Integration	TAI	The level of automation of the tool and its possibilities of integration with control and automation systems	No
6	Tooling Availability	TA	Production tool availability factor. Determines the time needed for the tool to be fully ready for production after a long standstill	No
7	Tooling Back to Toolmaker	TBT	Number of tools returns to the manufacturer for correction or improvement	No
8	Tooling Changeover Time	TCT	Tool change time on the machine	No
9	Tooling Commissioning at Tool Supplier	TCTS	Event of tools acceptance by the Tooling Engineer at tooling supplier facility	Yes
10	Tooling Cost	TC	Tooling cost, important for investment assessment and profitability	Yes
11	Tooling Cost Revenue Ratio	TCRR	The ratio of the cost of the tool to the revenue generated by production	No
12	Tooling Design Approval	TD	Tool design approval step	Yes
13	Tooling Design Compliance	TDRC	Conformity of the manufactured tooling with the design	No
14	Tooling Design First Time Right	TDFTR	Correctness of tool design in the first attempt	No
15	Tooling Design Reviews Number	TDRN	Number of tool design reviews before approval	No
16	Tooling Entry To Production Time	TETPT	Time from tooling design approval to full production readiness	No

17	Tooling Ergonomics Rating	TER	Assessment of tool ergonomics, impact on operator safety and comfort	No
18	Tooling First-Off-Tool Parts	TFOT	Event when first parts are produced out of tool	Yes
19	Tooling First Part Right	TFPR	Percentage of first parts produced that meet part quality requirements	No
20	Tooling First Time Right	TFTR	Percentage of tools that passed tests without requiring corrections	No
21	Tooling Lead Time	TLT	Tooling development time- from a project nomination until first parts production at dedicated plant	Yes
22	Tooling Maintenance Cost	TMC	Tool automation level and its integration capabilities with control and automation systems	No
23	Tooling Manufacturing Time	TM	Time needed from the moment of tool design approval to tool acceptance at toolmaker facility	Yes
24	Tooling Modifications Possibility	TMP	Number of possible modifications to a tooling during its life cycle	No
25	Tooling Planned Maintenance	TPM	Percentage of scheduled inspections and maintenance	No
26	Tooling Process Consistency	TPC	The impact of the tool on production repeatability and standardization.	No
27	Tooling Quality	TQ	The quality of tooling with the impact on the final quality of production.	Yes
28	Tooling Recovery Time	RT	The time it takes to restore a tool to full functionality after a breakdown or repair	No
29	Tooling Repair Time Parts	TRTP	Average repair time and spare parts availability	No
30	Tooling Rework Need	RN	Percentage of waste and defects after modification	No
31	Tooling Specification Clarity	TSC	Tooling specification written in a way that it is understood for all parties	No
32	Tooling Specification First Time Right	TSFTR	Tool specification compliance at first release	No
33	Tooling Specification Readiness	TSR	Tool specification ready for next process	No

34	Tooling Specification Reviews Number	TSRN	Number of tool specification reviews before approval	No
35	Tooling Specification with Design Compliance	TSwDC	Compliance of specifications and design with requirements.	No
36	Tooling Supplier Aftersales Service Evaluation	TSASE	Assessment of the supplier in context of support during tooling startup at the production plant	No
37	Tooling Supplier Design Evaluation	TSDeE	Assessment of the supplier in context of tool design reliability	No
38	Tooling supplier Documentation Evaluation	TSDoE	Assessment of the supplier in context of tool documentation quality	No
39	Tooling supplier Timing Evaluation	TSTE	Assessment of the tool supplier in terms of meeting deadlines	No
40	Tooling supplier Tool Handover Evaluation	TSTHE	Assessment of the supplier in context of tool readiness for tool handover at tool supplier facility	No
41	Tooling Transport	TTR	Time from tool dispatch from the toolmaker facility to availability at the production plant	Yes
42	Tooling User Satisfaction	TUS	Satisfaction of operators and production departments with the tool.	No

The eight selected metrics in Table 7 represent the most relevant dimensions of the tooling development process, according to the expert assessment. The remaining metrics from the initial list were retained only for the exploratory phase, as their qualitative character or limited measurability made them unsuitable for further analysis. In the next steps all the critical metrics will be described in more detailed way in order of its appearance in the Table 7.

Tooling Commissioning at Tool Supplier (TCTS)

Tooling commissioning comprises all activities associated with the verification, testing, and qualification of a completed tool before its shipment to the production facility. The process includes dimensional inspections, functional tests, documentation reviews, and performance assessments to confirm full compliance with the approved tooling design. Depending on the tooling type, commissioning may also involve complete assembly and disassembly, as well as static and dynamic testing. In the optimal scenario, commissioning is validated through the production of a trial batch confirming First-Off Tool Parts (FOT) feasibility and conformity with defined quality requirements.

The outcome of the commissioning process depends on several key factors [121], [122]:

- Tooling readiness to perform commissioning.
- Availability and completeness of tooling documentation, including declarations of incorporation, CE certificates, 2D/3D drawings, assembly documentation, schematics, and maintenance instructions.
- Capabilities of the toolmaker's facility, including equipment availability and the ability to perform production trials in the required technology.
- Availability of raw materials for conducting commissioning tests.
- Availability of qualified personnel experienced in the specific production technology.
- Correct setup of all process parameters in accordance with the tooling specification.

Tooling Cost (TC)

Proper selection of the production concept, technology, and manufacturing approach - together with reasonable tooling cost, expected lifetime, resistance to operating conditions, reliability, and potential for modifications - determines whether the tool can contribute to competitive advantage and cost reduction across the manufacturing process [123].

Regardless of the applied production technology, tooling cost is shaped by several key parameters [73], [124]:

- Part complexity [65], [125]: higher geometric complexity, undercuts, tight tolerances, thin walls, or intricate features require more advanced tooling concepts, additional movable elements (e.g., sliders, vents), and often multi-axis machining, which increases manufacturing and operational costs.
- Tool material [81]: high-volume tools require durable, wear-resistant materials capable of withstanding elevated temperatures, pressure, and mechanical loads. Special process - dependent features may additionally increase material cost.
- Size of the part [81]: larger components require proportionally larger tools, which increases design effort, material usage, machining time, handling requirements, transportation needs and energy consumption, ultimately raising the total tooling cost.
- Material of the produced part: the material of the manufactured part influences tooling cost because of demanding process conditions - such as high injection pressure, abrasive fillers or corrosive material characteristics - may require dedicated tool steels and additional surface treatments (e.g., hardening, nitriding, chrome plating), increasing manufacturing effort and overall tool cost [47].
- Number of tool cavities: increasing the number of tool cavities improves production efficiency by enabling higher output per cycle, but simultaneously raises tooling complexity, machining workload and design requirements, which significantly increases the cost of the tool.
- Use of standard components [126]: applying standardised catalogue components - such as base plates, guiding systems or venting elements - reduces design complexity and shortens manufacturing time, which substantially lowers tooling cost.

- Tool finishing: requirements - such as mirror polishing, surface texturing or adaptation to specific production equipment - extend processing time and increase tooling cost.
- Part tolerance requirements [127]: tight dimensional tolerances require highly precise tooling and stringent process control, which increases machining difficulty and overall tooling cost.

Tooling Design Approval (TDA)

Tooling design approval refers to all activities required to finalize and approve the design of tooling before manufacturing can proceed [128]. It is time taken for the tooling design from its initial stage until the moment of tooling design is reviewed and approved. The timing of tool design approval is compared against the supplier's confirmed schedule and the internally planned timeline. It is closely monitored to prevent delays in the tooling manufacturing phase and to maintain the overall project schedule. Its completion confirms the possibility of starting the tooling production stage. Deviations in design validation time can extend the overall tool development timeline, impacting the ability to meet customer requirements and maintain overall project timing.

Tooling design acceptance can be impacted by the following factors [128], [129], [130]:

- Design changes and revisions, both customer (CAD data, tolerance requirements) and development team (changes or missing information in the tooling specifications).
- The readiness of the CAD model for tooling development - including completeness of tool surfaces and confirmed part feasibility - significantly affects the duration of the design acceptance phase.
- The use of modular, standardised solutions accelerates design validation by reducing the need for custom engineering and additional verification steps.
- Ambiguous, inconsistent or incomplete tooling specifications lead to rework and repeated design iterations, prolonging the design acceptance process.
- Technical challenges - especially when introducing new or unproven design solutions - often require additional engineering analysis, feasibility checks and design iterations, which extend the duration of the design acceptance phase.
- Limited functionality of CAD/CAM software, outdated design tools, or inefficient communication workflows significantly slow down modelling, verification and exchange of design data, prolonging the design acceptance stage.
- Failures revealed during prototype testing, or the need for corrective adjustments in early design stages lead to additional iterations, delaying final tooling design acceptance.
- Insufficient collaboration, whether between the customer (OEM) and the development team, or between the development team and the tooling supplier - leads to misaligned expectations, delayed feedback and extended design approval loops.
- Resource limitations - such as insufficient availability of skilled designers or overloaded engineering teams - slow down review cycles and extend the duration of the design acceptance phase.

- Regulatory and compliance requirements - such as mandatory conformity checks, documentation reviews or additional approval steps - extend the design validation process and increase the duration of tooling design acceptance.

Tooling First - Off - Tool Parts (TFOT)

TFOT reflects the tool’s ability to produce the first parts that meet all quality and dimensional requirements, confirming the tool's readiness for production before full production run. This metric measures the effectiveness of the tool run process, including the production of initial test batches under production conditions, while maintaining appropriate technological and quality parameters. The primary goal of TFOT is to validate whether the tool produces parts that meet specifications from initial production, minimizing the risk of defects, rework and downtime. It supports validation processes such as geometry, structure, mass, tightness, assembly, and process parameters. The TFOT metric is used to monitor and optimize the tool launch process, ensure the quality of the first manufactured parts, and support early detection and elimination of potential problems during the full production phase.

Tooling Lead Time (TLT)

Tooling lead time is a critical factor affecting production efficiency and the competitiveness of manufacturing organizations. Companies capable of reducing tooling lead time are more likely to secure new projects and respond effectively to customer demands, making lead time reduction a strategic driver in tooling development processes [131]. Reducing tooling lead time enables earlier production startup, greater flexibility in responding to design or volume changes, and faster new product introduction. However, excessive pressure to shorten lead time - if not properly managed - may compromise tooling quality or increase the risk of rework. This balance remains a critical challenge for the development companies as well as the tooling suppliers.

Tooling lead time is strongly influenced by tool complexity, component availability, supplier process efficiency, and external market conditions, all of which determine the overall duration of the development cycle [123]. Modern lead time reduction strategies include the use of rapid tooling [47], [132], and additive manufacturing [133], particularly effective in low-volume or prototype applications, as well as early feasibility assessments and the use of prototype tools to accelerate development.

Tooling lead time might vary depending on the following factors [130], [134]:

- A larger number of tool sets ordered within the same batch increases workload for design, machining and assembly, thereby extending overall tooling lead time.
- Engineer competence, workload and experience directly influence the speed and quality of decision-making during tooling development, thereby affecting total lead time.
- Organisational expertise in specific technologies, supported by efficient internal processes, shortens tooling development time by enabling faster problem-solving and reducing the need for iterative clarification.

- The duration of design preparation and the efficiency of the design approval process significantly influence total tooling lead time, especially in cases involving multiple review cycles or late design revisions.
- Suppliers with strong technological expertise and proven experience execute tooling projects more efficiently, reducing the likelihood of errors, rework and delays, and thereby shortening tooling lead time.
- Higher tooling complexity increases manufacturing difficulty and typically requires more extensive testing and validation, which prolongs the overall lead time of the tooling development process.
- Late concept or design changes significantly extend tooling lead time due to the need for re-engineering, updated tooling surfaces, repeated reviews and potential remanufacturing of components.
- Stringent quality requirements and tight tolerances necessitate more precise machining, extended measurement routines and additional iterations in validation, all of which increase tooling lead time.
- The selection of tooling materials affects lead time due to differences in machinability, required heat treatment, post-processing steps and availability in the supply chain.
- Using readily available standard components shortens tooling lead time by eliminating the need for custom manufacturing and reducing design and procurement time.
- Overly optimistic deadlines defined prior to purchase order placement may lead to schedule overruns, insufficient design validation, and increased risk of errors, ultimately extending tooling lead time.

Tooling modification lead time is particularly critical in the production of large components, where the cost of producing stock parts may exceed the cost of manufacturing a new tool [103]. Late design changes significantly increase the likelihood of extended tooling lead time due to the need for re-engineering, re-machining and repeated validation.

Tooling Manufacturing (TM)

Tooling manufacturing encompasses all activities performed between design approval and completion of the finished tool ready for high volume production. The process typically includes material procurement, machining, assembly, fitting and functional trials.

Factors that can influence tooling manufacturing include [135], [136]:

- Complexity of the tooling design: intricate geometries, conformal cooling channels, or integrated functionalities often extend manufacturing time due to sophisticated machining or additive manufacturing processes.
- The choice of manufacturing methods - such as CNC machining, electrical discharge machining (EDM), casting, additive manufacturing, heat treatment and specialised coating - determines the duration and sequencing of production activities, directly influencing tooling manufacturing time.

- Material selection: high-performance materials may require specialized processing or post-processing that impacts tooling production.
- Stringent precision and quality requirements - such as tight tolerances or advanced surface finish standards necessitate meticulous machining, extended inspection routines, and possible rework loops, all of which prolong tooling manufacturing time.
- Material and component availability within the supply chain significantly affects tooling manufacturing time, particularly in the case of long lead-time items or specialised components.
- The integration of advanced technologies - such as rapid tooling, digital manufacturing workflows or Industry 4.0 monitoring systems can shorten manufacturing time by streamlining process control, reducing manual interventions, and improving traceability.
- Testing and validation through prototype trials or initial production runs may reveal manufacturing issues requiring corrections or additional adjustments, which extend the tooling manufacturing timeline.

Tooling Quality (TQ)

Tooling quality is determined by material properties, tooling design, manufacturing precision, and process parameter settings, all of which directly influence surface quality, dimensional accuracy, and the mechanical and thermal stability of the tool during operation [137]. In hot stamping applications, part quality - such as stable material thickness, weight consistency, and improved tensile strength - can be achieved through the use of tooling materials offering high hardness, wear resistance and thermal conductivity [138].

Regardless of the technology of tooling, its quality depends on several important factors, such as [135], [136]:

- Clear and comprehensive tooling specifications define the tool's functional role, performance requirements, and design constraints, forming the basis for achieving high tooling quality.
- High dimensional accuracy and tight tolerance requirements necessitate the use of advanced machining technologies and precise process control to ensure consistent tooling quality.
- High quality tooling materials provide wear resistance, dimensional stability, and extended service life, ensuring consistent part quality and reducing repair-related downtime.
- Tooling must withstand demanding operating conditions such as high temperatures, chemical exposure, mechanical loads, and abrasive wear to maintain stable production parameters and ensure long-term quality.
- Process repeatability and stability require tooling that consistently produces parts meeting specifications throughout its lifespan, minimising deviations and reducing the need for process adjustments.
- Modular and adaptable tooling designs allow for upgrades, adjustments, and adaptation to evolving product requirements, helping maintain high production quality over time.

- High durability and wear resistance increase tooling lifespan, reduce the frequency of failures, and help maintain stable part quality during extended production runs.
- Compliance with industry standards and the use of certified catalogue components enhance tooling reliability and support consistent quality performance.
- The ability to perform quick repairs or retooling operations minimises downtime and helps maintain consistent production quality.
- Comprehensive tooling documentation enables accurate reproduction of non-standard components - such as customised cutting dies or interchangeable inserts - supporting maintainability and long-term tool quality.
- Tooling compatibility with different machine types increases operational flexibility and ensures consistent quality across varied production environments.

Tooling Transport (TTR)

Tooling transport time refers to the period between tool dispatch from the supplier and its arrival at the production facility. It includes all logistical operations - such as sea, air or land transport and customs clearance or import formalities. Transport time is a critical factor in production planning, tooling launch schedules, and risk management, as delays in delivery can disrupt project timelines and increase costs [139]. Extended transport times - particularly for overseas shipments - require proactive resource planning, safety stock allocation and contingency measures for customs or logistical delays [140]. Engineering changes or design errors identified during transport cannot be addressed until the tool reaches the production site, which may lead to schedule overruns and additional costs. Changing the transport method to speed up delivery, for example, from sea to air, generates a significant cost increase. All subsequent repairs or modifications are subsequently conducted through local (European) suppliers. Any post-delivery repairs or modifications are typically performed by local suppliers, which may involve additional coordination and cost implications. To provide a clear definition of the critical metrics for the production tooling development process, a concise summary was prepared and presented in Table 8.

Table 8 Production tooling development basic metrics and its short description

Tooling metric	Description
Tooling Commissioning at Tool Supplier (TCTS)	Tooling commissioning at the supplier site covers dimensional inspections, functional tests, documentation review, and performance checks to confirm readiness before shipment to the production plant
Tooling Cost (TC)	Tooling cost is driven by part complexity, tool material, part size, number of cavities, selected technology and product requirements (including tolerance and surface finish)
Tooling Design Approval (TDA)	Tooling design approval is the formal review, validation and sign-off of the tool design prior to manufacturing; its timing and quality affect both lead time and total cost

Tooling First-Off Tool Parts (TFOT)	Tooling first-off tool parts validate whether the tool produces specification-conform parts under near-production conditions, reducing the risk of rework and defects before full ramp-up
Tooling Lead Time (TLT)	Tooling lead time covers design, manufacturing and approval stages; shortening TLT improves competitiveness but requires maintaining quality standards to avoid rework and delays
Tooling Manufacturing (TM)	Tooling manufacturing comprises material procurement, machining, assembly, fitting, and trials; its duration depends on chosen technologies, tool complexity and quality requirements
Tooling Quality (TQ)	Tooling quality reflects precision, material selection, resistance to operating conditions, durability and design adaptability, ensuring stable and repeatable production performance
Tooling Transport (TTR)	Tooling transport time from supplier dispatch to arrival at the production site is critical for launch planning and schedule risk, particularly in overseas logistics

The subsequent step involved ranking the importance of the metrics listed in Table 8. This was achieved using the Analytic Hierarchy Process (AHP), a method widely applied in multi-criteria decision-making [141], [142], [143].

Determination of metric weights for the production tooling development process using the Analytic Hierarchy Process (AHP)

The Analytic Hierarchy Process (AHP), introduced by T.L. Saaty in 1980, is a structured method for multi-criteria decision analysis (MCDA). It is widely applied in diverse domains, including environmental management, economics, engineering and industrial decision-making [144]. AHP was identified as a suitable method for assessing and weighting the metrics of the production tooling development process. In this study, AHP was applied in a criteria weighting setup without alternative variants, focusing solely on the relative importance of the identified metrics.

Pairwise comparisons of the metrics listed in Table 8 were performed by the experts presented in Table 6 following the comparison guidelines provided in Table 9.

Table 9 Scale of comparison for the AHP method. Source: author's own work based on [145]

Definition	Intensity of importance
Equal importance	1
Moderate importance	3
Strong importance	5
Very strong importance	7

Extreme importance	9
Intermediate values for comparisons between these levels	2, 4, 6, 8

The scale in Table 9 assigns higher values to more important criteria. The principle of inverse preference also applies here, meaning that if the first element is more important than the second, then the second element is proportionally less important than the first. Three principal cases are distinguished:

- equal importance (score: 1).
- the first element is more important than the second (score: 2, 3, 4, 5, 6, 7, 8, 9).
- the second element is more important than the first (score: 1/2, 1/3, 1/4, 1/5, 1/6, 1/7, 1/8, 1/9).

The pairwise comparisons provided by the experts according to the scale in Table 9 were aggregated using the geometric mean method, resulting in the group comparison matrix ("Matrix A") presented in Table 10.

Table 10 Matrix A – pairwise comparison matrix

Metric:	**TCTS**	**TC**	**TDA**	**TFOT**	**TLT**	**TM**	**TQ**	**TTR**
TCTS	1.00	0.21	0.24	0.26	0.20	0.50	0.25	0.50
TC	4.69	1.00	3.00	3.80	1.00	6.00	2.00	6.20
TDA	4.17	0.33	1.00	2.00	0.33	2.00	0.33	3.20
TFOT	3.90	0.26	0.50	1.00	0.11	1.00	0.33	3.00
TLT	5.00	1.00	3.00	9.00	1.00	4.80	1.00	5.00
TM	2.00	0.17	0.50	1.00	0.21	1.00	0.21	1.00
TQ	4.00	0.50	3.00	3.00	1.00	4.76	1.00	5.00
TTR	2.00	0.16	0.31	0.33	0.20	1.00	0.20	1.00
Total	**26.75**	**3.64**	**11.55**	**20.39**	**4.05**	**21.06**	**5.33**	**24.90**

In the next step the normalized comparison "Matrix B" was obtained using Formula 1 [146],

$$b_{ij} = \frac{a_{ij}}{\sum_{i=1}^{n} a_{ij}} \qquad (1)$$

where:

- *n - number of metrics.*

- *a - element of "Matrix A".*

Metric weights were computed using Formula 2 [146],

$$w_i = \frac{1}{n} \sum_{j=1}^{n} b_{ij} \tag{2}$$

where:

- *n - number of metrics.*
- *b - element of "Matrix B".*

The resulting normalized matrix "Matrix B" is shown in Table 11, together with the derived weights.

Table 11 Matrix B - normalized comparison matrix

Metric	TCTS	TC	TDA	TFOT	TLT	TM	TQ	TTR	*Weight (w)*
TCTS	0.04	0.06	0.02	0.01	0.05	0.02	0.05	0.02	***0.034***
TC	0.18	0.27	0.26	0.19	0.25	0.28	0.38	0.25	***0.257***
TDA	0.16	0.09	0.09	0.10	0.08	0.09	0.06	0.13	***0.100***
TFOT	0.15	0.07	0.04	0.05	0.03	0.05	0.06	0.12	***0.071***
TLT	0.19	0.27	0.26	0.44	0.25	0.23	0.19	0.20	***0.253***
TM	0.07	0.05	0.04	0.05	0.05	0.05	0.04	0.04	***0.049***
TQ	0.15	0.14	0.26	0.15	0.25	0.23	0.19	0.20	***0.194***
TTR	0.07	0.04	0.03	0.02	0.05	0.05	0.04	0.04	***0.042***

The highest weights were obtained for three metrics: TC = 0.257, TLT = 0.253, and TQ = 0.194 indicating their dominant importance in the evaluation. The results were validated by consistency checks using consistency index CI according to the Formula 3 [146], and cohesion index CR according to the Formula 4 [146]. A value of CR <10% indicated acceptable consistency [146].

$$CI = \frac{\lambda_{max} - n}{n-1} \tag{3}$$

where:

- *λ_{max} - maximum eigenvalue of "Matrix A".*

- *n - number of metrics.*

Table 12 Eigenvalue of “*Matrix A*” *[147]*

Metric	TCTS	TC	TDA	TFOT	TLT	TM	TQ	TTR
λ	8.18	8.50	8.49	8.28	8.91	8.50	8.58	8.17

$$CR = \frac{CI}{r} * 100\% \quad (4)$$

where:

- *r - the average value of the consistency indices of random pairwise comparisons according to the Table 13.*

Table 13 Average value of consistency indices of random pairwise comparisons [147]

n	2	3	4	5	6	7	8	9	10
r	0.00	0.52	0.89	1.11	1.25	1.35	1.4	1.45	1.49

For the matrix in Table 10, the computed indices were CR = 0.0461 and CI = 0.065, confirming acceptable consistency of the expert judgment. Consequently, in the subsequent parts of the dissertation, Tooling Cost (TC), Tooling Lead Time (TLT), and Tooling Quality (TQ) are adopted as the primary metrics for the production tooling development process.

The analysis revealed a lack of a unified methodology for production tooling development in the literature, which creates significant risks for organizations. In response to this gap, a proprietary model integrating the tooling development process with the APQP, along with a set of metrics for its assessment, was proposed. The results of the Analytic Hierarchy Process (AHP) indicate the importance of three criteria: tool cost, quality, and lead time. These elements form the foundation for further research into risk analysis and reduction methodology of assessing and reducing the risk of development of tooling in automotive industry.

1.4 Summary of product and process development research gaps

The literature review on product development and production tooling development reveals several significant research gaps that remain insufficiently addressed in both academic studies and industrial practice. The most important gaps identified in Chapter 1 include:

1. Lack of a unified and standardized definition of the production tooling.

The literature provides few general definitions (equipment, set of tools, different kinds of products).

2. Lack of a unified and standardized definition of the production tooling development process.

Existing publications describe only isolated aspects of tooling, such as technology-specific design, selected manufacturing operations, or material considerations, without providing a coherent and complete process definition.

3. Insufficient integrations between the product development process and the production tooling development process.

Widely used automotive standards (e.g., APQP, VDA, AIAG) dedicate limited attention to tooling workflows, resulting in a weak conceptual link between product development stages and the tooling activities that enable industrialization.

4. Absence of a structured, stage-based model for production tooling development.

Literature typically divides tooling development into only three broad phases (planning–design–manufacturing), lacking a detailed, step-based framework aligned with industrial project governance.

5. Lack of dedicated performance metrics for evaluating the effectiveness and maturity of tooling development.

Existing metrics found in the literature are limited to general manufacturing KPIs (e.g., availability, utilization, scrap), which do not capture the specific characteristics or risks of tooling development projects.

To address the above research gaps, Chapter 1 of the dissertation introduces the following original contributions presented in Table 14.

Table 14 Mapping of Chapter 1 research gaps to corresponding contributions

Research gap identified	Contribution provided in the dissertation	Location of the proposed contribution addressing the research gap
1. Lack of a unified and standardized definition of the production tooling	Introduction of an original, author-developed definition of the production tooling	Chapter 1.2, page 30

2. Lack of a unified and standardized definition of the production tooling development process	Introduction of an original, author-developed definition of the production tooling development process	Chapter 1.2, page 34
3. Insufficient integrations between product development and tooling development processes	Introduction of a tooling development model integrated with APQP frameworks	Chapter 1.2, Figure 5
4. Absence of a structured, stage-based model for production tooling development	Introduction of a stage-based tooling development model separating core tooling stages and supporting activities, with feedback integrated through continuous improvement	Chapter 1.2, Figure 5
5. Lack of dedicated performance metrics for evaluating tooling development	Identification and expert-based selection of tooling development metrics (8 critical metrics)	Chapter 1.3, Table 7, Table 8

The identified gaps highlight a significant lack of comprehensive frameworks and practical tools for managing production tooling development in alignment with product development processes. Addressing these deficiencies is essential to improve production tooling development process and mitigate its risks in highly competitive and innovation-driven industries such as automotive.

2. Review and assessment of knowledge about risk

This chapter provides an overview of risk-related issues in the context of innovative projects and production tooling development. It presents the definitions of risk, its origins, the distinction between risk and uncertainty, and various classification approaches. Risk management frameworks and standards (ISO 31000, ISO 31010) are presented, along with their limitations when applied to innovation-driven projects. The chapter reviews risk analysis methods, with particular emphasis on FMEA and its variants, and identifies their shortcomings in the context of tooling development. It concludes by outlining research gaps and the need for a dedicated methodology of assessing and reducing the risk of development of tooling in automotive industry.

The development of a new product is an innovative, new, complex process, limited in terms of achieving the intended results, and therefore an action under risk conditions [148], [149], [28], [150]. The more innovative product is subjected to development, and therefore different in comparison to what is commonly known, the greater the risk of its successful implementation. In the conditions of the need to stand out and surprise customers with new products, today, the basic action of each enterprise is a standardized process of implementing innovations, the key element of which is risk management.

2.1 Risk and its definitions

Risk is an inherent component of every action or lack thereof. For most activities performed, especially in technical terminology, associated with something negative, but in the financial environment, (e.g., investing), associated with the benefits of achieving a higher rate of return on investment, The etymological roots of the term risk are: old Italian - "risicare" – (to dare), Arabic - "rizk" - (living dependent on fate), Persian - "rozi" - (daily bread) [149], [151]. These origins suggest an interpretation of risk in terms of uncertainty, highlighting the need to distinguish between uncertainty and risk in analysis. Risk occurs when the probability and consequences of events are known. Meanwhile, uncertainty refers to situations where there is insufficient information to estimate the likelihood of events or their consequences. Under conditions of uncertainty, the range of possible events is unknown, nor is the probability of their occurrence [152].

Risk can be unipolar or bipolar [8]. Unipolar means that the potential effects or outcomes associated with the risk are concentrated in one direction of negative consequences. Unipolar risk should be interpreted as a threat or loss. Bipolar risk refers to situations where the risk is associated with both the possibility of negative and positive effects, i.e. with potential losses and gains. In such a case, risk can be considered as an element balancing both threats and opportunities. This type of risk is also called risk with a negative deviation, where it is associated with the risk of an undesirable event occurring, or positive, where the loss can be compensated by the possibility of a positive event occurring.

Risk terminology varies by field and is defined as:

- Probability of loss [149].
- An event that can affect the effectiveness or efficiency of core organisational processes [153].
- Uncertainty and severity of consequences for activities or events affecting human values [154].
- Possibility of failure in an undertaking with unknown outcomes [155].
- Effect of uncertainty on objectives [156], [157].

With comments to the last definition that the effect might be a deviation from what expected. It can be positive, negative or both, and can address, create or result in opportunities or threats. Objectives can have various aspects and categories and can be applied at different levels. Risk is usually expressed in terms of risk sources, potential events, their consequences, and their likelihood [20].

These definitions are broad and widely applicable; analysing them in the context of innovative product implementation reveals certain insights. They emphasize losses adequate for financial risk but insufficient for implementation processes, which require a multidimensional view of risk sources: technological, organisational, qualitative, and more, including delays, poor decisions, and customer dissatisfaction. They overlook process interdependencies - critical in development and ignore the nature of innovative projects, dynamic change, and the need to manage diverse risk.

2.2 Risk classification

Given the diversity of risk definitions, its classification is essential for effective identification, analysis, evaluation, and method selection. Risk takes many forms and common universal divisions include:

- Aspect-based division: subjective vs. objective risk [151].

Subjective risk reflects individual or group perceptions shaped by preferences, knowledge, experience, and context; it may stem from limited knowledge or psychological factors. Objective risk relies on data, statistics, and established knowledge, typically expressed as event probability.

- Volatility perspective: constant vs. variable risk [149].

Risk that concerns the entire system (constant) or only its fragment (non-constant or variable risk). Constant risk affects entire systems and variable risk targets subsystems. Example: national economy faces systemic risks (inflation), while firms encounter variable risks (raw material prices). Dividing risk into fixed and variable distinguishes global factors from those an organization can influence.

- Time horizon: short-term vs. long-term risk [158].

Short-term risk, lasting a relatively short period, up to 1 year, and long-term risk lasting over 2-5 years or more. This division supports planning tailored to short- and long-term risk categories.

- Determination method: probabilistic vs. statistical risk [149].

Probabilistic risk relies on models and calculations (e.g., estimating bearing failure from design and strength analysis). Statistical risk uses empirical data and observations, enabling a realistic assessment. Example: assessing bearing failure risk using historical data from similar machines. Empirical risk relies on databases. Distinguishing these approaches clarifies which risks need data and which require modelling or simulation.

- Decision-making perspective: risk by choice vs. risk by necessity [159].

Risk by choice is consciously accepted to pursue potential benefits despite known threats. Examples include stock market investing, launching a new product, or starting a business. Risk by necessity arises under pressure or constraint, often without full awareness of options or context. Examples: aiding fire victims, halting production due to raw material shortages, or adapting staff to new legal or tax regulations.

- Source-based division: internal vs. external risk [160].

External (systemic) risk stems from uncontrollable factors, broad in scope, hard to predict, yet unavoidable. Internal (specific) risk arises from controllable factors, mitigated through recovery plans, training, and lessons learned.

Another approach to risk classification is division according to their sources. An example of a risk classification for an organization involved in product development is presented in Figure 6.

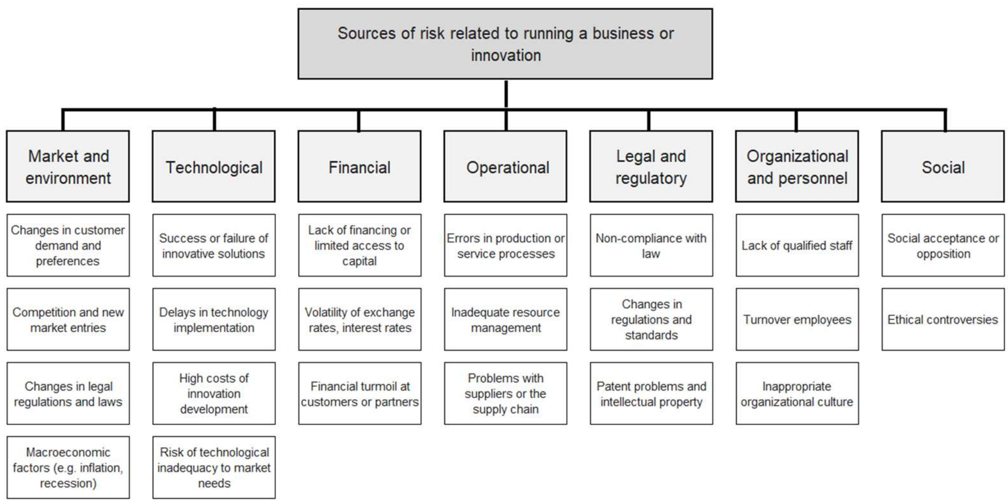


Figure 6 Possible sources of risk related to running a business or innovation. Source: author's own work

The diagram illustrates key categories of risks relevant to organizations engaged in product development. These include market and environmental risks, those related to shifting customer preferences, and regulatory changes. Technological risks highlight the challenges associated with new technologies and their potentially high costs. Financial risks focus on financing and economic volatility. Operational risks encompass internal processes and resource management. Legal and regulatory risks address regulatory compliance and intellectual property. Organisational risks concern human resources and company culture. Social risks address social acceptance and ethical issues. The multi-faceted nature of risk demands a tailored management approach. Categorizing risk by source, duration, and control method enables precise identification and classification of threats - critical during initial analysis. This structure improves understanding of each risk type, its potential impact, and options for mitigation or elimination.

2.3 Risk management in new product development

Risk management is an action aimed at achieving an acceptable level of risk [154]. It comprises four core activities:

- Risk identification.
- Risk measurement.
- Risk control.
- Risk monitoring and review.

Across risk types and sources, manageability requires quantification and consistent numerical measures. Risk management operates under uncertainty and should remain proportionate to expected benefits [161].

The most common risk management standards include:

- "ISO 31000:2018 – Risk management – Guidelines" – the most universal standard that specifies the principles and framework for effective risk management in various organizations and industries.
- "ISO 27005:2018 – Information security risk management" – focuses on managing risks related to information security and data protection.
- "ISO 14971:2019 – Risk management in medical devices" – dedicated to the medical industry, covering the process of identifying and assessing risks related to medical devices.
- "ISO 22301:2019 – Business continuity management" – guidelines for managing risks related to threats to the continuity of an organization's operations.
- "ISO 13485:2016 – Quality management systems for medical devices" – risk management in the production of medical devices.
- "ISO 9001:2015 – Quality Management Systems" – provides guidelines for risk management as an element of continuous improvement of the quality system.

The possibility of certification applies only to the ISO 9001:2015 standard, which provides general guidelines, but only emphasizes the need to identify and assess risks and opportunities related to the organization's activities. The remaining ones only outline good practices for risk management. This gives some freedom in their interpretation, while not providing clear guidelines or steps on how to effectively manage risk.

Meanwhile, innovation projects are characterized by high levels of uncertainty, uniqueness, and the risk of failure. Effective management requires methods that identify, assess, and mitigate threats without constraining creativity and innovation. The balance between control and autonomy is crucial to ensure both security and the flexibility necessary for innovation. The greatest challenges in the context of effective innovation project management include [162], [163], [164], [165]:

- High complexity and uncertainty regarding the project's outcomes [162], [163].
- Difficulties in interpreting and classifying risks [164].
- Difficulties resulting from cooperation between employees and with external entities [165].
- Lack of reliable data for making accurate decisions.
- Inadequacy of available risk management methods to the innovation realities [162], [164].

For new product development, ISO 31000 provides the most relevant overarching guidance. According to "ISO 31000:2018 – Risk management – Guidelines" the risk management cannot be a stand-alone process, but integrated with other processes, being part of the organization's structure, possible to modify, improve and adapt to changing internal and external conditions [155]. Presented in the Figure 7, the three components of the guideline - principles, framework and process might already exist in full or in part within the organization, however, they might need to be adapted or improved so that managing risk is efficient, effective and consistent.

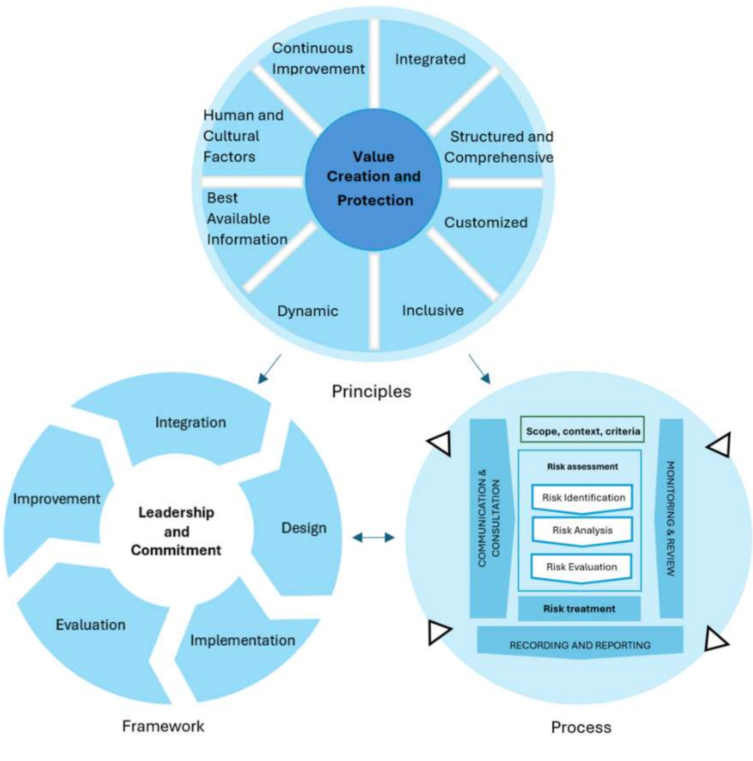


Figure 7 Principles, framework and process of ISO31000:2018. Source: author's own work based on [156]

The effectiveness of the risk management process depends on the coherence and involvement of all persons, including top management. On the other hand, this standard in the aspect of its use for risk management of innovative projects, reveals it to be insufficient and has certain disadvantages. The most important mentioned in the literature on the subject are [166], [167], [168]:

- Overly general guidelines without proposed tools and methods to support the risk management processes.
- Insufficient flexibility in adapting to dynamic environments.
- Difficulties in practical implementation by organizations.
- Lack of connection to modern technologies, which are the basis for innovative projects.

ISO 31000:2018 therefore provides a solid basis for risk management in innovation projects, but its effectiveness depends on full implementation, adaptation to the specific nature of the project, management support, and integration with other management tools. ISO 31000:2018, on one hand, is considered the most flexible and easy to implement, providing a good basis for integration with other standards, but on the other hand research indicates that it does not provide sufficient guidance on practical risk analysis, especially in complex socio-technical systems, and its recommendations are not always consistent with the latest scientific literature [169].

2.4 Assessment of risk analysis tools

Effective risk management requires assigning value to it using the same measures and methods [170], [171]. For this purpose, the literature on the subject suggests the use of methods that have been categorized as [3], [172], [173]:

- Qualitative - based on assessments founded on good practices and experience, where risks and their potential consequences are presented in a descriptive manner.
- Quantitative - where risk assessment is based on numerical data.
- Hybrid - being a mix of the two methods mentioned above.

ISO 31000:2018 [174] complemented by ISO 31010:2019 [175], a key international standard that provides guidance on 41 risk assessment techniques presented in the Table 15 provides a brief description of each technique.

Table 15 Risk assessment methods described in ISO 31010:2019 [175]

No	Method	Description	Example
1	2	3	4
1	ALARP	Requires risks to be reduced to a level where the cost, time, and effort to mitigate further are grossly disproportionate to the reduction in risk achieved, in use mainly in security systems	[176]
2	Bayesian analysis	Inference about model parameters using Bayes' theorem which has the capability of incorporating empirical data into prior judgements about probabilities	[177]

3	Bayesian networks	A graphical model of variables and their cause-effect relationships expressed using probabilities. includes variables representing uncertainties, consequences and actions	[178]
4	Bow tie analysis	A diagrammatic way of describing the pathways from sources of risk to outcomes and of reviewing controls	[179]
5	Brainstorming	A heuristic method that uses teamwork to solve problems	[180]
6	Business impact analysis	Prioritization of an organization's products and services and, thereby, the priorities of the activities and resources which deliver them	[181]
7	Causal mapping	Analysis of root causes threatening the functioning of the organization in the form of mapping	[182]
8	Cause-consequence analysis	A combination of fault and event tree analysis that allows inclusion of time delays. Both causes and consequences of an initiating event are considered	[183]
9	Checklist	A list of activities in the order of implementation, used as support in omitting tasks	[184]
10	Cindynic approach	Considers goals, values, rules, data and models of stakeholders and identifies inconsistencies, ambiguities, omissions and ignorance. These form systemic sources and drivers of risk	[185]
11	Consequence/ likelihood matrix	Compares individual risks by selecting a consequence/likelihood pair and displaying them on a matrix with consequence on one axis and likelihood on the other	[186]
12	Cost/benefit analysis	Uses money as a scale for estimating positive and negative, tangible and intangible, consequences of different options	[187]
13	Cross impact analysis	Evaluates changes in the probability of the occurrence of a given set of events consequents on the actual occurrence of one of them	[188]
14	Decision tree analysis	Uses a tree-like representation or model of decisions and their possible consequences. Outcomes are usually expressed in monetary terms or in terms of utility	[189]
15	Delphi technique	Reliable consensus of opinion from a group of experts	[190]
16	Event tree analysis	Model's outcomes from an initiating event and control status, analysing frequencies or probabilities	[191]
17	FMEA - Failure mode and effects analysis	Considers the ways in which each component of a system might fail and the failure causes and effects	[192]
18	FMECA - Failure mode and effects and criticality analysis	Can be followed by a criticality analysis which defines the significance of each failure mode	[193]
19	Fault tree analysis	Analyses cause of a focus event using Boolean logic to describe combinations of faults. Variations include a success tree where the top event is desired, and a cause tree used to investigate past events	[194]
20	F-N diagrams	Special case of quantitative consequence/likelihood graph applied to consideration of tolerability of risk to human life	[158]
21	Game theory	The study of strategic decision making to model the impact of the decisions of different players involved in the game. Example application area can be risk-based pricing	[195]
22	HACCP-hazard analysis and critical control points	Analyses the risk reduction that can be achieved by various layers of protection	[196]

23	HAZOP hazard and operability study	A structured and systematic examination of a planned or existing process or operation, in order to identify and evaluate problems that might represent risk to personnel or equipment or prevent efficient operation	[197]
24	Human reliability analysis (HRA)	A set of techniques for identifying the potential for human error and estimating the likelihood of failure	[198]
25	Ishikawa (fishbone)	Graphical analysis of cause-effect relationships of defects and their causes	[199]
26	LOPA - Layer protection analysis	Analyses the risk reduction that can be achieved by various layers of protection	[200]
27	Markov analysis	Calculates the probability that a system, which has the capacity to be in one of a number of states, will be in a particular state at a time t in the future	[201]
28	Monte Carlo simulation	Calculates the probability of outcomes by running multiple simulations using random variables	[202]
29	Multi-criteria analysis (MCA)	Compares options in a way that makes trade-offs explicit. Provides an alternative to cost/benefit analysis that does not need a monetary value to be allocated to all inputs	[30]
30	Nominal group technique	Technique for eliciting views from a group of people, where initial participation is as individuals with no interaction, then group discussion of ideas follows	[203]
31	Pareto charts	The Pareto principle (the 80 - 20 rule) states that, for many events, roughly 80% of the effects come from 20% of the causes	[204]
32	PIA/DPIA - Privacy impact analysis/ data privacy impact assessment	Analyses how incidents and events could affect a person's privacy (PI) and identifies and quantifies the capabilities that would be needed to manage it	[205]
33	Reliability centred maintenance	A risk-based assessment used to identify the appropriate maintenance tasks for a system and its components	[206]
34	Risk indices	Rates the significance of risks based on ratings applied to factors which are believed to influence the magnitude of the risk	[207]
35	Scenario analysis	Identifies possible future scenarios through imagination, extrapolation from the present or modelling. Risk is then considered for each of these scenarios	[208]
36	S-curves	A means of displaying the relationship between consequences and their likelihood, plotted as a cumulative distribution function (S-curve)	[209]
37	Structured or semi-structured interviews	An interview in which previously prepared questions are asked in a specific order	[210]
38	Structured What If Technique (SWIFT)	A simpler form of HAZOP, with prompts of "what if" to identify deviations from the expected	[211]
39	Surveys	Paper- or computer-based questionnaires to elicit views	[212]
40	Toxicological risk assessment	A series of steps taken to obtain a measure for the risk to humans or ecological systems due to exposure to chemicals	[213]

41	VaR - Value at risk	Financial measure of risk that uses an assumed probability distribution of losses in a stable market condition, to calculate the value of a loss that might occur with a specified probability within a defined time span	[214]

For this dissertation, ISO 31010:2019 methods - among the most recognized in risk management - are evaluated for their applicability to innovative projects and specific stages of production tooling development, as outlined in Figure 5. Usefulness of each method was assessed using ISO 31010 descriptions, expert evaluations from tooling development specialists, and a supporting literature review. The assessment criteria applied were divided into two groups. The first group covers general characteristics of each method, including its qualitative, quantitative or hybrid nature, typical application areas and the expected level of complexity. The second group concerns the possibility of including a given method in individual stages of the production-tooling development process representing potential applicability zones. The results are presented in the Table 16.

Table 16 Risk assessment methods according to ISO/IEC 31010:2019 along with an assessment of their suitability for use in innovative projects and the process of production tooling development. Source: author's own work based on [175]

Number	Method	Qualitative / Quantitative / Hybrid	Application in innovative projects	Complexity	Risk Assessment					Production Tooling Development Process						
					Risk identification	Risk analysis - consequences	Risk analysis - likelihood	Risk analysis - level of risk	Risk evaluation	Tooling concept definition	Tooling specification validation	Tooling supplier nomination	Tooling design validation	Tooling manufacturing validation	Tooling startup	Tooling serial parts production
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1	ALARP	HY	L	H	NA	NA	NA	NA	SA	L	VL	VL	VL	VL	VL	VL
2	Bayesian analysis	QT	L	H	NA	NA	SA	NA	NA	VL	VL	VL	VL	VL	VL	VL
3	Bayesian networks	QT	M	H	NA	NA	SA	NA	SA	L	VL	VL	VL	VL	VL	VL
4	Bow tie analysis	HY	L	L	A	SA	A	A	A	M	M	M	L	L	L	L
5	Brainstorming	QL	H	L	SA	A	NA	NA	NA	H	M	L	L	VL	VL	VL
6	Business impact analysis	HY	M	M	A	SA	NA	NA	NA	VL	VL	VL	VL	VL	VL	VL
7	Causal mapping	QL	L	M	A	A	NA	NA	NA	VL	VL	VL	VL	VL	VL	VL

8	Cause-consequence analysis	QT	H	M	A	SA	SA	A	A	M	M	M	M	L	L	L
9	Checklist	QL	H	N	SA	NA	NA	NA	NA	M	M	M	M	M	H	H
10	Cindynic approach	QL	VL	H	SA	NA	NA	NA	NA	VL	VL	VL	VL	VL	VL	VL
11	Consequence/likeli homatrix	HY	L	L	NA	A	A	SA	A	VL	VL	VL	VL	VL	VL	VL
12	Cost/benefit analysis	QT	H	L	NA	SA	NA	NA	SA	M	L	L	L	L	L	L
13	Cross impact analysis	QT	M	M	NA	NA	SA	NA	NA	M	L	L	L	L	L	L
14	Decision tree analysis	QT	M	M	NA	SA	SA	A	A	M	M	M	M	L	L	L
15	Delphi technique	QL	H	M	SA	NA	NA	NA	NA	M	M	L	L	L	L	L
16	Event tree analysis	HY	M	M	NA	SA	A	A	A	L	L	L	L	L	L	L
17	**FMEA - Failure mode and effects analysis**	**HY**	**M**	**M**	**SA**	**SA**	**NA**	**NA**	**NA**	**H**	**M**	**H**	**H**	**M**	**L**	**L**
18	**FMECA - Failure mode and effects and criticality analysis**	**HY**	**M**	**H**	**SA**	**SA**	**SA**	**SA**	**SA**	**H**	**M**	**H**	**H**	**M**	**L**	**L**
19	Fault tree analysis	HY	M	M	A	NA	SA	A	A	L	M	L	M	L	L	L
20	F-N diagrams	QT	L	H	A	SA	SA	A	SA	L	L	L	L	L	L	L
21	Game theory	QT	M	H	A	SA	NA	NA	SA	VL	VL	VL	VL	VL	VL	VL
22	HACCP- hazard analysis and critical control points	QL	M	M	SA	SA	NA	NA	SA	VL	VL	VL	VL	VL	VL	VL
23	HAZOP hazard and operability study	QL	M	M	SA	A	NA	NA	NA	VL	VL	VL	VL	VL	VL	VL
24	Human reliability analysis (HRA)	QL	M	H	SA	SA	SA	SA	A	VL	VL	VL	VL	VL	VL	VL
25	Ishikawa (fishbone)	QL	H	M	SA	A	NA	NA	NA	M	M	M	M	M	L	L
26	LOPA - Layer protection analysis	HY	M	H	A	SA	A	A	NA	L	L	L	L	L	L	L
27	Markov analysis	QT	L	M	A	A	SA	NA	NA	VL	VL	VL	VL	VL	VL	VL
28	Monte Carlo simulation	QT	M	H	NA	A	A	A	SA	VL	VL	VL	VL	VL	VL	VL
29	Multi-criteria analysis (MCA)	QT	H	H	A	NA	NA	NA	SA	VH	H	M	M	L	L	L

30	Nominal group technique	QL	VH	M	SA	A	A	NA	NA	VH	M	M	M	M	H	H
31	Pareto charts	HY	M	L	NA	A	A	A	SA	M	L	L	L	L	L	M
32	PIA/DPIA - Privacy impact analysis/ data privacy impact assessment	QL	L	M	A	SA	A	A	SA	VL	VL	VL	VL	VL	VL	VL
33	Reliability centered maintenance	HY	L	M	A	A	A	A	SA	VL	VL	VL	VL	VL	L	L
34	Risk indicators	QT	M	L	NA	SA	SA	A	SA	M	M	M	M	L	L	L
35	Scenario analysis	QL	M	L	SA	SA	A	A	A	M	M	M	L	L	L	L
36	S-curves	QT	H	M	NA	A	A	SA	SA	L	L	L	VL	VL	VL	VL
37	Structured or semi-structured interviews	QL	M	H	SA	NA	NA	NA	NA	H	M	M	M	L	L	L
38	Structured What If Technique (SWIFT))	QL	M	L	SA	SA	A	A	A	M	M	M	L	L	L	L
39	Surveys	QL	H	H	SA	NA	NA	NA	NA	L	L	L	L	L	L	L
40	Toxicological risk assessment	QT	L	H	SA	SA	SA	SA	SA	VL	VL	VL	VL	VL	VL	VL
41	VaR - Value at Risk	QT	M	M	NA	A	A	SA	SA	VL	VL	VL	VL	VL	VL	VL

Legend:

Method: QT - qualitative, QT - qualitative, HY - hybrid.

Application in innovative projects: L - low, M - medium, H - high.

Complexity: L - low, M - medium, H - high.

Risk Assessment: NA - not applicable, A - applicable, SA - strongly applicable.

Production Tooling Development Process: VL - very low, L - low, M - medium, H - high, VH - very high.

The comparative analysis in Table 16 identifies FMEA and FMECA as the most suitable methods for risk analysis in production tooling development. Cause-consequence and decision tree analyses also merit attention, as they complement FMEA. Some techniques scored higher at specific stages of tooling development process, suggesting that organizations should tailor methods to each phase rather than rely on a single approach. In practice, this approach proves too complex for many organizations; industrial realities often lead teams to adopt a single method for risk assessment [215], [216].

Although, according to the conducted analysis, the FMEA method turns out to be the most appropriate for use in the risk analysis of the production tooling development, the literature also highlights the disadvantages of this method, the most important of which include, among others [175]:

- FMEA can only be used to identify single failure modes, not combinations of failure modes.
- Unless adequately controlled and focused, the studies can be time-consuming and costly.
- FMEA can be difficult and tedious for complex multi-layered systems.

Despite such conclusions, FMEA analysis and its varieties remain the most frequently used tool by development organizations to assess the risk [217], [218], [219], therefore in the next chapter of this dissertation, this method will be described in more detailed way.

Risk is strategically important in innovation, but existing methods and tools for risk management are insufficient and do not fully address the specific uncertainties encountered during the development of highly innovative products, including dedicated production tooling. This gap in the literature and practice reveals a critical research deficit: the lack of a tailored, comprehensive methodology for assessing and reducing risk in this domain. The inadequacy of current techniques poses significant challenges for organizations which often rely on generic risk assessment models that do not consider the unique aspects of innovation-driven projects. Therefore, there is a pressing need to develop dedicated frameworks that can more accurately identify, evaluate, and mitigate risks specific to innovative products and the process of production tooling development.

2.5 FMEA in the risk assessment process for production tooling development

Failure Mode and Effects Analysis (FMEA), a method that allows for the analysis of the causes of defects and the effects of potential errors, began its history after the end of World War II in the United States arms industry. FMEA was published on November 9, 1949, in the USA as MIL-P-1629 "Procedure for Performing a Failure Mode, Effects and Criticality Analysis". The purpose of FMEA was to classify the causes and effects of potential and actual failures of munitions and equipment, in terms of their impact on military mission success and personnel safety [220]. FMEA analysis was quickly transferred to other areas like the space industry. In 1963, NASA used it in the Apollo program to ensure the safety and reliability of spacecraft component designs [221]. The method started to be used also in aviation and the automotive industry. In 1977, Ford Motor Company introduced FMEA to ensure the safety and compliance of its products with legal requirements by publishing the Potential Failure Mode and Effects Analysis Handbook in 1984 to promote the method. Later, the automobile manufacturers in America also introduced FMEA into the management of suppliers in context of quality assurance [222]. Nowadays the FMEA method is used as a tool for analysing and minimizing the risk of engineering projects in almost all industries, as well as in medicine, logistics, and IT.

Currently, the FMEA method is included in the most important quality management standards, such as:

- ISO 9001, intended for all organizations, regardless of their type and size.

- QS-9000 (Quality System Requirements) standard intended for the automotive industry.
- ISO/TS 16949, which contains a set of requirements that includes the QS 9000 standard and the quality system requirements of automotive manufacturers.
- AS/EN 9100 standard, based on the assumptions of ISO 9001, but concerning quality management in the aviation, space, and defence industries.

The purpose of FMEA is to analyse the area under investigation from the perspective of possible errors and the consequences they may cause. Each effect that causes an error is then analysed in terms of actions that should be taken to limit or, ideally, eliminate it. Errors considered may include the loss of certain desired product properties, endanger the user's health or life, or deliver a defective product to the customer.

According to the most influential handbooks, FMEA is divided into main three types: monitoring and system response FMEA, design FMEA and process FMEA [61], [192], [223], all of them in a sequence for the new product development process as presented in the Figure 8 and defined as follows:

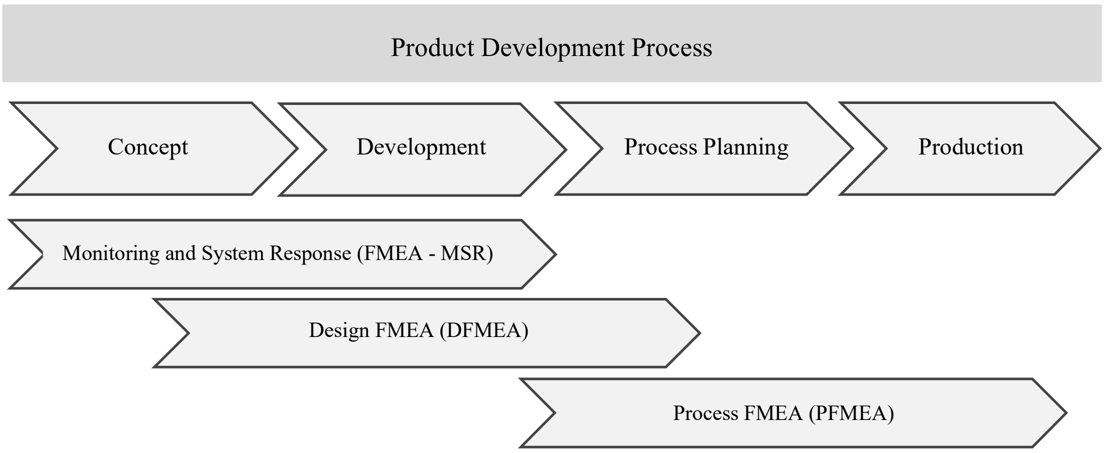


Figure 8 Relationship of system, process, and design FMEA in product development process. Source: author's own work based on [217]

- FMEA - MSR - highest level FMEA, analysing the complete system, including its various subsystems in terms of how the subsystems interact and how failures in one part of the system can affect others, focuses on potential failure modes associated with the proposed functions of a concept.
- DFMEA – identify, evaluate, and eliminate potential design issues that could lead to product failure. This process focuses on the early stages of development, identifying the causes and effects of defects related to the design of systems, components, and processes.
- PFMEA – identify, evaluate, and eliminate potential production process issue related to operator safety, next user, downstream users, machines/equipment, operation, compliance with government regulations, and others.

Other varieties include machine FMEA (MFMEA) or FMECA (Failure Mode, Effects, and Criticality Analysis) - an extension of FMEA that adds an assessment of the criticality of failures, helping to prioritize corrective actions. Recently, an important role in risk analysis play FMEA variants such as Fuzzy FMEA and mixed methods containing Multi Criteria Decision Making (MCDM), such as AHP or ANP methods [224], [225], as well as integration of FMEA with other techniques like Problem Solving (QFD, Ishikawa Diagrams, Root cause analysis) [226] and integration with other risk analysis methods such as Monte Carlo, HAZOP, and others [227].

FMEA analysis is performed by a multidisciplinary team of specialists. The team is coordinated by a leader whose task is to conduct the analysis and resolve any disputes among its members. The FMEA process flow is presented in Figure 9.

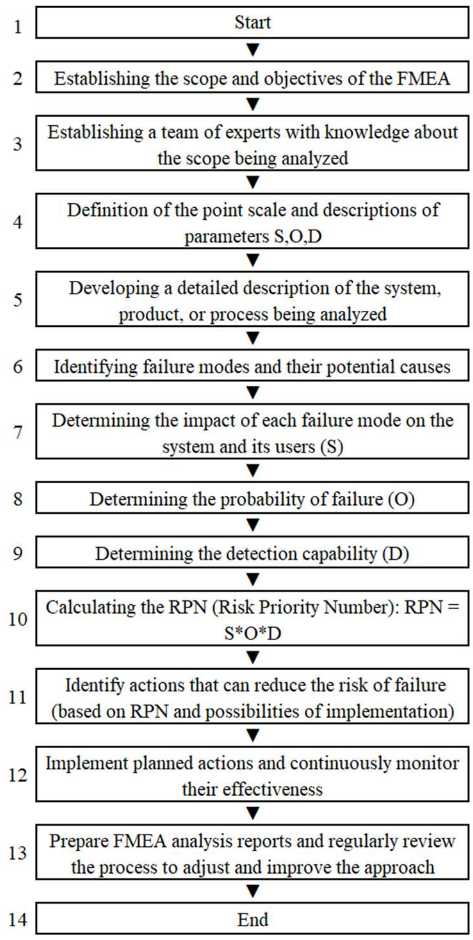


Figure 9 Failure Mode and Effect Analysis steps. Source: author's own work based on [8], [192].

In FMEA error classification is based on an assessment of its probability of occurrence (O), its significance to the customer in terms of severity (S), and the possibility of detecting the error (D). The product of the S, O, and D indices, each assessed on a scale of 1 to 10 presented in the Table 17, creates a risk priority number (RPN) ranging from 1 to 1000 according to equation (*5*). This number, when exceeded over certain level indicates that the analysed error should be considered and prioritized in action list. The approach to determining the correct values for the severity, occurrence, detection, and RPN indices varies widely [192].

$$RPN = S \times O \times D \tag{5}$$

Table 17 Parameter scale and risk value. Source: author's own work based on [8]

Parameter		Product value									
		1	2	3	4	5	6	7	8	9	10
Severity	S	Estimated risk →									
Occurence	O	Estimated risk →									
Detection	D	← Estimated risk									

PFMEA under AIAG guidelines defines strict criteria for severity (Table 18), occurrence (Table 19), and detection (Table 20), and introduces in addition the Action Priority (AP) (Table 21) in order to give more emphasis on severity first, then to occurrence and detection [61], [192].

Table 18 Evaluation criteria of severity (S) in PFMEA [192]

S	Effect	Impact to Your Plant	Impact to Ship-to Plant (when known)	Impact to End User (when known)
10	High	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians
9		Failure may result in in-plant regulatory noncompliance	Failure may result in in-plant regulatory noncompliance	Noncompliance with regulations
8	Moderately high	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Loss of primary vehicle function necessary for normal driving during expected service life

7		Product may have to be sorted, and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed; added manpower	Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	Degradation of primary vehicle function necessary for normal driving during expected service life
6	Moderately low	100% of production run may have to be reworked offline and accepted	Line shutdown up to one hour	Loss of secondary vehicle function
5		A portion of the production run may have to be reworked offline and accepted	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown	Degradation of secondary vehicle function
4		100% of production run may have to be reworked in station before it is processed	Defective product triggers significant reaction plan; additional defective products not likely; sort not required	Very objectionable appearance, sound, vibration, harshness, or haptics
3	Low	A portion of the production run may have to be reworked in-station before it is processed	Defective product triggers minor reaction plan; additional defective products not likely; sort not required	Moderately objectionable appearance, sound, vibration, harshness, or haptics
2		Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan; additional defective products not likely; sort not required; requires feedback to supplier	Slightly objectionable appearance, sound, vibration, harshness, or haptics
1	Very low	No discernible effect	No discernible effect or no effect	No discernible effect

Table 19 Evaluation criteria of occurrence (O) in PFMEA [192]

O	Prediction of Failure Cause Occurring	Type of Control	Prevention Controls
10	Extremely high	None	No prevention controls
9	Very high	Behavioural	Prevention controls will have little effect in preventing failure cause
8			
7	High	Behavioural or Technical	Prevention controls somewhat effective in preventing failure cause
6			
5	Moderate		Prevention controls are effective in preventing failure cause
4			
3	Low	Best Practices: Behavioural or Technical	Prevention controls are highly effective in preventing failure cause
2	Very low		

1	Extremely low	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling) design. Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause

Table 20 Evaluation criteria of detection (D) in PFMEA [192]

D	Ability to Detect	Detection Method Maturity	Opportunity for Detection
10	Very low	No testing or inspection method has been established or is known	The failure mode will not or cannot be detected
9	Very low	It is unlikely that the testing or inspection method will detect the failure mode	The failure mode is not easily detected through random or sporadic audits
8	Low	Test or inspection method has not been proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause
7	Low	Test or inspection method has not been proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.)	Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause
6	Moderate	Test or inspection method has been proven to be effective and reliable (e.g. plant has experience with method; gauge R&R results are acceptable on comparable process or this application, etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks)
5	Moderate	Test or inspection method has been proven to be effective and reliable (e.g. plant has experience with method; gauge R&R results are acceptable on comparable process or this application, etc.)	Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks)
4	High	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode downstream, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a

			robust system that will prevent outflow of the product from the facility
3	High	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc	Machine-based automated detection method that will detect the failure mode in-station, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility
2	High	Detection method has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.)	Machine-based detection method that will detect the failure mode (discrepant product)
1	Very high	Failure mode cannot be physically produced as designed or processed, or detection methods proven to always detect the failure mode or failure cause	Machine-based detection method that will detect the failure mode or failure cause

Table 21 Action Priority for FMEA based on Severity (S), Occurrence (O) and Detection (D). Source: author's own work based on [192]

S	O	D	AP
9-10	4-10	2-10	H
		1	M
	2-3	7-10	H
	2-3	5-6	M
	2-3	1-4	L
	1	1-10	L
7-8	8-10	7-10	L
		1-6	H
	6-7	2-10	H
		1	M
	4-5	7-10	H
		1-6	M
	2-3	5-10	M
		1-4	L
	1	1-10	L
4-6	8-10	5-10	H
		1-4	M
	6-7	2-10	M
		1	L
	4-5	7-10	M

		1-6	L
	2-3	1-10	L
	1	1-10	L
2-3	8-10	5-10	M
		1-4	L
	6-7	1-10	L
	4-5	1-10	L
	2-3	1-10	L
	1	1-10	L
1	1-10	1-10	L

In Table 21, the priority is driven primarily by severity (S), followed by occurrence (O), and then detection (D), ensuring that the most critical risks are addressed first. After prioritizing the action list, the team's actions should focus on eliminating the root causes, and if that is not possible, on reducing the severity of their effects or increasing the possibility of detecting them. A simplified form for conducting FMEA analysis is presented in Table 22.

Table 22 Example of FMEA formular. Source: author's own work based on [228]

FMEA											
Process step	Failure mode	Failure model effect	Severity	Occurancy	Detection	Risk priority number	Action priority	Recommented action	Responsible	Status	Deadline
			S	O	D	RPN	AP				

Although FMEA is widely recommended, with clear steps and a simple RPN calculation, it has significant drawbacks summarized in Table 23.

Table 23 Drawbacks of FMEA. Source: author's own work

Limitation	Explanation	Reference
High level of team member competence	It requires a team of experts with extensive process or product knowledge	[229]
Time-, effort-, and cost-intensive	There are no automation mechanisms, no integration with databases and ERP/PLM systems; the method is considered inflexible and difficult for the customer to understand	[230]
Lack of cost-based approach	RPN is not linked to cost, time, or efficiency metrics; there is no way to assess losses	[231], [232]

Need for top management involvement	Requires management support for effective implementation	[8]
Limited perspective	Focusing on components ignores system, process, human, and environmental errors	[219], [230], [233]
Subjectivity of assessments	Assigning values to S, O, and D is imprecise and subjective; the analysis is not repeatable; different teams obtain different results	[234]
Difficulty updating changes, which is expensive and time-consuming	Requires constant updating whenever the design changes, which is expensive and time-consuming.	[8]
Inadequate prioritization	Classic RPN is sensitive to changes in evaluations; different combinations of S, O, and D produce the same RPN; there is no way to differentiate the impact of parameters	[8]
Lack of precision	Generic descriptions and incorrect attribution of effects to causes lead to missed problems. Errors in assessing S, O, and D lead to incorrect prioritization of activities	[235], [228]
Inadequate evaluation	Errors in assessing S, O, and D lead to incorrect prioritization of activities	[235], [228]
Incomplete analysis	Ignoring defects or effects due to ignorance or failure to analyse all possible causes	[236]
Implementation and updating problems	Neglecting updates and failing to implement preventive tools weakens the effectiveness of the process	[217]
Incorrect differentiation of activities	Confusing preventive and control activities leads to misclassifications	[217]

One of the key drawbacks of the FMEA method is its lack of integrity and limited interaction between individual analysis stages. FMEA focuses on a narrowly defined area, ignoring direct connections with other processes, even though such connections do exist and can significantly impact risk assessment. Another significant limitation is the lack of consideration of risk in the context of time and cost, which, for production and development organizations, is a key factor in determining competitiveness and market viability.

Moreover, from the perspective of using the FMEA method to analyse the risk of developing production tooling for a new product, the following difficulties can be deduced that disqualify the FMEA method:

- FMEA is using identifying potential failure modes based on experience and data from previous projects. In the case of new production tooling, reliable data, such as failure rates, is lacking, making parameter assessments of FMEA subjective and imprecise.
- FMEA analyses components and their functions but does not consider the complex system interactions typical of new technologies and production tooling. In tooling development, the relationships between processes, materials, the environment, and ergonomics are crucial, as are market conditions, trial capabilities, machine availability, and many others.
- FMEA does not consider risk in the context of cost, schedule, and resources, which are crucial in development projects. Organizations need to analyse the impact of risk on budgets and deadlines, whereas FMEA focuses solely on quality and reliability.

- Every design change requires updating the FMEA, which is time-consuming and costly. During the development phase, when changes are frequent, the method becomes impractical.

Therefore, there is a need to define a methodology for assessing and reducing the risk of developing production tooling that can be applied in industrial settings. The proposed methodology of assessing and reducing the risk of development of tooling in automotive industry will be presented in a Chapter 4 of this dissertation.

2.6 Summary of risk analysis research gaps

The review of literature on risk and its management in the context of innovative projects and production tooling development indicates the following gaps:

1. Insufficient adaptation of existing risk analysis tools (e.g., FMEA) to high-innovation conditions and multi-layered systems - resulting in subjectivity and limited accuracy.

Classical FMEA becomes subjective and difficult to maintain in innovation-driven, multi-dependency tooling projects, and it does not capture system interactions or frequent design changes effectively.

2. Absence of a dedicated risk management methodology for tooling development - available standards (e.g., ISO 31000) are too generic and fail to address the specifics of innovative projects.

General standards provide principles but do not deliver a tooling-specific, operational workflow for risk assessment and mitigation under the constraints and variability typical of tooling development projects.

3. Limited research on hybrid methods of risk assessment (e.g., FMEA + AHP) in tooling development - absence of practical models for industrial application.

Although hybrid approaches are discussed, the literature lacks practical, industry-ready models that combine qualitative and quantitative techniques in a way that is implementable for tooling development processes.

4. No integration of risk management with IT systems (ERP/PLM) and automation - reducing efficiency and timeliness of analyses in industrial practice.

Without ERP/PLM integration, risk analyses remain slow, manually maintained, and disconnected from live project data and documentation flows, reducing their timeliness and industrial usefulness.

5. Lack of integration of risk analysis with cost, schedule, and resource aspects - current methods focus on quality and reliability.

Many approaches emphasize quality and reliability but do not directly connect risk assessment with project-critical constraints such as budget, timing, and resource availability, limiting decision support in tooling development.

Table 24 Mapping of Chapter 2 research gaps to corresponding contributions

<table>
<tr><th>Research gap identified</th><th>Contribution provided in the dissertation</th><th>Location of the proposed contribution addressing the research gap</th></tr>
<tr><td>1. Insufficient adaptation of existing risk assessment tools to high-innovation conditions</td><td rowspan="2">Introduction of an original, tooling-dedicated methodology of assessing and reducing the risk of development of tooling in automotive industry, designed specifically to overcome the limitations of traditional tools such as FMEA</td><td rowspan="2">Chapter 4</td></tr>
<tr><td>2. Absence of a dedicated risk assessment methodology for tooling development</td></tr>
<tr><td>3. Limited research on hybrid methods of risk assessment in tooling development</td><td>Integration of qualitative expert assessment with quantitative fuzzy modelling and structural risk decomposition (RC × RL), forming a hybrid analytical framework applicable to tooling development processes</td><td>Chapter 4 (Sections 4.2-4.3)</td></tr>
<tr><td>4. Lack of integration of risk analysis with cost, schedule, and resource aspects</td><td>The methodology of assessing and reducing the risk of development of tooling in automotive industry partially addresses this gap by structuring risk assessment across development stages (process schedule perspective) and by incorporating risk limitations (RL) that may explicitly include cost and resource dimensions. Through the RC × RL architecture, risk exposure is evaluated in relation to cost, timing, and resource constraints, providing a structured link between risk analysis and core project performance dimensions</td><td>Chapter 4 (Sections 4.2-4.4)</td></tr>
</table>

The gaps identified reveal that current risk management approaches are not sufficiently tailored to the complexity and dynamic nature of production tooling development. Traditional methods, while widely used, fail to integrate critical dimensions and adaptability, and lack technological integration with modern digital systems. Addressing these shortcomings requires the development of flexible, hybrid methodologies that combine qualitative and quantitative techniques, incorporate real-time data, and align with industrial IT infrastructures to ensure effective risk mitigation in innovative projects.

3. Research problem, aim of the dissertation, research questions, contribution and justification of the dissertation

This chapter positions the topic of the dissertation within the context of the methodological gaps identified in the scientific literature and industrial practice related to risk-based management of production tooling development. It presents core research problem, formulates the central aim of the work, and specifies both the scientific and utilitarian objectives.

Research problem

A review of the literature and industry standards in the automotive sector reveals a clear gap: **there is no dedicated, stage based and comparable methodology for risk assessment in production tooling development**, integrated with the new product development process and capable of linking risk to critical process limitations. Existing tools - most notably FMEA - are fragmented, subjective, and difficult to maintain in innovative, multi dependency projects. They do not provide a bounded, decision-oriented exposure indicator at individual development stages. Standards such as ISO 31000/31010 remain high level of generality and do not offer an operational tool tailored to tooling development.

Summary of the literature gap:

- Lack of a unified and standardized definition of the production tooling (Chapter 1.2).
- Lack of a unified and standardized definition of the production tooling development process metrics (Chapter 1.2).
- Absence of a structured, stage-based model for production tooling development (Chapter 1.2).
- Insufficient integrations between product development and tooling development processes (Chapter 1.2).
- Lack of dedicated performance metrics for evaluating tooling development (Chapter 1.3).
- Insufficient adaptation of existing risk assessment tools to high innovation conditions (Chapter 2.4).
- Absence of a dedicated risk assessment methodology (including hybrid methods) for tooling development (Chapter 2.5)

Aim of the dissertation

The aim of this dissertation is to develop and validate an original, stage-based risk methodology for production tooling development in the automotive industry. The methodology of assessing and reducing the risk of development of tooling in automotive industry divides risk factors into Risk Categories (RC) - by source and mechanism - and evaluates them from the perspective of Risk Limitations (RL) - boundary conditions for assessing exposure in the production tooling development process.

The methodology proposes creating Assessment Questions (AQ) based on expert group analysis of contextual process information and risk information areas, followed by their evaluation using a unified linguistic scale (VL - VH). These Assessment Questions (AQ) evaluations are fuzzified via membership functions, aggregated within the Risk Limitations (RL) structure, and finally defuzzified into consistent numerical values - the first step of the quantitative exposure assessment.

Within this structure, Assessment Questions (AQ) are organised into two complementary risks: a project level, fixed Input Risk (R_I) and a stage specific Stage Risk (R_{STG}). After normalization, Input Risk (R_I) and a stage specific Stage Risk (R_{STG}) are aggregated multiplicatively to produce the bounded Total Stage Risk (R_{TSTG}) for each stage, which serves as the decision indicator at each stage.

The methodology of assessing and reducing the risk of development of tooling in automotive industry assesses exposure on a common, bounded scale and uses Risk Category (RC) and Risk Limitation (RL) dominance patterns to target mitigation, while fixed thresholds (L/M/H) mapped to Total Stage Risk (R_{TSTG}) translate the assessed exposure into stage decisions with clear ownership of mitigation actions at the stage level.

Research questions and hypotheses

Question 1. Does a hybrid (expert + fuzzy) approach with risk limitation (RL) and risk category (RC) driven decomposition ensure consistent and comparable risk assessment across development stages?

Hypothesis 1. Unified linguistic scale and membership functions provide stable, defuzzified risk values comparable across stages and projects.

Question 2. Does risk category (RC) and risk limitation (RL) structural analysis improve interpretability and decision making, i.e., explain why a stage is exposed and where mitigation should be applied?

Hypothesis 2. RC and RL contribution matrices reveal systematic dominance patterns that map directly to ownership and mitigation focus.

Question 3. Is the methodology of assessing and reducing the risk of development of tooling in automotive industry compatible with industrial metrics and process constraints?

Hypothesis 3. The methodology of assessing and reducing the risk of development of tooling in automotive industry aligns with APQP/PDCA and with the critical tooling development metrics, supporting practical implementation.

Scientific contribution

Definitions and process model

This dissertation introduces unified definitions of production tooling and production tooling development (Chapter 1.2), and develops an integrated, stage-based production tooling development model aligned with APQP and PDCA principles (Figure 5). This contribution provides a clearer conceptual framework and enables more consistent communication and decision making across tooling development projects.

Metrics foundation

The dissertation identifies and weights critical tooling-development metrics (Chapter 1.3, Table 8), reflecting technical, process and organisational dimensions relevant to tooling development risk. This metric foundation improves objectivity and comparability of project assessments, supporting prioritisation and more transparent evaluation of development progress.

Hybrid risk methodology

A hybrid methodology of assessing and reducing the risk of development of tooling in automotive industry is formulated combining risk category (RC) and risk limitation (RL) structures with unified linguistic scales, fuzzy-logic aggregation and threshold-based decision rules (Chapter 4). This hybridisation enhances the robustness of expert evaluations under uncertainty and enables actionable, stage-based decision thresholds.

Structural interpretation tools for risk composition

The dissertation introduces risk category (Chapter 4.2.1) and risk limitation (Chapter 4.2.2), contribution matrices enabling structural interpretation of risk composition at both stage and category levels. These tools support ownership assignment, clarify responsibility boundaries and facilitate targeted mitigation planning.

Demonstrators and validation

The methodology of assessing and reducing the risk of development of tooling in automotive industry is demonstrated on a simple example (hand-press) and validated on a full industrial project (Proj_1) with explicit risk value computation and mitigation planning (Chapter 5). These demonstrators confirm practical applicability and illustrate the method's capacity to provide transparent, quantitative and repeatable decision support.

Practical contribution

- Repeatable workflow: four phase methodology supported by templates (stages, assessment questions (AQ), scoring sheets, membership functions, thresholds, mitigation plans).
- Decision readiness: bounded total stage risk values with fixed thresholds enabling clear stage decisions.
- Action ownership: mapping mitigation tasks to responsible stakeholders according to risk category (RC) and risk limitation (RL) at each stage.
- Industry alignment: compatibility with APQP/PDCA and integration with critical tooling development metrics.

The methodology of assessing and reducing the risk of development of tooling in automotive industry defined in Chapter 4 provides a clear structural backbone for risk management in production tooling development. The four phases of the methodology of assessing and reducing the risk of development of tooling in automotive industry organise the process into coherent decision blocks, while the stage-based decomposition ensures traceability of risk across development steps. The use of unified linguistic scale and corresponding membership functions standardises expert judgements and improves comparability across projects and reviewers. The RC/RL combination - separating risk categories (RC) from risk limitations (RL) clarifies where risk originates and how it is constrained, which in turn supports targeted mitigation. Chapter 5 demonstrates the practical effectiveness of the methodology of assessing and reducing the risk of development of tooling in automotive industry on the industrial case (Proj_1). The calculated indicators differentiate stages and highlight dominant contributors in line with the expected RC/RL patterns. The threshold-based gate rules translate risk levels into clear go/hold/act decisions, and the contribution matrices map the dominant RC/RL drivers to stage-specific ownership, which facilitates focused mitigation planning and accountability.

Figure 10 presents overall structure of the dissertation and mapping of research tasks.

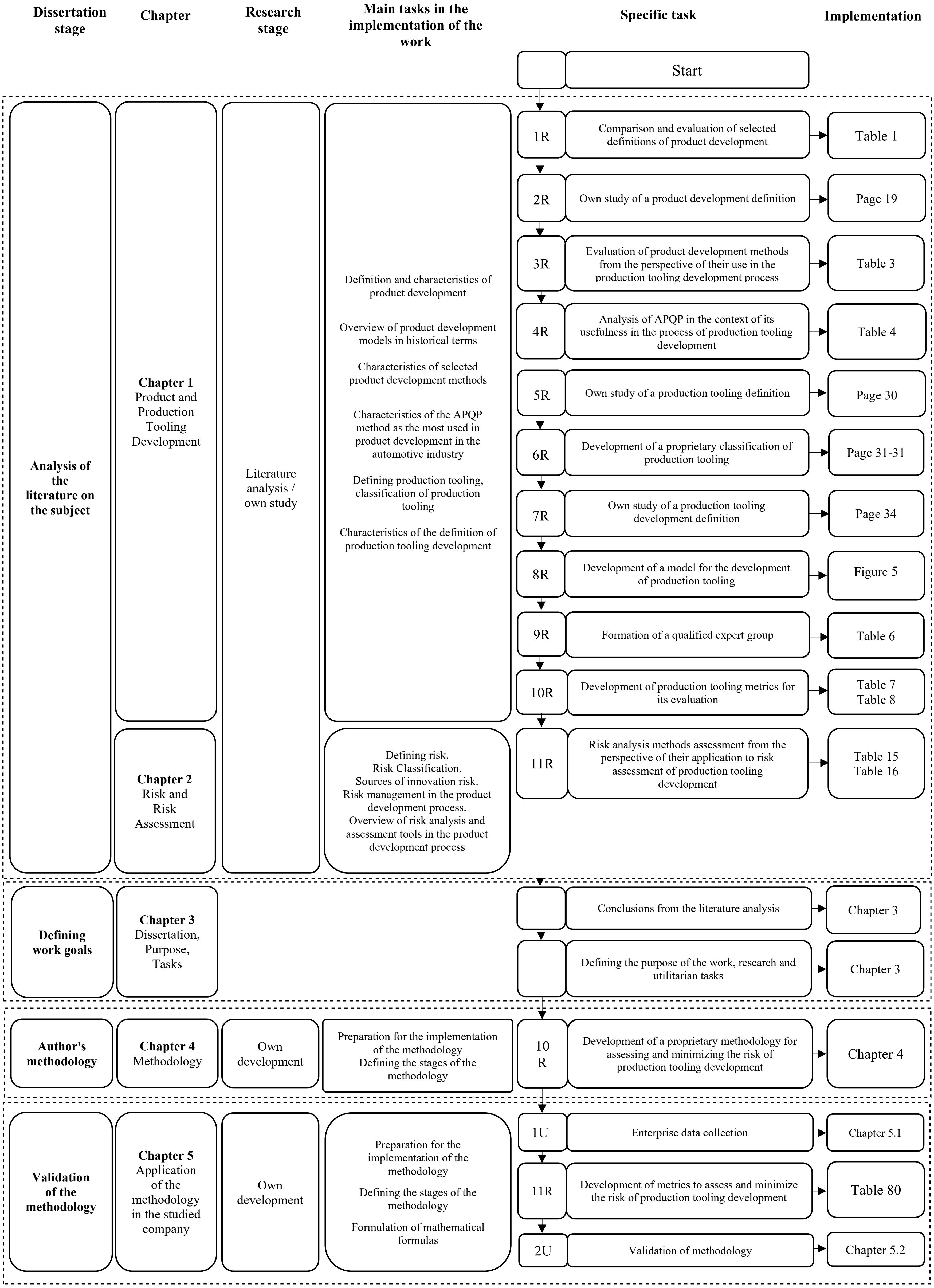


Figure 10 Overall structure of the dissertation and mapping of research tasks

4. Methodology of assessing and reducing the risk of development of tooling in automotive industry

This chapter presents a methodology of assessing and reducing the risk of development of tooling in automotive industry. The purpose of Chapter 4 is to concisely outline the assumptions, structure, and logic of the approach of the methodology - from process preparation, through defining risk factors, to the calculation and interpretation of risk values. The methodology of assessing and reducing the risk of development of tooling in automotive industry was developed based on a review of the literature, industrial practice and has been adapted to the specific characteristics of tooling projects in the automotive to address the gaps identified in Chapters 1–3.

Based on the outcomes of the literature review and identified research gaps, the original author's methodology of assessing and reducing the risk of development of tooling in automotive industry was developed focused on the development and introduction of a new product into serial production and the development of production tooling related to process development activities. The methodology of assessing and reducing the risk of development of tooling in automotive industry can be used when assessing risk, suitable for organizations implementing projects connected by a network of mutual dependencies, where, although each product is individual, the process under consideration follows a similar pattern. Proposed approach is based on a risk matrix and divides the project development process into phases to monitor and reduce risk. This methodology of assessing and reducing the risk of development of tooling in automotive industry enables managers to prioritize resources involved in the process of product development and act quickly on project stages with the higher risk focused on risk limitations and categories and is intended to improve the flow of information in organizations, which enables quick adaptation to necessary changes, increasing the possibility of achieving additional financial benefits or reducing the risk of project failure. Corrective actions may include additional investments, increasing the budget, searching for new business partners, managing personnel, negotiating with clients, and creating prototype tools.

The methodology of assessing and reducing the risk of development of tooling in automotive industry includes four main phases described in the Figure 11:

- Phase 1 - Process preparation.
- Phase 2 - Risk analysis preparation.
- Phase 3 - Risk calculation.
- Phase 4 - Risk values analysis and minimization.

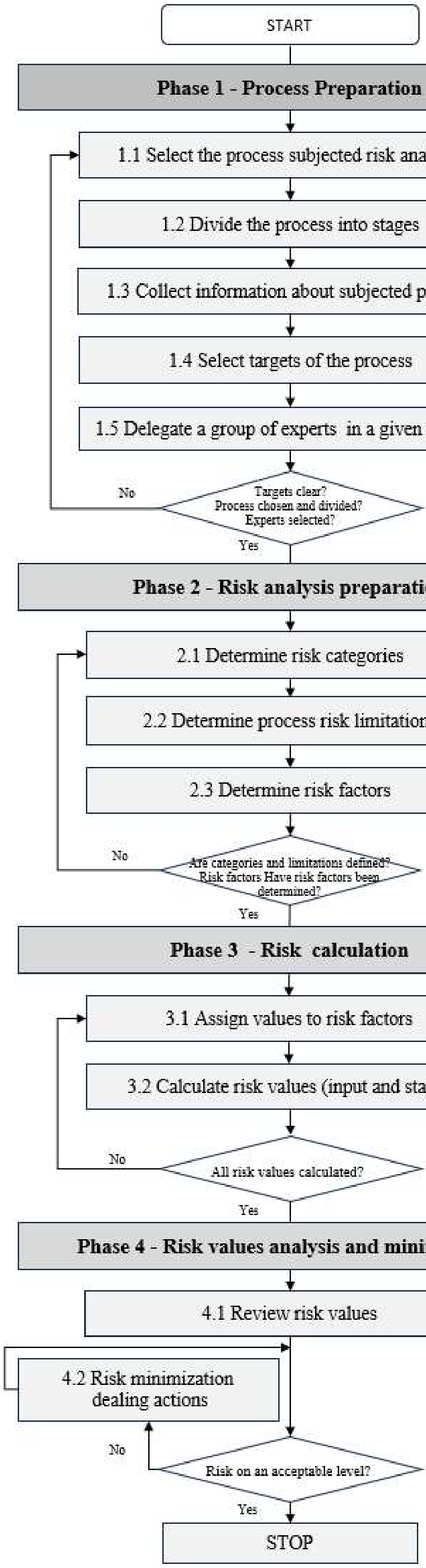


Figure 11 Flow chart for implementing the risk analysis methodology of assessing and reducing the risk of development of tooling in automotive industry

Example (Hand-press)

To enhance the readability and practical clarity of the proposed methodology of assessing and reducing the risk of development of tooling in automotive industry, a simple illustrative example is introduced and referenced throughout the explanation of each step. Presented hand-press simple example is intentionally minimalistic and concerns the risk assessment and mitigation activities performed during the development of a basic piece of production tooling - a hand-press equipped with a punch die. This example enables each phase of the methodology of assessing and reducing the risk of development of tooling in automotive industry to be followed in a transparent and intuitive manner to illustrate the logic and sequential flow before its full-scale application in Chapter 5.

4.1 Phase 1 - Process preparation

Phase 1 (Figure 12) defines the structural foundations required for a complete and repeatable risk assessment process. It specifies the scope and organisational framework for comprehensive risk analysis, including process selection, stage division, goal identification, and expert group assignment. Its correct implementation is the basis for further steps of the described methodology of assessing and reducing the risk of development of tooling in automotive industry.

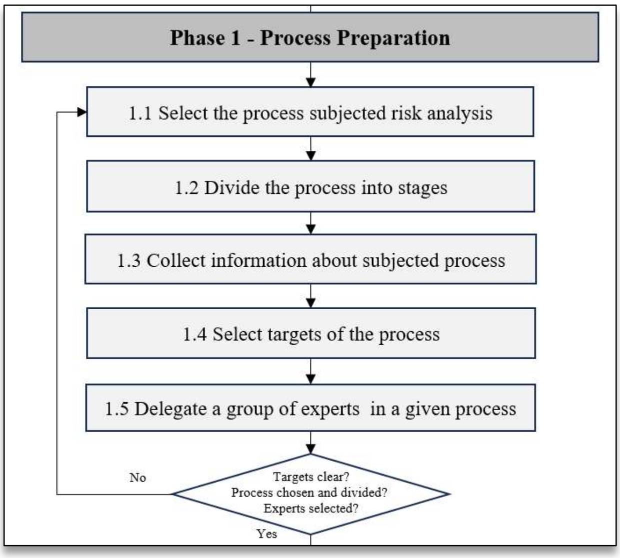


Figure 12 Phase 1 of the methodology of assessing and reducing the risk of development of tooling in automotive industry – process preparation

4.1.1 Select the process subjected risk analysis (Phase 1, Point 1.1)

Phase 1 begins with selecting the process that will be subject to risk analysis. This point of the phase involves establishing its boundaries by defining its beginning, end, and overall goal. The selected process can represent the full development product cycle (e.g., from the first product idea to market launch) or just a clearly defined segment, depending on the analysis's purpose. Once selected, the process remains unchanged throughout all subsequent phases.

Example (hand-press)

In the simplified example, the analysed process includes the development and initial deployment of a hand-press tool used to punch a 10-mm-diameter hole in a sheet-metal part. The process starts with the initial concept definition and ends with the acceptance of the completed press at the production site, where the tool is verified under representative manufacturing conditions.

4.1.2 Divide the process into stages (Phase 1, Point 1.2)

After defining the process, it is divided into fixed stages that remain constant throughout the entire analysis. Each stage must have a clearly defined start, end and expected output. Process decomposition becomes increasingly important with rising system complexity.

Stage division is a standard practice in project management [237], particularly for complex product development and enhances control and ensures completion of required tasks before advancing. Choice of division method depends on factors such as project objectives, stage duration and resource allocation. Stages should be defined by explicit start/end points, logical links between them and specific objectives aligned with the overall process goals.

The literature describes multiple dividing approaches, agile frameworks and visual mapping techniques [33], [37], [41]. However, in this dissertation the analysed process is divided into stages (STG), and this stage division must meet the following criteria:

- Reflect natural changes in process characteristics.
- Enable cause-and-effect analysis (evaluation of each stage towards a final score, considering the interrelationships between stages).
- Enable a clearer and more structured understanding of the process.

The methodology of assessing and reducing the risk of development of tooling in automotive industry proposes Table 25 to summarize the division of the process into stages.

Table 25 Division of the process into stages

Designation	Start condition	Stage definition	End condition
STG1			
STG2			
….			

Example (hand-press)

In the simplified example, process of development of the hand-press reflects the natural sequence of activities occurring during the development and is divided into following stages:

Stage 1 - Hand-press design creation. This stage includes the collection of fundamental functional requirements for and design of the hand-press

Stage 2 - Hand-press manufacturing. Fabrication of the tool according to the approved design.

Stage 3 - Hand-press start-up at the production site. The completed tool is tested under production conditions, and its correct operation is verified and confirmed. Table 26 illustrates the application of the template (Table 25) for hand-press example.

Table 26 Division of the process into stages - hand-press example

Designation	***Start condition***	***Stage definition***	***End condition***
STG1	*Need to develop a hand-press is identified*	*Hand-press design creation*	*Design concept completed and internally agreed*
STG2	*Hand-press design concept internally agreed*	*Hand-press manufacturing*	*Hand-press manufacturing completed and readiness for plant trials confirmed.*
STG3	*Hand-press delivered and installed at the production site*	*Hand-press start-up at the production site*	*Operational performance of the hand-press verified under production conditions*

4.1.3 Collect information about subjected process (Phase 1, Point 1.3)

This point organises all information necessary to describe the analysed tooling development process and to prepare the foundation for the subsequent identification and assessment of risk. The collected information establishes the process structure, its operational context, the involved stakeholders and the conditions under which the development is executed, enabling a coherent and comparable application of the methodology of assessing and reducing the risk of development of tooling in automotive industry across different tooling projects. To ensure clarity and comparability across tooling projects, the information gathered in this step is structured into two complementary categories: contextual process information and risk information areas.

Contextual process information provides a structured description of the project and its execution environment. They define:

- The tooling being developed (function, scope, characteristics).
- The product and part geometry that the tooling supports.
- The project framework (customer, number of toolsets, milestones, team composition).
- The organisational and execution setting (plant, production technology).
- High-level historical information describing typical duration and complexity patterns for similar tools.

This information describes the process, ensure its repeatable interpretation, and provide a consistent reference for comparing tooling development projects.

Table 27 stores important details about the contextual process information.

Table 27 Contextual process information – template

Project name	
Product family	
Customer	
Number of tool sets	
Others	

Risk information areas are structured areas in which uncertainty or variation may affect the outcome of tooling development. At this phase of the methodology of assessing and reducing the risk of development of tooling in automotive industry, they are not yet risk factors and do not belong to the analytical structure; rather, they indicate where relevant information resides before formal analysis, and serve as structured sources of information supporting the identification of risk factors in Phase 2. In practice, these areas refer to:

- Quality of engineering information.
- Maturity of technology and process.
- Supplier capabilities.
- Plant readiness.
- Competence and availability of project roles.
- Project history and lessons learned.
- Availability of critical resources.
- Organisational factors and governance.

These areas therefore function as a bridge between general sources of uncertainty and the formal risk factors identified in the following phase of the methodology of assessing and reducing the risk of development of tooling in automotive industry. They act as structured areas of inquiry - analogous to the branches of an Ishikawa diagram - which guide the identification of potential risks. Individual risk descriptions are therefore assigned to the areas providing a systematic frame for locating and discussing them.

Example (hand-press)

In the simplified example, the information collection step focuses on identifying the minimum dataset required to describe the tooling-development workflow. The information includes:

Contextual process information:

- *Technical information about the hand-press and its intended function.*
- *A part drawing defining the geometry produced with the tool.*
- *A shortlist of suppliers with experience in comparable workshop-level presses.*

Risk information areas:

- *Quality of engineering information (availability of basic part information).*
- *Supplier capabilities (availability of small-scale toolmakers).*
- *Plant readiness (feasibility of using the tool under workshop-level conditions).*

In the hand-press example, the risk information areas are limited to the minimum.

4.1.4 Select targets of the process (Phase 1, Point 1.4)

Selecting targets of the process establishes clear, measurable outcomes that confirm completion of each stage and readiness to proceed. Within the Stage-Gate framework, stage-specific targets take the form of milestones (measurable evidence) which are reviewed at gates-formal decision points that structure the process and ensure controlled progression to subsequent stages.

In practical terms, each milestone shall meet the following conditions [47], [158]:

- The outcome of each stage must be clearly defined and understood by all stakeholders; the criteria for proceeding to the next stage must be known in advance.
- Milestone outcomes are measurable, confirming stage completion and enabling objective gate decisions.
- Decisions at gate rely on evidence - documented process deliverables.
- Milestones are communicated clearly and in a timely manner to all relevant stakeholders to ensure alignment on expectations and progress.

To assign the objectives for each stage of the analysed process, the methodology of assessing and reducing the risk of development of tooling in automotive industry uses a dedicated milestone table (Table 28), in which every stage listed in Table 25 is linked with its measurable milestone.

Table 28 Process stage milestones - template

Stage	Milestone
STG1	
STG2	
…..	

The output of this step is a complete set of measurable milestones, recorded in Table 28.

Example (hand-press)

For the hand-press development process, the stage-specific targets are defined directly according to the three stages established in Phase 1.2. Each milestone represents measurable evidence confirming the completion of its corresponding stage. The overall process milestone is reached once the hand-press is delivered, tested and accepted at the production site. Table 29 presents the assigned milestones.

Table 29 Hand-press development process - milestones

Stage	*Milestone*
STG1	*Hand-press design accepted.*
STG2	*Hand-press manufacturing completed.*
STG3	*Hand-press handed over for serial production.*

4.1.5 Delegate a group of experts in a given process (Phase 1, Point 1.5)

The purpose of delegating the expert group is to support rapid and accurate decision-making throughout the process [238]. Effective expert groups share a common mental model [239], [240], enabling coherent judgment, consistent interpretation of process information and efficient collaboration. Their function in the methodology of assessing and reducing the risk of development of tooling in automotive industry is to provide the inputs required in subsequent steps, including risk assessment, evaluation of assumptions and verification of process-specific data.

Expert selection criteria may include, but are not limited to, factors such as experience, education, reputation, seniority within the company, neutrality, avoidance of conflicts of interest, impartiality, reliability, achievements, willingness to take risks, and availability. The experts appointed at this stage will provide all expert-based judgments required by this methodology throughout its application.

The expert group is appointed by the designated authority responsible for the analysed process, ensuring that the selected experts fulfil the competence and neutrality requirements.

Output of this step is a formally appointed expert group with defined roles, responsibilities and competencies, authorised to provide expert-based judgments for all subsequent steps of the methodology.

Example (hand-press)

In the hand-press example, tree experts were assigned to the hand-press development process:

Expert_A - workshop toolmaker.

Expert_B - workshop mechanic responsible for prototype and small tooling builds.

Expert_C - production operator involved in tool start-up and first-batch execution.

4.2 Phase 2 - Risk analysis preparation

Phase 2 prepares the risk analysis by defining and organising process risks for downstream evaluation, as presented in Figure 13. In this phase, it is essential to establish the common risk limitations (RL) and risk categories (RC) for the production tooling development process and to identify the specific risk factors that influence objectives at the level of individual stages.

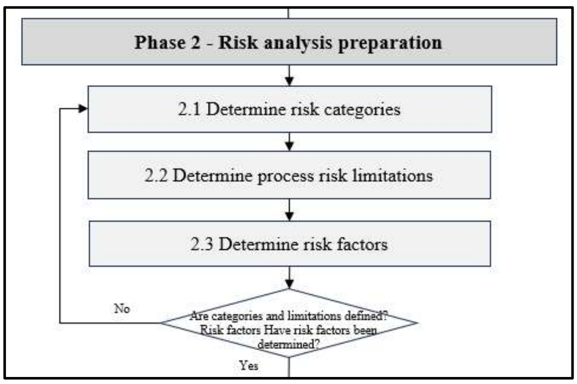


Figure 13 Phase 2 of the methodology of assessing and reducing the risk of development of tooling in automotive industry - risk analysis preparation

The methodology of assessing and reducing the risk of development of tooling in automotive industry does not impose a fixed number of risk categories (RC) or risk limitations (RL). Their selection depends on the specificity of the analysed process, data availability, and the terminology commonly used within the organisation. It is recommended, however, to minimise the number of categories and limitations to ensure clarity and to facilitate subsequent stages of the risk-assessment process. The naming of risk categories and limitations is also flexible. Organisations may adopt terminology consistent with their internal standards, industry language, or existing process narratives, provided that:

- All identified risk factors can be consistently assigned to the selected categories and limitations.
- The categories and limitations preserve their functional meaning within the methodology of assessing and reducing the risk of development of tooling in automotive industry.

4.2.1 Determine risk categories (Phase 2, Point 2.1)

Determination of risk categories involves groups of individual risk factors (RF) based on their shared sources, characteristics, organisational context or expected impact [148], [241]. Its purpose is to improve the quality of the risk analysis and to increase the efficiency of risk-management activities [242] by clarifying the differences between individual risk factors and by enabling their structured aggregation.

A risk category (RC) is therefore a group of risk factors that share a common origin, influence, or mechanism of action. Risk categories serve as an organising layer above individual risk factors and help structure the analysis, especially when the number of factors is large.

Examples of common product development risk categories include [243], [244]:

- Technological - risk factors related to technical uncertainty, immaturity of solutions or integration difficulties.
- Market - risk factors associated with unmet customer requirements, low demand or insufficient competitiveness.
- Legal / regulatory - risk factors arising from compliance requirements, certification constraints or intellectual-property issues.
- Financial - risk factors concerning budget limitations, cost overruns or funding uncertainty.
- Human / organisational competence - risk factors linked to team availability, skills, or organisational capability.
- Environmental - risk factors related to sustainability constraints or environmental regulations.
- Safety – risk factors related to user safety, product hazards or non-conformance to safety standards.

These risk categories (RC) do not replace risk factors. They serve only as higher-level organisational groupings that support systematic identification, communication and prioritisation of risk factors during the analysis.

When applying the risk categories (RC), organisations may extend or adapt the set of categories depending on the specifics of their processes, technologies or governance requirements. The methodology of assessing and reducing the risk of development of tooling in automotive industry does not prescribe a fixed list; instead, it provides a structured way of aggregating risk factors into coherent groups.

Table 30 presents the template for documenting risk categories (RC)

Table 30 Determination of risk categories - template

Risk Category (RC)	Examples of risk factors	Description
RC_1	…	…
RC_2	…	…
…	…	…

Example (hand-press)

For the hand-press example, two risk categories (RC) were identified: technical and organisational. In this context, the team's perception of risk is driven primarily by the technical capability of the press itself - its design assumptions, feasibility, material behaviour, manufacturability, and its ability to achieve stable functional performance during start-up. The representative risk factors for the hand-press example are presented in Table 31.

Table 31 Determination of risk categories – hand press example

Risk Category (RC)	*Examples of risk factors*	*Description*
RC_1 - Technical	*Material behaviour, cutting-edge geometry correctness, required punching force, manufacturability of tool components*	*Technical aspects affecting the ability of the tool to function properly and meet dimensional and performance requirements*
RC_2 - Organisational	*Availability of personnel, ergonomic and safety requirements, availability of machine time for trials, coordination during start-up*	*Organisational aspects affecting planning, resource availability and readiness to perform initial tool trials*

4.2.2 Determine process risk limitations (Phase 2, Point 2.2)

Determination of risk limitations (RL) involves defining the boundary conditions within which the production tooling development process is evaluated for risk exposure. Identifying the main threats to achieving the intended process goals is essential, as these threats define where the impact of risk becomes most critical and constitute the primary focus for the organisation conducting the analysis. In contrast to risk categories (RC), which describe where risks originate, risk limitations (RL) define the perspective from which risks must be minimized.

The selection of the risk limitations (RL) is performed by the expert group to ensure that they reflect the organization's operational reality and support consistent evaluation.

In automotive processes and especially in product development, typical limitations include execution time, budget, safety, product quality, and risk associated with a new product introducing a new product into serial production

These limitations are not exhaustive; additional limitations may apply depending on the product and project characteristics. Identifying limitations accelerates the recognition of risk factors and supports mitigation or risk transfer (e.g., outsourcing, analogous projects, insurance). When identifying and grouping risk factors, the focus should be on where the risk manifests and becomes critical, rather than on root causes. In practical applications, risk limitations (RL) may also be defined through existing project KPIs, provided that these indicators reflect the key constraints of the analysed process.

Each risk limitation (RL) is defined at the process level and described in accordance with this section. The output of this point of this phase is a consolidated set of risk limitations (RL) structured in Table 32.

Table 32 Determination of process risk limitations - template

Risk Limitation (RL)	Examples of risk limitation drivers	Description
RL_1	…	…
RL_2	…	…
…	…	…

Subsequently, individual risk factors are assigned both a risk category (RC) and a risk limitation (RL) in the assessment matrices.

Example (hand-press)

In the hand-press example, the relevant risk limitations (RL) were Timing (T) and Quality (Q), reflecting the need for the tool to be delivered within the planned schedule and to produce specification-compliant parts. The detailed definitions for T and Q in this example are summarised in Table 33.

Table 33 Determination of process risk limitations - hand-press example

Risk Limitation (RL)	*Examples of risk limitation drivers*	*Description*
RL_1 Quality	*Behaviour of the material used in the hand-press construction, overall construction and robustness of the hand-press design, generated force relative to the required operation, adequacy of the cutting-edge geometry for performing the operation*	*Hand-press delivered in a condition that ensure parts production according to*

		requirements of the product definition
RL_2 Timing	*Availability of workspace for first trials, availability of personnel and resources for initial tool start up*	*Hand-press delivered on time*

4.2.3 Determine risk factors (Phase 2, Point 2.3)

In this point of the phase, risk factors (RF) associated with the previously defined risk categories (RC) are determined. In this methodology, risk factors are understood as specific conditions, dependencies or process-related elements that may generate or intensify exposure by influencing the analysed process within the boundaries set by the defined risk limitations (RL).

To identify risk factors, this study applies a structured expert workshop built around an Ishikawa diagram and a moderated brainstorming session. The workshop is conducted by the expert group and can be supported by a small, qualified team representing the tooling development workflow. Its goal is to extract concrete, observable risk factors by systematically mapping, refining, and consolidating risk information areas into specific risk factors. A single input domain may yield one or multiple risks depending on its complexity and relevance. When defining risk factors, it is essential to distinguish between two fundamental types:

- Input Risk (R_I), which is normally fixed, unchanging and static throughout the entire process subject to risk analysis, but as well to the whole organization. It may arise from technical constraints (e.g., material behaviour, technological limitations), logistical aspects (e.g., internal transport, tooling weight), organisational conditions (e.g., team readiness, customer experience), quality-related requirements (e.g., tolerance frameworks), financial factors (e.g., budget, component prices), timing constraints (e.g., milestone dates, lead times), or safety obligations (e.g., compliance, inherent operational hazards). It establishes the baseline vulnerability of the project to risk exposure.

- Stage Risk (R_{STG}), which is variable and dynamic, and might change throughout the entire process. They may include technical issues (e.g., incorrect tool assembly, unstable temperatures, part sticking), logistical shortages (e.g., missing trial material), organisational gaps (e.g., inexperienced technicians, unavailable engineers), quality-related deficiencies (e.g., outdated CAD data, missing standards), financial impacts (e.g., excess material use, extended cycle times), timing disruptions (e.g., late deliveries, machine unavailability), and safety hazards (e.g., ergonomic issues, potential hot-oil leakage). They reflect dynamic operational deviations occurring throughout the process.

In the next step, to allow a structured and repeatable assessment of risk factors, it is necessary to develop a set of Assessment Questions (AQ). Assessment questions are standardized prompts that translate identified risks into observable and rateable criteria. They do not create or discover risks; rather, they provide a consistent means to evaluate a risk's presence, relevance, and severity within the defined risk boundaries.

Assessment questions operationalize identified input and stage risks in the context of risk categories (RC) and risk limitations (RL).

Each assessment question should:

- Relate to the risk category (RC) defined in previous step.
- Relate to input risk (R_I) or stage risk (R_{STG}).
- Be formulated in a way that allows it to be answered within the context of the defined risk limitation (RL).
- Be tailored to the specific organisational context, including its procedures, operational practices, and lessons learned.

The complete set of assessment questions (AQ) defined at this stage becomes the formal assessment instrument for determining input risk (R_I) and stage risk (R_{STG}) in the subsequent phases of the methodology of assessing and reducing the risk of development of tooling in automotive industry. To illustrate how this transformation occurs, the methodology of assessing and reducing the risk of development of tooling in automotive industry first derives a risk description (risk factor) from the underlying informational domain and then converts this risk description into a corresponding assessment question (AQ). Table 34 presents this intermediary step by mapping each identified risk factor to its originating risk information area, ensuring a traceable link between the source of uncertainty and the formalised risk statement.

Table 34 Mapping of risk factors to risk information areas

Input Risk (R_I) or Stage Risk (R_{STG})	Risk factor name	Risk description	Risk information area
..		..	..
..		..	..

For the technical and cost limitations within the logistic risk category, the assessment question derived from the risk information area “Maturity of technology and process” input risk statement “material shrinkage due to thermal expansion” can be formulated as follows:

“Is the material delivered under conditions that ensure stable thermal-expansion properties, allowing the dimensional requirements of the part to be met without generating additional cost?”

Artificial intelligence-based tools may support the drafting of preliminary AQ variants by identifying patterns or suggesting alternative formulations, but their role is limited to accelerating the initial preparation of question candidates. The final assessment questions should be reviewed, revised, and approved by the expert group to ensure alignment with the organisational context, process requirements, and the specifics of the process being analysed. Determining the assessment questions that operationalize the identified risk factors may be one of the most challenging parts of the methodology of assessing and reducing the risk of development of tooling in automotive industry, and the precision has a significant impact on the resulting analysis.

In the Table 35, risk categories (RC_1 to RCm) and defined limitations (RL_1 to RL_n) are combined with individual input risk (R_{I1} to R_{Ip}) and their corresponding assessment question (AQ_{RI1} to AQ_{RIp}).

Table 35 Input risk assessment matrix - template

Input Risk (R_I) description	Assessment Question (AQ)	Risk Category ($RC_1 \ldots RC_m$)	Risk Limitation (RL)		
			RL_1	RL_2	RL_n
R_{I1}	AQ_{RI1}	…	…	…	…
R_{I2}	AQ_{RI2}	…	…	…	…
…	…	…	…	…	…
R_{Ip}	AQ_{IRp}	…	…	…	…

In the Table 36, risk categories (RC_1 to RCm) for defined limitations (RL_1 to RL_n) groups are combined with individual stage risk (R_{STG1_1} to R_{STGs_t}) related to assessment question (AQR_{STG1_1} to AQR_{STGs_t}).

Table 36 Stage risk assessment matrix - template

Stage Risk (R_{STG}) description	Assessment Question	Risk Category ($RC_1 \ldots RC_m$)	Risk Limitation (RL)		
			RL_1	RL_2	RL_n
R_{STG1_1}	AQR_{STG1_1}		…	…	…
R_{STG1_2}	AQR_{STG1_2}		…	…	…
…	…		…	…	…
R_{STGs_t}	AQR_{STGs_t}		…	…	…

Table 35 and Table 36 are the output of this step of the methodology of assessing and reducing the risk of development of tooling in automotive industry and provide a structured representation of how each input risk (R_I) and stage risk (R_{STG}) is operationalized and evaluated within the context of risk categories (RC) and risk limitations (RL).

Example (Hand-press)

In the hand-press example, the workflow starts from the fixed set of eight risk information areas (Chapter 4.1.3), which serve as the thinking frame for discussing and locating risks. Each identified risk is first captured as a risk description and assigned to its originating *informational area. Next, the risk is classified as an input risk (R_I)Table 37 a stage risk (R_{STG}) in Table 38 .*

Table 37 Hand-press example - mapping of Input Risk (R_I) factors to risk information areas

Input Risk (R_I) factor	*Risk factor name*	*Risk description*	*Risk information area*
R_{I1}	*Hand-press feasibility vs. tolerance demand*	*Risk that due to quality/tolerance demands (e.g., cutting force implied by tight contours), a hand-press cannot meet the specified performance, forcing a technology change (e.g., hydraulic press)*	*Maturity of technology and process*
R_{I2}	*Team experience gap - hand-press*	*Risk that the project team lacks sufficient experience with comparable hand-press tools, increasing the likelihood of design gaps and late corrections.*	*Competence and availability of project roles*

Table 38 Hand-press example - mapping of Stage Risk (R_{STG}) factors to risk information areas

Stage Risk (R_{STG}) factor	*Risk factor name*	*Risk description*	*Risk information area*
R_{STG1_1}	*Incomplete functional requirements*	*Risk that functional requirements of the hand-press were not fully collected and approved before design release, leading to rework and delay*	*Quality of engineering information*
R_{STG1_2}	*Ergonomics and safety misalignment*	*Risk that hand-press ergonomics and safety criteria were not aligned with production, creating compliance or launch issues*	*Organisational factors and governance*
R_{STG2_1}	*Manufacturability on workshop machines*	*Risk that some hand-press components cannot be manufactured on the available workshop machines, causing redesign or outsourcing needs*	*Supplier capabilities*
R_{STG2_2}	*Trial-material unavailability*	*Risk that material meeting required parameters is not secured for build/trials, jeopardising schedule and test validity*	*Availability of critical resources*
R_{STG3_1}	*Start-up resource gap*	*Risk that required resources (e.g., operator, supervision, supplier support) are not confirmed for the planned start-up window*	*Competence and availability of project roles*

R_{STG3_2}	*Insufficient trial slot*	*Risk that the production schedule does not reserve sufficient time for the first trial batch, constraining verification and adjustments*	*Organisational factors and governance*

Finally, in the subsequent matrices, the classified risks are operationalised into assessment questions (AQ) and accompanied by their risk category (RC) and risk limitations (RL) for expert evaluation in Table 39 and Table 40.

The named factors listed above are operationalised into assessment questions (AQ) for expert scoring; Tables 39–40 present the resulting AQ matrices together with the assigned risk categories (RC) and limitations (RL).

Table 39 Input risk assessment matrix for the hand-press example

Input Risk (R_I) description	*Assessment Question (AQ)*	*Risk Category (RC)*	*Risk Limitation (RL)*	
			Timing	*Quality*
R_{I1}	*Are product requirements achievable within hand-press type of the tooling?*	RC_1 *Tech*	...	...
R_{I2}	*Does the project team responsible for the hand-press development have adequate experience with similar tools?*	RC_2 *Org*	...	...

Table 40 Stage risk assessment matrix for the hand-press example

Stage Risk (R_{STG}) description	*Assessment Question (AQ)*	*Category (RC)*	*Risk Limitation (RL)*	
			Timing	*Quality*
R_{STG1_1}	*Have the functional requirements of the hand-press been collected in a complete manner?*	RC_1 *Tech*	...	...
R_{STG1_2}	*Have all workstation, ergonomic and safety requirements been aligned with the production team?*	RC_2 *Org*	...	...
R_{STG2_1}	*Can all hand-press components be manufactured using the available workshop machines?*	RC_2 *Org*	...	...
R_{STG2_2}	*Are materials with appropriate parameters available for the press manufacturing?*	RC_1 *Tech*	...	...
R_{STG3_1}	*Will the required resources be available at the planned press start-up time?*	RC_2 *Org*	...	...

R_{STG3_2}	*Is the time required for the first trial batch available in the production schedule?*	RC_2 *Org*	...	...

4.3 Phase 3 - Risk calculation

The purpose of this phase (see Figure 14) is to quantify the previously identified risk factors and to evaluate them separately for input risk (R_I) and stage risk (R_{STG}). Expert judgements collected for each assessment question (AQ) are expressed on unified linguistic scale and converted into numerical scores with respect to the defined risk limitations (RL). The resulting values form the basis for consistent risk prioritisation and decision-making in the subsequent phase.

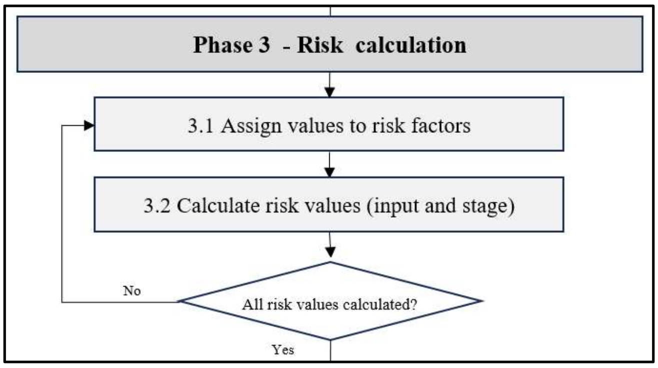


Figure 14 Phase 3 of the methodology - risk calculation

4.3.1 Assign values to risk factors (Phase 3, Point 3.1)

Within this methodology of assessing and reducing the risk of development of tooling in automotive industry, expert-based qualitative ratings are collected on unified linguistic scale and converted into numerical scores in the context of defined risk limitations (RL). Fuzzy logic serves as the standard conversion mechanism, ensuring consistent and comparable evaluation across process stages and projects. The selected approach must be applied consistently across process stages and projects to ensure comparability.

Each identified risk factor (via its assessment question, AQ) is rated against the relevant risk limitations (RL) by an expert group using the common linguistic scale. These ratings are then mapped to numerical values to obtain a consolidated score for subsequent prioritisation and decision-making. While discrete numerical scales (e.g., 1–10) are commonly used in engineering risk analysis, this methodology adopts linguistic terms as the default and converts them into numbers to better reflect the natural mode of expert reasoning and to improve inter-rater consistency.

To translate linguistic ratings into numerical scores in a transparent and repeatable way, the methodology of assessing and reducing the risk of development of tooling in automotive industry uses fuzzy logic as the default conversion mechanism. Simple triangular or trapezoidal membership functions are employed intentionally: they offer high interpretability for experts, preserve monotonicity with respect to risk severity, and avoid unnecessary parameter tuning.

The first step is to define the unified linguistic scale for all selected risk limitations (RL). This scale serves as a common reference for scoring every AQ and as the basis for conversion to numerical values. Table 41 provides a five-term template (Very Low, Low, Medium, High, Very High) to be instantiated with project-specific descriptions per RL.

Table 41 Linguistic scale for risk limitations (RL) - template

Linguistic term	Risk Limitation (RL)		
	RL_1	RL_2	RL_n
Very Low (VL)	project specific description	project specific description	…
Low (L)	…	…	…
Medium (M)	…	…	…
High (H)	…	…	…
Very High (VH)	…	…	…

Next, Table 42 specifies the membership function parameters corresponding to the linguistic terms and the chosen output scale. These two artefacts establish a shared frame for expert evaluation and subsequent conversion.

Table 42 Membership function values - template

Linguistic term	Membership function values for the Risk Limitation (RL)	Membership function values for the output (RPN)
Very Low (VL)		
Low (L)		
Medium (M)		
High (H)		
Very High (VH)		

Using the unified linguistic scale (Table 41) and the membership function definitions (Table 42), the expert group evaluates each input risk (R_I) and stage risk (R_{STG}). For every assessment question (AQ), each expert independently assigns a linguistic rating with respect to the relevant risk limitations (RL). These individual ratings are recorded in structured evaluation sheets (Table 43 for R_I and Table 44 for R_{STG}), ensuring consistent documentation of expert input.

Table 43 Input risk R_I evaluation - template

Input Risk (R_I)	Assessment Question (AQ)	Project Information	Risk Category (RC)	Expert_ A			…	Expert_C			Average		
				Risk Limitation (RL)			…	Risk Limitation (RL)			Risk Limitation (RL)		
				RL_1	…	RL_n	…	RL_1	…	RL_n	RL_1	…	RL_n
1	2	3	4	5	6	7	8	9	10	11	12	13	14
R_{I1}													

R_{I2}													
…													
R_{Im}													

Table 44 Stage risk R_{STG} evaluation - template

Stage Risk (R_{STG})	Assessment Question (AQ)	Risk Category (RC)	Expert_A			…	Expert_C			Average		
			Risk Limitation (RL)			…	Risk Limitation (RL)			Risk Limitation (RL)		
			RL_1	…	RL_n	…	RL_1	…	RL_n	RL_1	…	RL_n
1	2	3	4	5	6	7	8	9	10	11	12	13
R_{STG1}												
R_{STG2}												
…												
R_{STGm}												

Once all linguistic ratings are collected, they are converted into numerical values using the membership functions defined in Table 42. The resulting numerical scores for each risk limitation RL dimension are then aggregated across experts, producing a consolidated evaluation for every input risk R_I and stage risk R_{STG}. These aggregated values serve as the basis for computing the fuzzy risk priority numbers (Fuzzy RPN) summarised in Table 45 (R_I) and Table 46 (R_{STG}) in the next step of the methodology of assessing and reducing the risk of development of tooling in automotive industry.

Table 45 Summary of assessment results for input risks R_I - template

Input risk	**RL_1**	**RL_2**	**…**	**RLn**	**Fuzzy RPN**
R_I	..	..	..	…	..

Table 46 Summary of assessment results for stage risks R_{STG} - template

Stage risk	**RL_1**	**RL_2**	**…**	**RLn**	**Fuzzy RPN**
R_{STG1}	..	..	..	…	..
R_{STG2}					
R_{STGs}					

The consolidated results presented in Table 45 and Table 46 represent the defuzzified numerical evaluation of all risk factors with respect to the defined risk limitations (RL). These values provide a consistent, comparable measure of risk contribution across process stages and enable the identification of factors with the highest influence defined risk limitations (RL). The resulting fuzzy risk priority numbers (Fuzzy RPN) form the quantitative foundation for the next phase, in which input risk and stage risk values are combined to derive the overall process-risk profile and to support structured prioritisation and mitigation planning.

Example (Hand-press)

In the hand-press example, the expert group assigned linguistic ratings to all assessment questions (AQ) defined in Phase 2. Two risk limitations (RL) are relevant for this example: Quality (Q) and Timing (T), reflecting the need to deliver the tool within the planned schedule and to ensure that the produced parts meet specification requirements.

To support consistent expert judgements, project-specific descriptions of the linguistic scale were defined for both limitations, according to membership function values (Table 42, simplified to a 3-level scale for this example) as shown in Table 47.

Table 47 Linguistic scale for risk limitation (RL) in the hand-press example

Linguistic term	*Risk Limitation (RL)*	
	Quality	*Timing*
Low (L)	*Minor impact - easily correctable impact on the produced part*	*Small delay (1day)*
Medium (M)	*Moderate impact - requiring basic on-site adjustment*	*Moderate delay (2–3 days)*
High (H)	*Major impact - may disturb achieving the required result*	*Major delay (4–5 days)*

Each expert rated all input risks (R_I) and stage risks (R_{STG}) using the unified linguistic scale. Table 48 and

Table 49 *show the linguistic ratings provided by the experts and the corresponding aggregated values for the risk limitations (RL): quality (Q) and timing (T).*

Table 48 Hand-press example input risk assessment

Input Risk (R_I)	*Assessment Question (AQ)*	*Project Information*	*Risk Category (RC)*	*Expert_A*		*Expert_B*		*Expert_C*		*Avg.*	
				RL		*RL*		*RL*		*RL*	
				Q	*T*	*Q*	*T*	*Q*	*T*	*Q*	*T*
R_{I1}	*Are product requirements achievable within hand-press type of the tooling?*	*Part drawing*	*Tech*	*L*	*L*	*L*	*M*	*M*	*M*	***3.00***	***4.00***

R_{I2}	*Does the project team responsible for the hand-press development have adequate experience with similar tools?*	*Project team*	*Org*	*L*	*L*	*L*	*L*	*L*	*M*	***2.00***	***3.00***

Table 49 Hand-press example stage risk assessment

Stage Risk (R_{STG})	*Assessment Question (AQ)*	*Risk Category (RC)*	*Expert_A*		*Expert_B*		*Expert_C*		*Avg.*	
			RL		*RL*		*RL*		*RL*	
			Q	*T*	*Q*	*T*	*Q*	*T*	*Q*	*T*
R_{STG1_1}	*Have the functional requirements of the hand-press been collected in a complete manner?*	*Tech*	*L*	*L*	*L*	*L*	*L*	*L*	***2.00***	***2.00***
R_{STG1_2}	*Have all workstation, ergonomic and safety requirements been aligned with the production team?*	*Org*	*L*	*L*	*M*	*L*	*M*	*L*	***4.00***	***2.00***
R_{STG2_1}	*Can all hand-press components be manufactured using the available workshop machines?*	*Org*	*L*	*L*	*L*	*L*	*M*	*M*	***3.00***	***3.00***
R_{STG2_2}	*Are materials with appropriate parameters available for the press manufacturing?*	*Tech*	*L*	*L*	*M*	*M*	*M*	*M*	***4.00***	***4.00***
R_{STG3_1}	*Will the required technical skilled resources be available at the planned press start-up time?*	*Tech*	*L*	*L*	*L*	*L*	*M*	*L*	***3.00***	***2.00***
R_{STG3_2}	*Is the time required for the first trial batch available in the production schedule?*	*Org*	*M*	*L*	*H*	*M*	*H*	*L*	***7.00***	***3.00***

The linguistic terms were converted into numerical scores using the triangular membership functions defined for this example (Table 50).

Table 50 Membership function values for hand-press example

Linguistic term	*Membership function values for the Risk Limitation (RL)*	*Membership function values for the output (RPN)*
Low (L)	*(0;2;4)*	*(0;200;400)*
Medium (M)	*(3;5;7)*	*(200;500;800)*
High (H)	*(6;8;10)*	*(600;800;1000)*

The defuzzified results for the hand-press input risks (R_I) are summarised in Table 51, and the results for stage risks (R_{STG}) in Table 52. These values represent the final fuzzy risk priority numbers (Fuzzy RPN) for the example.

Table 51 Summary of hand-press example assessment results for input risks RI

Input risk (R_I)	***Q***	***T***	***RPN***
R_I	*2.50*	*3.50*	*394*

Table 52 Summary of hand-press example assessment results for stage risks R_{STG}

Stage risk (R_{STG})	***Q***	***T***	***RPN***
R_{STG1}	*3.00*	*2.00*	*200*
R_{STG2}	*3.50*	*3.50*	*394*
R_{STG3}	*5.00*	*2.50*	*500*

4.3.2 Calculate risk values (Phase 3, Point 3.2)

In this point of the phase, the numerical risk values are calculated by consolidating the defuzzified expert scores into a single indicator representing the level of exposure associated with each process stage. The calculation relies on:

- The risk limitations (RL) defined in Phase 2.
- The risk categories (RC).
- Individual Input Risk R_I and Stage Risk R_{STG}.
- Defuzzified expert scores obtained from the assessment questions (AQ).

At this step, the Total Stage Risk is obtained by combining the project level Input Risk (R_I) and the Stage Specific Risk (R_{STGs}) through normalization and a multiplicative operator [245], [246]:

$$R_{TS\quad s} = \left(\frac{R_I}{1000}\right) \cdot \left(\frac{R_{STG_S}}{1000}\right) \tag{6}$$

where:

- *R_{TSTGs} - Total Stage Risk for stage s; the final exposure used for decision making and comparisons across stages.*
- *R_I - Input Risk (Table 45 and Table 51).*
- *R_{STGs} - Stage Risk (Table 46).*

Eq. (6) uses multiplicative aggregation to captures the interaction between the project baseline exposure and the stage-specific variability.

Table 53 summarises the total stage risks calculated for each stage.

Table 53 Summary of assessment results for the total stage risks R_{TSTGs} - template

Total risk	Project stage	Risk value
R_{TSTG1}	STG1	…
R_{TSTG2}	STG2	…
…	…	…
R_{TSTGs}	STGs	…

Example (Hand-press)

In the hand-press example, defuzzified scores yielded input risk $R_I = 394$, and stage risks $R_{STG\_1} = 200$, $R_{STG\_2} = 394$, $R_{STG\_3} = 500$ (averaged across expert ratings and corresponding AQs). Because input and stage risks are correlated (initial conditions modulate stage-level behaviour), the multiplicative model is applied.

To enable meaningful multiplication, R_I and R_{STG} values are normalised to a common 0–1 scale using the reference range defined for the example (see Phase 3.1). The resulting total stage risks are shown in Table 54.

Table 54 Risk value for each stage of the hand-press development

Total risk	***Project stage***	***Risk value***
R_{TSTG1}	*Hand-press design creation*	*0.079*
R_{TSTG2}	*Hand-press manufacturing*	*0.115*
R_{TSTG3}	*Hand-press handed over for serial production*	*0.197*

4.4 Phase 4 - Risk values analysis and minimization

This phase (Figure 15) focuses on interpreting the computed risk values and using them to support decisions aimed at reducing exposure to an acceptable level. It transforms the outcomes of Phase 3 into actionable mitigation steps by analysing input risk (R_I), stage-specific risk (R_{STG}) and their distribution across the predefined risk categories (RC) and risk limitations (RL). The analysis also identifies cases where the total stage risk (R_{TSTG}) exceeds defined thresholds, ensuring continuous monitoring of risk levels and enabling targeted interventions aligned with project objectives and limitation-driven priorities.

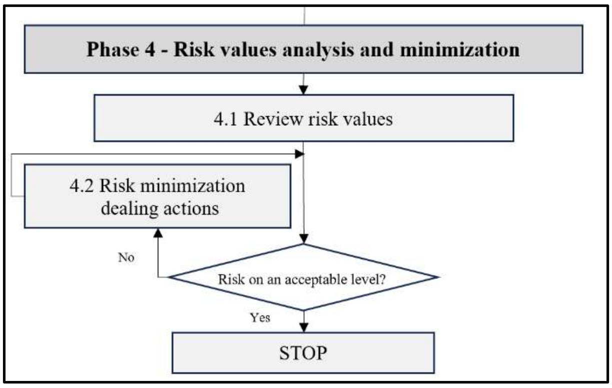


Figure 15 Phase 4 of the methodology of assessing and reducing the risk of development of tooling in automotive industry - risk values analysis and minimization

4.4.1 Review risk values (Phase 4, Point 4.1)

Reviewing the calculated risk values is the first decision-making activity in Phase 4. In this point, the objective is to establish whether the obtained results are complete and consistent, and whether they exceed risk thresholds that require action.

4.4.1.1 Verification of data consistency

The verification stage may include the following activities:

- Checking the completeness and internal consistency of the results.
- Identifying outlier or non-representative values.
- Validating the assessment-relevant input data.
- Recording the results.
- Identifying areas that require corrective action.

4.4.1.2 Structural analysis of risk distribution

The methodology of assessing and reducing the risk of development of tooling in automotive industry introduces two structural matrices that support the systematic interpretation of how risk is distributed across the analysed process. Both matrices convert numerical results into percentage values, which reveal the concentration, dominance and variability of risk across defined categories and limitations.

The first matrix (Table 55) summarizes the distribution of risk across the risk categories ($RC_1 \ldots RC_m$), by decomposing the input risk (R_I) and stage risk (R_{STG}), values into percentage contributions assigned to each category.

Table 55 Risk category distribution matrix

Risk Category (RC)	R_I	R_{STG1}	R_{STG2}	…	R_{STGs}
RC_1	…%	…%	…%	…%	…%
RC_2	…%	…%	…%	…%	…%
…	…%	…%	…%	…%	…%
RC_m	…%	…%	…%	…%	…%
$\sum$	100%	100%	100%	100%	100%

The second matrix (Table 56) presents the analogous distribution across the predefined risk limitations (RL1…RLn) showing the extent to which the limitations contribute to the input risk R_I and stage risk R_{STG}.

Table 56 Risk limitation distribution matrix

Risk Limitation (RL)	R_I	R_{STG1}	R_{STG2}	…	R_{STGs}
RL_1	…%	…%	…%	…%	…%
RL_2	…%	…%	…%	…%	…%
…	…%	…%	…%	…%	…%
RL_n	…%	…%	…%	…%	…%
$\sum$	100%	100%	100%	100%	100%

In both matrices, percentages are normalised within each column. For each column (R_I, R_{STG1}, R_{STG2}, …., R_{STGs}) the percentages across all Risk Categories (RC) categories sum to 100%, analogously, for each column the percentages across all Risk Limitations (RL) dimensions sum to 100%. This representation enables direct comparison between process steps, identification of disproportionate exposures, recognition of stage-specific vulnerabilities, and provides a structural basis for prioritising mitigation actions in subsequent phases. RC or RL is considered dominant when its contribution shows a material advantage over the alternative; where no clear advantage is observed, RC and RL are treated as co-dominant.

The purpose of each matrix is to identify:

- Which risk categories or limitations contribute most strongly to the input risk (R_I) and the stage risk (R_{STG}).
- How the influence of individual categories or limitations evolves throughout the analysed process.
- Which categories or limitations shows elevated exposure and therefore represent priority areas for further investigation.
- Which elements should be addressed first during mitigation activities based on their relative contribution to the overall risk.
- Whether the observed risk distribution exceeds organisational thresholds or predefined acceptance criteria.

Both matrices serve as inputs to the mitigation process described in Phase 4 by providing the structural context required for interpreting the total risk values.

4.4.1.3 Evaluation through decision thresholds

Evaluation through decision thresholds provides an objective basis for classifying the calculated Input Risk (R_I), Stage Risk (R_{STG}) and Total Stage Risk (R_{TSTG}) into predefined exposure levels. These thresholds define three decision categories – low (L), medium (M) and high (H) - which ensure consistent and repeatable interpretation of risk values across projects.

In this evaluation, R_I describes the overall sensitivity of the project to risk, R_{STG} reflects local flexibility at individual stages, while R_{TSTG} serves as the decisive criterion for determining whether mitigation actions are required. A low R_{TSTG} indicates acceptable exposure, a medium value signals the need for preventive measures, and a high value requires immediate corrective action. Because thresholds remain constant for all implementations of the methodology of assessing and reducing the risk of development of tooling in automotive industry, the same risk level always results in the same decision path, regardless of the tooling type, supplier or product family.

A low (L) risk classification allows the process to proceed without additional actions. A medium (M) risk classification requires the implementation of preventive mitigation measures selected according to the dominant Risk Category (RC) and Risk Limitation (RL). A high (H) risk classification indicates a critical condition where the stage must not progress until the risk is reduced through urgent corrective actions, possibly including resource escalation, re-planning or technical redesign, and short-term corrective actions.

The decision thresholds applied to R_I, R_{STG} and R_{TSTG} have to be established based on historical project data and expert evaluation. Table 57 presents an example of a risk-mitigation matrix serving to define and collect evaluation thresholds.

Table 57 Risk mitigation thresholds table

Risk priority level	Input risk (R_I) range	Stage risk (R_{STG}) range	Total stage risk (R_{TSTG}) range
Low	R_I < ?	R_{STG} < ?	R_{TSTG} < ?

Medium	? ≤ R_I < ?	? < R_{STG} < ?	? ≤ R_{TSTG} < ?
High	R_I ≥ ?	R_{STG} ≥ ?	R_{TSTG} ≥ ?

Recommendations for mitigation measures are formulated by a panel of experts, whereas decisions regarding implementation and resource allocation remain the responsibility of the project team.

The thresholds in Table 57 illustrate the conceptual decision logic of the methodology of assessing and reducing the risk of development of tooling in automotive industry. In practical implementation, decision thresholds for $R_{I,}$ R_{STG} and R_{TSTG} are defined once and remain unchanged across all projects to ensure comparability and consistent evaluation. This fixed structure preserves comparability across projects.

4.4.1.4 Recording the results

Recording the results of the threshold-based evaluation ensures transparency, traceability and consistent decision-making in the subsequent steps of the methodology of assessing and reducing the risk of development of tooling in automotive industry. Once the Total Stage Risk (R_{TSTG}) values have been assigned to the predefined exposure levels, the outcomes are documented in a dedicated summary table, where they form the reference basis for mitigation planning in Phase 4.2.

The consolidated results for each process stage are presented in Table 58, which assigns every R_{TSTG} value to its corresponding risk level.

Table 58 Total stage risk level for individual stage

Total risk	***Project stage***	***Risk value***	***Risk level***
R_{TSTG1}			
R_{TSTG2}			
R_{TSTGs}			

Example (Hand-press)

The review of the risk values confirms that all collected data are internally consistent, with no outliers or contradictory assessments identified across either the input risk or stage risk evaluations. The obtained values therefore require no corrective adjustments at the data-quality level and can be directly used for subsequent risk analysis and interpretation.

The percentage-based distributions of the hand-press example across categories and limitations are presented in

Table 59 and Table 60.

Table 59 Hand-press example risk category ratio

Risk category (RC)	R_I	R_{STG1}	R_{STG2}	R_{STG3}
1	*2*	*3*	*4*	*5*
Technical	*58%*	*40%*	*57%*	*33%*
Organisational	*42%*	*60%*	*43%*	*67%*

Table 60 Hand-press example risk limitation ratio

Risk Limitation (RL)	R_I	R_{STG1}	R_{STG2}	R_{STG3}
1	*2*	*3*	*4*	*5*
Quality	*42%*	*60%*	*50%*	*67%*
Timing	*58%*	*40%*	*50%*	*33%*

The results show that the early stages (R_I and R_{STG1}) are dominated by organisational factors, while later stages gradually shift towards technical influences, with R_{STG3} being driven entirely by organisational conditions due to start-up-related constraints. Similarly, the limitation-based distribution indicates that timing is the dominant exposure at the input level, while quality becomes increasingly influential in later stages, reaching its highest share in R_{STG3}. These patterns illustrate how risk origins and constraints evolve throughout the process and provide a clear indication of which areas require attention during subsequent mitigation planning.

The risk-priority thresholds used to classify input risk (R_I), stage risk (R_{STG}) and total stage risk (R_{TSTG}) values for the hand-press example are presented in Table 61.

Table 61 Risk priority thresholds for the hand-press example.

Risk priority level	*Input risk (R_I) range*	*Stage risk (R_{STG}) range*	*Total stage risk (R_{TSTG}) range*
Low	$R_I < 300$	$R_{STG} < 300$	$R_{TSTG} < 0.090$
Medium	$300 \leq R_I < 700$	$300 \leq R_{STG} < 700$	$0.090 \leq R_{TSTG} < 0.210$
High	$R_I \geq 700$	$R_{STG} \geq 700$	$R_{TSTG} \geq 0.21$

Using the thresholds defined in Table 61, the classification of the input-risk and stage-risk values presented in Table 54 is as follows:

- *Input risk: $R_I = 394$ falls within the medium range.*
- *Stage risks: $R_{STG1} = 200$ is low; $R_{STG2} = 394$ and $R_{STG3} = 500$ falls within the medium range*

On this basis, the aggregated total stage risk values (R_{TSTG}) derived according to the multiplicative model are categorised in Table 62.

Table 62 Total stage risk levels for the hand-press example

Total risk	***Project stage***	***Risk value***	***Risk level***
R_{TSTG1}	*Hand-press design creation (STG1)*	*0.079*	*Low*
R_{TSTG2}	*Hand-press manufacturing (STG2)*	*0.115*	*Medium*
R_{TSTG3}	*Hand-press handed over for serial production (STG3)*	*0.197*	*Medium*

These results indicate that the initial design stage of the hand-press does not require additional action, whereas the manufacturing and start-up stages exhibit medium-level exposure and therefore require preventive planning to reduce the likelihood of delays or quality deviations in later phases of the process.

4.4.2 Risk minimization (Phase 4, Point 4.2)

4.4.2.1 Identification of stages requiring action

Identification of stages requiring action is the first step in the risk-minimisation process. Based on the threshold-based evaluation carried out in Phase 4.4.1, each process stage is assigned to one of the predefined exposure levels (low, medium or high). This categorisation determines whether a stage progresses without intervention or whether additional preventive or corrective measures must be planned.

A stage is considered safe when its total stage risk (R_{TSTG}) falls within the low-exposure range. In such cases, no mitigation activities are required, and the development process can proceed as planned. Stages classified within the medium exposure range indicate elevated vulnerability; although they do not pose an immediate threat to project execution, they require preventive planning to stabilise subsequent activities. Stages classified as high exposure represent critical points in the process and necessitate immediate corrective actions to prevent delays, quality issues or cost overruns.

This identification step summarises the results of the risk assessment and isolates those stages that must be prioritised during mitigation planning. By linking the exposure level directly to the R_{TSTG} evaluation, the methodology of assessing and reducing the risk of development of tooling in automotive industry ensures that attention and resources are focused precisely where risk is both significant and actionable.

4.4.2.2 Selection of mitigation measures

The selection of mitigation measures in this methodology of assessing and reducing the risk of development of tooling in automotive industry is directly driven by the identification of the input risk (R_I), total stage risk (R_{TSTG}) as well as dominant risk category (RC) and risk limitation (RL) for each process stage. Table 63 presents the decision logic applied in the methodology of assessing and reducing the risk of development of tooling in automotive industry for selecting mitigation actions, operationalises the risk-based decision process depended on the level of risk as well as whether RC or RL - either individually or jointly - exert dominant influence on the stage-level risk.

Table 63 Decision matrix for selecting mitigation actions based on R_I, R_{TSTG}, RC and RL dominance

Input Risk (R_I) level	Total Stage Risk (R_{TSTGs}) level	Risk category (RC) dominant?	Risk limitation (RL) dominant?	Mitigation action recommendations
High / Medium / Low	High	Y	Y	
			N	
		N	Y	
			N	
	Medium	Y	Y	
			N	
		N	Y	
			N	
	Low	Y	Y	
			N	
		N	Y	
			N	

In this methodology, a risk category (RC) or risk limitation (RL) is considered dominant when its contribution is clearly higher than that of the alternative. If no clear dominance is visible, RC and RL are treated as co-dominant, and mitigation measures are applied to both dimensions, supported by a brief diagnostic to identify - if possible - the primary driver. By explicitly distinguishing between dominant, co-dominant and non-dominant RC/RL patterns, the matrix ensures that each intervention is precisely aligned with the underlying driver of the risk and proportionally scaled to the severity of R_{TSTG} and R_I. This results in consistent boundary conditions in mitigation planning across all stages.

Table 64Table 65 provides a stage-level template for documenting the selected mitigation measures based on the R_I and R_{TSTG} as well as dominant RC–RL combination.

Table 64 Stage-level mitigation planning based on dominant risk limitations and risk categories

Process Stage (STG)	Risk level	Dominant Risk Category	Dominant Risk Limitation	Selected mitigation actions	Responsible role	Planned completion date

Examples of mitigation actions might be selected depending on the category according to the list below:

- Technical: additional analytical activities, prototyping, trials, simulation-based assessments under varied or extreme conditions, benchmarking technical solutions, early involvement of technical experts, cross-checking tooling and machine interfaces, aligning technical scope and tolerances with supplier quotations, verifying tooling and equipment readiness before startup, preparing startup acceptance criteria (TFOT, scrap, cycle time), and ensuring on-site supplier technical support during critical phases.
- Logistic: establishing alternative suppliers or secondary sourcing paths, early reservation of critical components with long lead times, buffer stock creation, logistic timeline compression through parallel planning, dedicated tracking of supply-chain status and potential disruptions, validating supplier capacity and delivery reliability.
- Organization: dynamic resource reallocation to high-risk areas, augmenting teams with additional specialists, establishing cross-functional coordination routines, securing management support for priority tasks, conducting weekly status reviews before key milestones, performing mandatory cross-functional specification reviews with documented minutes, applying checklist-based verification routines before releasing specifications, defining escalation and change-cost handling rules, coordinating supplier schedules and internal teams, and aligning engineering, production and quality functions prior to production startup.
- Quality: enhanced incoming inspection or supplier quality checks, early introduction of quality gates at critical milestones, additional audits of processes or documentation, increased sampling frequency during early production stages.
- Finance: establishing financial buffers for high-uncertainty tasks, early negotiation of pricing or volume agreements with suppliers, monitoring cost deviations more frequently at project hotspots, scenario-based budgeting (best/worst/most-likely).
- Safety: early involvement of safety engineers in the design phase, increasing test coverage for safety-critical scenarios, conducting safety training for relevant personnel, applying stricter acceptance criteria for safety-relevant components, integrating additional safety checkpoints into project reviews.

These measures represent typical interventions applied in industrial tooling development environments and can be adapted depending on the source and magnitude of the identified risks. Organizations implementing the methodology of assessing and reducing the risk of development of tooling in automotive industry should, where practicable, maintain a standard set of mitigation actions mapped to the dominant risk limitations (RL) and risk categories (RC), and tailor them to the specific stage and context of each project.

The final confirmation of the effectiveness of mitigation actions is performed at the project-governance level. In the proposed methodology of assessing and reducing the risk of development of tooling in automotive industry, the residual risk for a given stage is considered acceptable once the corresponding project stage-gate (STG) is passed with a green status. Approval of the gate constitutes a formal decision point confirming that no further mitigation actions are required for that stage and that the project may proceed to the next phase.

Example (Hand-press)

Based on Input Risk (R_I) evaluated with medium (M) risk the Total Stage Risk (R_{TSTG}) classifications presented in Table 62, Stage 2 (STG2) and Stage 3 (STG3) require medium-level mitigation, while Stage 1 (STG1) remains within the acceptable range and does not require additional action. Table 65 truncated for the needs of the hand-press example, presents the procedure for selecting the recommended mitigation actions for this case.

Table 65 Hand-press example decision matrix for selecting mitigation actions based on R_I, R_{TSTG}, RC and RL dominance

Input risk (R_I) level	Total stage risk (R_{TSTG}) level	Risk category (RC) dominant	Risk limitation (RL) dominant	Mitigation action recommendations
High	…	…	…	…
Medium	Medium	Y	Y	Actions focus on mitigations related to dominant category and limitation
		Y	N	Actions focus on mitigations related to dominant category
	Low	Y	Y	No activity
Low	…	…	…	…

For R_I Medium for all R_{TSTG}:

1 R_{TSTG1} Low / RC dominant (Y) / RL dominant (Y) – no activity

2 R_{TSTG2} Medium / RC dominant (Y) / RL dominant (Y) – actions focus on mitigations related to dominant category and limitation

3 R_{TSTG3} Medium / RC dominant (Y) / RL dominant (N) –Actions focus on mitigations related to dominant category

In line with the recommendations derived from Table 65, Table 66 presents the stage-level mitigation planning for the hand-press example, including assigned responsibilities and due dates.

Table 66 Stage-level mitigation planning based on dominant risk limitations and risk categories – Hand-press example

Stage (STG)	Risc level	Dominant Risc Category	Dominant Risk Limitation	Selected mitigation actions	Responsible role	Planned completion date
R_{TSTG1}	L	-	-	-	-	-

R_{TSTG2}	*M*	*Technical (57%)*	*Quality (67%)*	*Confirm workshop machines availability*	*Workshop Manager*	*CW7*
				Hand-press design handover for production	*Protoshop Manager*	*CW7*
R_{TSTG3}	*M*	*Organizational (67%)*	*Timing & Quality (50%/50%)*	*Confirm process engineer availability during first parts production*	*Engineering Manager*	*CW9*

Summary

To present the methodology of assessing and reducing the risk of development of tooling in automotive industry in a clear and concise structural form, Table 67 provides a compact overview of all phases and their corresponding analytical steps.

Table 67 Summary map of the methodology of assessing and reducing the risk of development of tooling in automotive industry

Phase	Description	Outputs
1.1 Select the process subjected risk analysis	Formally define the process to be assessed, including its start and end points, boundary conditions and objectives; fix the process structure for subsequent phases	Process selected
1.2 Divide the process into stages	Decompose the process into fixed stages (STG1…STGn), each with an explicit start, end and measurable output, enabling structured governance and risk assessment	Table 25
1.3 Collect information about subjected process	Specify contextual data and risk information area	Table 27
1.4 Select targets of the process	Establish stage-specific, measurable milestones acting as decision gates and acceptance criteria for progression to the next stage	Table 28
1.5 Delegate a group of experts in each process	Appoint the expert group, define roles and responsibilities, and ensure competence and neutrality for consistent expert-based judgements	Experts selected
2.1 Determine risk categories	Consolidate risk sources into coherent Risk Categories (RC) that cover the analysed process and can be assigned clear ownership for mitigation	Table 30

2.2 Determine process risk limitations	Define Risk Limitations (RL) that express the constraints within which risk is evaluated	Table 32
2.3 Determine risk factors	Identify Input Risk (R_I) and Stage Risk (R_{STG}) factors; map them to RC and RL; formalise Assessment Questions (AQ) enabling repeatable expert scoring	Table 35 Table 36
3.1 Assign values to risk factors	Rate each AQ per RL using unified linguistic scale (Table 41); apply fuzzification/defuzzification (Table 42) to obtain numerical scores for R_I and R_{STG}	Table 43 Table 44 Table 45 Table 46
3.2 Calculate risk values	Compute Total Stage Risk (R_{TSTG}) using the defined aggregation model	Table 53
4.1 Review risk values	Verify data consistency; interpret RC and RL distributions, collect risk relevant information and assess it against mitigation thresholds (Table 57)	Table 55 Table 56 Table 58
4.2 Risk minimization	Plan and assign mitigation actions recommendations (Table 65) aligned with dominant RC and RL, create stage level mitigation planning schedule and targets. Effectiveness of mitigation actions confirm with passing the project stage-gate for the corresponding stage (STG)	Table 64

5. Validation of the methodology of assessing and reducing the risk of development of tooling in automotive industry

The purpose of this chapter is to present the industrial context for validating of the methodology proposed in this dissertation. It aims to explain why and under what conditions the methodology was applied, emphasizing its integration into the operational framework of production tooling development. The scope includes: a synthetic characterization of the company Autoneum Poland (profile, product portfolio, and industry-specific requirements relevant to risk), a description of the tooling development process and its key roles, an overview of process milestones within the APQP-based gateway model, and an analysis of the challenges and risk exposures inherent to tooling development.

5.1 Characteristics of the organization (Autoneum Poland Sp. z o.o.)

The study setting is an international automotive supplier company Autoneum Poland Sp. z o.o. with a global manufacturing footprint (50+ plants; ~14,000 employees). The company specializes in thermal and acoustic insulation for vehicles and provides solutions for acoustic measurement. The organization houses a Development Center (DEC) responsible for product development and series launches at European plants. In 2025 the over 600 tooling sets were developed by the engineering development team. This scale ensures repeated, comparable tooling projects and provides a suitable environment for validating a stage-based methodology of assessing and reducing the risk of development of tooling in automotive industry.

Product characteristics

The company's portfolio covers three main vehicle areas: engine bay, underbody, and interior (Table 68).

Table 68 Product families of the organization

Product family	Selected products
Engine Bay	engine and gearbox encapsulations, hoodliners, outer dashes and other body-mounted absorbers
Underbody	underbody systems, wheelhouse outer liners, battery and spare wheel pans, heatshields
Interior	tufted and needlepunch carpets, inner dashes, floor insulators, floor mats and inner wheelhouse insulators

The components serve to reduce noise and vibration, provide thermal insulation, and improve comfort and safety. Industry requirements include low weight, recyclability, flammability standards, and emission limits for hazardous substances. Industry requirements relevant to parts performance: weight reduction (often in tension with thermal/acoustic performance), environmental compatibility (recyclability), flammability and combustion emission standards, and dimensional stability. Selection of technology, materials, and process solutions strongly influences production tooling quality. These requirements impose technical and manufacturing constraints on the tooling and thereby contribute to the overall complexity of the tooling-development workflow described in the next section.

Production tooling development in the organization

The tooling development process at the company forms part of the APQP-based product development framework. Projects progress through defined gates from concept to serial production launch. Key roles in the process of production tooling development are the following:

- Tooling Engineer (TE) - leads tooling from specification to final handover to production.
- Product and Process Engineer (PPE) - defines product concept and process parameters.
- Project Manufacturing Leader (PML) - ensures industrialization at the target plant.
- Project Manager (PM) - manages schedule and budget.
- Tooling Supplier (TSU) - designs and manufactures the tools.
- Tooling Buyer (TB) - manages sourcing and commercial negotiations.

Production tooling development process and milestones

The production tooling development process is followed in the organization is in line with product development process and is divided into specific stages, which are the same regardless of the type of production tooling. The production tooling development process is organized based on the milestones, each of related directly to the tooling development activities described below, and with the following ones particularly important:

- Project handover from the quotation phase to development.
- Tooling specification approval (TS), supplier nomination (TSU), tooling purchase order sent to supplier (TPO).
- Tooling design approval (TD), tooling manufacturing, tooling startup at the production facility.
- Final handover of the tool to the production plant (PP) after successful start-up.

For clarity, the tooling development process is summarized in Table 69 and illustrated in the Figure 16.

Table 69 Mapping of tooling development process performed in Autoneum Poland Sp. z o.o.

Phase	Objective	Key inputs	Key roles
Tooling concept	Concept specified	BOM, production concept, process, parameters; plant constraints standards	TE, PPE, PML
Tooling order	Supplier selected; order issued; schedule confirmed	Supplier panel; offers; confirmed milestones; commercial constraints	TB, TE, PM
Tool design	Tool design reviewed and approved	CAD/PLM documentation; design review outputs; standards compliance	TSU, TE, PPE, PML
Tool manufacturing	Tool manufactured per design/spec	Manufacturing progress; material/component availability; deviations	TSU, TE
Tooling preliminary handover	Tool accepted at supplier, ready to ship	Acceptance protocol; documentation completeness; trial readiness	TE, TSU
Tooling final handover	Tool validated; first parts produced	Plant readiness; BOM material availability; resource availability; start-up conditions	PML, TE, PP, TSU

While Figure 16 presents the process at the APQP gateway level, the validation in Chapter 5 applies a finer stage-based decomposition that maps onto these gateways as indicated in Table 69.

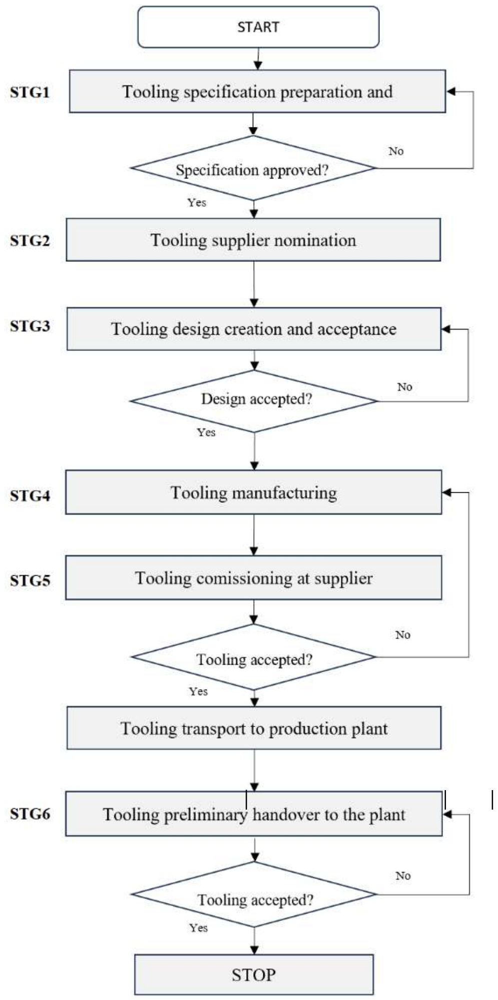


Figure 16 Process of tooling development in Autoneum Poland Sp. z o.o.

Production tooling development process characteristics

The development of production tooling at Autoneum Poland Sp. z o.o. is carried out under conditions that combine high complexity, strict industry requirements, and significant time pressure. Each tooling set is unique, tailored to specific product geometry, process parameters, and machine constraints, which makes the process highly individualized and resource intensive.

The following observations are based on the Autoneum Poland Sp. z o.o. project evidence and expert judgements collected during the validation.

Tooling development process difficulties and constraints

- Project complexity - every tool requires a custom design approach due to unique part geometry and process conditions.
- Time pressure - limited timeframes for tool design approval and manufacturing, often under competitive lead-time targets.
- Frequent changes - modifications driven by OEM engineering changes, new quality requirements, or corrections to initial specifications.
- Multi-stakeholder coordination - continuous alignment between Tooling Engineer (TE), Product and Process Engineer (PPE), Project Manufacturing

Leader (PML), Project Manager (PM), Tooling Buyer (TB), and external Tooling Supplier (TSU).
- Resource limitations - constraints in machine availability, material supply, or skilled personnel during tool launch at the plant.
- Strict standards – tooling specifications must meet internal guidelines and OEM requirements.
- Global collaboration - coordination across multiple plants and suppliers.
- Technological diversity - different production technologies and innovative solutions for lightweight, recyclable, and flame-retardant materials.

Taken together, these constraints illustrate why the tooling development workflow operates under high uncertainty and requires structured risk identification and monitoring across successive process milestones.

The tooling development process is exposed to several categories of risk not limited to:

- Schedule risk - delays caused by design changes, specification errors, or supplier capacity issues.
- Cost risk - additional expenses due to material reorders, accelerated work (e.g., overtime at suppliers), or concept changes.
- Quality risk - tools failing to meet process or part quality requirements.
- Communication risk - misinterpretation of specifications or unclear requirements.
- Launch risk - incomplete resource availability at the plant, leading to partial or incorrect tool validation.
- Supplier-related risk: - insufficient experience, lack of testing capabilities, or production overload.

These challenges and risks frame the operational context for applying methodology of assessing and reducing the risk of development of tooling in automotive industry developed in this dissertation. They highlight the need for structured evaluation and proactive mitigation strategies to ensure tooling readiness.

To validate the proposed methodology of assessing and reducing the risk of development of tooling in automotive industry under real industrial constraints, Chapter 5.2 applies it to selected tooling development projects executed in the organization Autoneum Poland Sp. z o.o. The verification follows a complete walkthrough of all methodology of assessing and reducing the risk of development of tooling in automotive industry phases - from process preparation and risk identification through risk assessment, interpretation of results, and selection of mitigation measures - based on project evidence and operational data collected in the organization.

5.2 Validation of the methodology of assessing and reducing the risk of development of tooling in automotive industry in Autoneum Poland Sp. z o.o.

The purpose of this chapter is to present a practical verification of the proposed methodology of assessing and reducing the risk of development of tooling in *automotive industry. The verification was conducted based on data collected within the organization Autoneum Poland Sp. z o.o. and encompassed a complete walkthrough of all phases of the methodology - from process preparation, through risk identification and assessment, to result interpretation and selection of mitigation measures. This verification allows to assess the methodology of assessing and reducing the risk of development of tooling in automotive industry suitability in real world project conditions and determine its impact on decision-making and resource planning.*

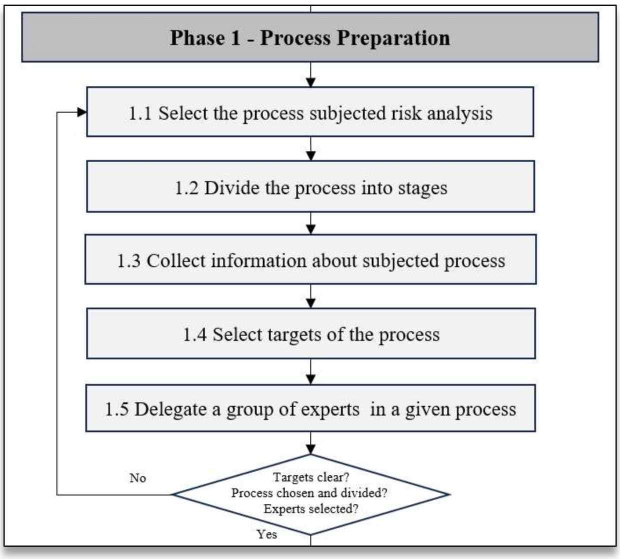
The development of production tooling represents a critical yet partial phase within the organization's broader product development framework. However, the analysed production tooling development process is extensive and complex; therefore, its description omits most technical details and is presented in a simplified structure.
To test the methodology of assessing and reducing the risk of development of tooling in automotive industry, several organisational processes were selected, each of which was at a different development stage at the time of analysis. This selection of processes also enabled the demonstration of the methodology of assessing and reducing the risk of development of tooling in automotive industry step in which risk is transferred between projects to reduce it to an acceptable level across multiple parallel projects.

The verification was carried out using project Proj_1, selected as a representative case due to its complete dataset, typical process structure, and relevance to the organization's tooling development activities. This section presents the application of all phases of the methodology of assessing and reducing the risk of development of tooling in automotive industry to this project, including process preparation, risk categorization, risk assessment, and interpretation of the results. The following subsections provide a step-by-step overview of the verification procedure.

5.2.1 Validation of Phase 1 - Process preparation

Phase 1 establishes the validation baseline specific to the project executed in the organization. The workflow is represented using the organization's fixed six-stage structure (STG1 - STG6), as defined in Phase 1.2 of the methodology of assessing and reducing the risk of development of tooling in automotive industry, reflecting tooling milestones up to start-up and final handover at the production plant. Project documentation and operational records collected for this project are used in Phases 3 and 4 of the methodology of assessing and reducing the risk of development of tooling in automotive industry. An internal expert group is appointed in Phase 1 to provide the linguistic judgments applied in Phases 2–3.

Table 70 Phase 1 of the methodology of assessing and reducing the risk of development of tooling in automotive industry – process preparation (recap of Figure 12)



5.2.1.1 Select the process subjected the risk analysis (Phase 1, Point 1.1)

The process selected for validation is the development of the tooling for the production of an interior floor foaming component carried out in the project Proj_1.

5.2.1.2 Divide the process into stages (Phase 1, Point 1.2)

For this validation, the tooling development workflow is divided into six unchanging stages (STG1 - STG6) that reflect the tooling stages applied in the organization. These stages follow the practical sequence used in tooling development projects, from specification and supplier nomination through design and manufacturing, commissioning at the supplier, and the start-up and final handover at the production plant. These stages are consistent with the tooling development model proposed in this dissertation (Figure 6), and they aligned the organisational milestones described in Section 5.1 - 5.2. This fixed decomposition is used consistently throughout Section 5.3 and is summarized in Table 71.

Table 71 Division of the process Proj_1 into stages

Designation	Start condition	Stage definition	End condition
STG1	Project need and boundary conditions are confirmed	Tooling specification creation and acceptance	Specification completed and internally agreed
STG2	Specification internally agreed and released to sourcing	Tooling supplier nomination	Supplier nomination decision confirmed
STG3	Tooling supplier nominated; design work starts based on the approved specification	Tooling design creation and acceptance	Tooling design completed and accepted

STG4	Approved design is released to fabrication	Tooling manufacturing	Tooling manufacturing completed, readiness for commissioning confirmed
STG5	Tooling ready for commissioning	Tooling commissioning at supplier	Tooling commissioning completed; capability verified at supplier level
STG6	Tooling is delivered and installed at the production line	Tooling start-up at production plant	Tool operational performance verified under plant conditions; acceptance conditions met

5.2.1.3 Collect information about subjected process (Phase 1, Point 1.3)

The procedure for developing production tooling is standardised across the organization; however, individual projects differ depending on factors such as the OEM, design-team composition, technology, product family, number of tooling sets, and the target production plant.

Contextual process information:
One representative project executed within the organization (Proj_1) was selected to support the practical validation of the proposed methodology of assessing and reducing the risk of development of tooling in automotive industry. A complete set of contextual process information for this case study is provided in Table 72.

Table 72 Contextual process information for Proj_1

Project name	Proj_1
Product family	Interior Floor
Customer	OEM_1
Number of tool sets	2
Tool type	Foaming
Tool kick off date	10.01.2024
Tool test at the plant	16.08.2024
Project tooling budget	50000 [EUR]
Tooling Engineer name	TE_1
Product and Process Engineer name	PPE_2
Project Manufacturing Leader name	PML_1
Project Manager name	PM_1
Tooling Supplier name	TSU_3
Production plant name	PP_4
Tooling Buyer name	TB_2

Risk information areas:
In addition to the contextual process information above, the validation applies the fixed set of eight risk information areas defined in Section 4.1.3. These areas serve as structured areas of inquiry-analogous to the branches of an Ishikawa diagram that

indicate where relevant information resides prior to formal risk identification and assessment. The eight risk information areas considered are: quality of engineering information; maturity of technology and process; supplier capabilities; plant readiness; competence and availability of project roles; project history and lessons learned; availability of critical resources; organisational factors and governance. All risk information areas defined in Chapter 4 were considered.

5.2.1.4 Select targets of the process (Phase 1, Point 1.4)

The target of the production tooling development process is to deliver tooling that meets the requirements of both the external customer (OEM) and the internal customer (production plant), ensuring stable, repeatable and specification-compliant manufacturing, together with efficient tool operation, handling, transport and maintenance under defined production parameters. To achieve this target, the process is executed within a predefined timeframe and structured into clearly defined, coordinated stages (each concluded with a measurable milestone acting as a decision gate). The execution of these stages requires coordinated activities, including:

- Resource management: effective allocation of human, material and technological resources, supported by close collaboration with suppliers and customers.
- Tool specification: precise definition of tooling requirements aligned with customer expectations, organisational standards and the production plant's capabilities.
- Supplier offering and nomination: offer collection, technical and commercial alignment, and supplier selection leading to purchase order and a confirmed manufacturing schedule.
- Tooling design: collaborative design in line with organisational standards, leading to design approval and concept release for manufacturing.
- Tool manufacturing and supplier acceptance: execution of tooling manufacture according to the approved design and standards, followed by commissioning and official acceptance at the supplier.
- Start-up and readiness for serial production: effective launch of the equipment at the target production line and verification of its performance through functional checks, material-consumption monitoring, and production of parts compliant with customer requirements and predefined process parameters.

Because the process involves multiple stages and technical, organisational and timing constraints, proper structuring and coordination are essential for achieving project goals and enabling evidence-based risk assessment in subsequent phases. For the validation of this methodology, measurable stage-specific targets were defined in accordance with the Stage-Gate principles; these targets represent the outcomes required to proceed to subsequent stages, ensuring transparency and objectivity in evaluating tooling development. The stage-specific milestones are presented in Table 73.

Table 73 Process stage milestones for Proj_1

Stage	Milestone
STG1 Specification creation/acceptance	Specification acceptance record (signed approval of tooling specification)
STG2 Supplier nomination	Supplier nomination decision (sourcing evaluation summary and nomination decision)
STG3 Design creation/acceptance	Design approval record (approved drawings/3D model/specification baseline)
STG4 Manufacturing	Internal manufacturing-acceptance evidence (conformity check and readiness for commissioning)
STG5 Commissioning at supplier	Supplier commissioning report / capability evidence (trial results summary)
STG6 Start-up at production plant / final handover	Plant-acceptance / final handover protocol (tool released for production use)

5.2.1.5 Delegate a group of experts (Phase 1, Point 1.5)

To ensure an impartial and experience-based evaluation of the methodology of assessing and reducing the risk of development of tooling in automotive industry, the expert group consisted of representatives from the organization who had previously participated in multiple tooling development projects across different product families, technologies and suppliers. This ensured a high degree of independence, broad process knowledge, and avoidance of project-specific bias. The experts were selected in accordance with the following criteria:

- Proven technical and organisational competence relevant to tooling development.
- Familiarity with tooling development process applied in the organization.
- Ability to work with linguistic evaluation scales and provide consistent judgments.
- Neutrality and absence of conflicts of interest.

The final expert group included individuals representing key operational roles within the organization, such as Tooling Engineer (E1), Product and Process Engineer (E2), Project Manufacturing Leader (E3), Project Manager (E4), Tooling Buyer (E5). The expert group defined in this subsection serves as the permanent evaluation group and will be involved throughout all subsequent stages of the methodology of assessing and reducing the risk of development of tooling in automotive industry validation presented in Chapter 5.

5.2.2 Validation of Phase 2 – Risk analysis preparation

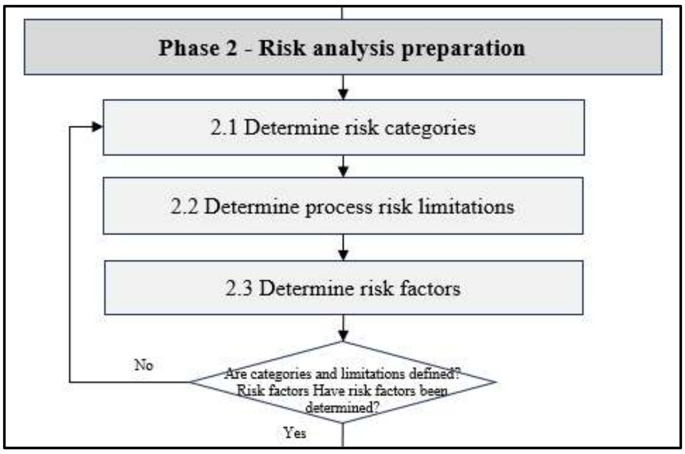


Figure 17 Phase 2 of the methodology of assessing and reducing the risk of development of tooling in automotive industry - risk analysis preparation (recup of Figure 13

5.2.2.1 Determine risk categories (Phase 2, Point 2.1)

To determine risk categories, the expert group defined in Phase 1, Point 1.5 was asked to identify the most common types of failures that may occur throughout the production tooling development process. Using an Ishikawa diagram, the experts determined a list of the risk factors, grouping them into two categories – organisational (ORG) and technical (TECH). The results are presented in Table 74.

Table 74 Determination of risk categories in the production tooling development process in the organization

Risk Category (RC)	Examples of risk factors	Description
RC_1 TECH	Insufficient quality, incompleteness of the specification, CAD-related and technical documentation risks, material-related risks, measurement and validation problems, deviations in the tool manufacturing process at the supplier	Technical risks refer to uncertainties inherent in the design, engineering and manufacturing aspects of tooling development. They arise from incomplete or inconsistent input data, design flaws, material selection errors, or process deviations occurring at any stage of the supplier's manufacturing workflow. These risks directly affect manufacturability, dimensional accuracy, functional validation, and the overall capability of the tool to meet customer requirements. Their early identification and mitigation are critical for ensuring stable production and avoiding late-stage redesigns or delays
RC_2 ORG	Errors in information flow and project communication, lack of experience, insufficient competence of the project team, tooling supplier issues,	Organisational risks stem from human, procedural and communication-related factors within the project environment. They include deficiencies in knowledge, competence and coordination among stakeholders, ineffective decision-making, misaligned responsibilities, and project planning weaknesses. Such risks may lead to delays,

	Planning and scheduling deficiencies	misunderstandings, inconsistent requirements, or disruptions in cooperation with the tooling supplier. Proper management of these risks ensures transparent communication, stable execution and predictable project timing

The categories that encompass all areas identified in the Ishikawa analysis and were selected to reflect the primary sources of risk inherent in production tooling development processes. This determination also mirrors the allocation of responsibilities within the project team: the Project Manager oversees organisational aspects (ORG), while the Tooling Engineer is accountable for technical aspects (TECH).

5.2.2.2 Determine process risk limitations (Phase 2, Point 2.2)

The determination of risk limitations for the production tooling development process was directly aligned with the process metric criteria defined in Chapter 1.3 of this dissertation. These limitations provide the structural basis for assessing cost, timing, and quality risks in subsequent phases of the methodology of assessing and reducing the risk of development of tooling in automotive industry. The results, together with an organization-specific description, are presented in Table 75.

Table 75 Determination of process risk limitations for the tooling development process in the organization

Risk Limitation (RL)	Examples of risk limitation drivers	Description
RL_1 - Cost (C)	Additional tool modifications, engineering changes affecting tool design, need for express shipment or repeat transport, rework at the supplier or plant, use of non-standard or premium materials increasing tool cost	Development of production tooling - from order placement through delivery and startup at the target production plant, including any improvements, design changes, concept adjustments, engineering modifications, or transport-related activities - must be completed within the assumed project budget
RL_2 - Timing (T)	Delays in tool design or design approval, limited availability of resources for tool trials, machine unavailability at the plant, late delivery of materials or components, scheduling conflicts between workshop, supplier and plant	Delivery and startup of the production tooling at the designated plant must be completed within the timeframe defined in the project schedule
RL_3 - Quality (Q)	Incorrect or unstable tool geometry, poor material behaviour (e.g., shrinkage, deformation), inaccurate measurements or insufficient validation of the produced parts, deviations introduced during tool manufacturing, insufficient process capability during first-off trials	The delivery conditions of the production tooling must comply with the TFTR (Tool First Time Right) approach [33], meaning that the tool delivered to the target production plant does not require return to the tooling supplier due to malfunction. Any adjustments, repairs, or corrections related to such malfunction must be feasible within the production plant facility

In the context of the organization's tooling portfolio and recurrent industrialization cycles, cost (C), timing (T), and quality (Q) constitute the primary determinants of project success; using them as risk mitigations therefore reflects the real decision-making factors that impact the success of the production tooling development process.

5.2.2.3 Determine risk factors (Phase 2, Point 2.3)

To determine risk factors necessary for assessing both input risk (R_I) and stage risk (R_{STG}), a moderated brainstorming session was conducted with the expert group defined in Phase 1, Point 1.5, with the aim of generating a comprehensive set of risk factors serving as the basis for formulating the assessment questions (AQ). The session was moderated by Expert E1, whose extensive experience in tooling development and prior involvement in cross-functional risk assessment activities qualified them to ensure methodological consistency, facilitate structured discussion, and support the accurate formulation of risk related inputs.

The risk factor lists were created in a two-step process. First, the expert group performed a structured brainstorming guided by the eight informational areas (Chapter 4.1.3), recording each observation as a precise risk description. Second, duplicated or overlapping entries were merged, and each unique item was formalised as a named risk factor and assigned to its originating informational area. Factors were then classified as either input risk (R_I) or stage risk (R_{STG}) according to whether they refer to project-level context or to a specific stage of the six-stage workflow (STG1–STG6). The result is an explicit, named set of risk factors (Table 76 and Table 77) that serves as the basis for formulating assessment questions (AQ) in the next step.

Table 76 Mapping of Input Risk (R_I) factors to risk information areas in project Proj_1

Input Risk (R_I)	Risk factor name	Risk description	Risk information area
R_{I1}	Customer reliability and stability	Risk that variability in the customer's decision-making, approvals or requirement stability undermines predictable execution of the tooling-development process	Organisational factors and governance
R_{I2}	Process engineer experience adequacy	Risk that the selected process engineer lacks experience and operational reliability in projects of a similar type, increasing the likelihood of design/implementation gaps	Competence and availability of project roles
R_{I3}	Manufacturing leader oversight capability	Risk that the Project Manufacturing Leader's competence and oversight are insufficient for tooling-related activities, leading to coordination issues and late corrections	Competence and availability of project roles

R_{I4}	Project-management maturity and effectiveness	Risk that low project-management maturity (planning, change control, communication) degrades cross-functional alignment and on-time decision-making	Organisational factors and governance
R_{I5}	Plant competence and experience	Risk that plant-side competence and experience are inadequate for the intended tooling/process, affecting readiness for commissioning and start-up	Plant readiness
R_{I6}	Technology/process maturity and predictability	Risk that the selected production technology lacks maturity/predictability for the intended application, increasing the probability of instability during realization	Maturity of technology and process

Table 77 Mapping of Stage Risk (R_{STG}) factors to risk information areas in project Proj_1

Stage Risk (R_{STG})	Risk factor name	Risk description	Risk information area
R_{STG1_1}	Incomplete functional requirements	Risk that functional requirements of the tooling were not fully collected and approved before design release, leading to rework and delay	Quality of engineering information
R_{STG1_2}	Ergonomics and safety misalignment	Risk that ergonomics and safety criteria were not aligned with production, creating compliance or launch issues	Organisational factors and governance
R_{STG1_3}	Missing technical consultations	Risk that necessary consultations with the technical team were not completed before specification freeze	Organisational factors and governance
R_{STG1_4}	Spec–capability mismatch (plant)	Risk that the specification does not accurately reflect the technological capabilities of the production plant	Maturity of technology and process

R_{STG1_5}	Spec review/approval/archival gap	Risk that the specification has not been properly reviewed, approved, and archived in the documentation system	Organisational factors and governance
R_{STG2_1}	Insufficient supplier panel	Risk that an adequate supplier panel is not available for the required technology	Supplier capabilities
R_{STG2_2}	Supplier - scope misfit	Risk that the selected supplier is not appropriate for the scope and complexity of the tooling	Supplier capabilities
R_{STG2_3}	Supplier spec understanding gap	Risk that the supplier does not fully understand the tooling specification and does not confirm it in the offer	Quality of engineering information
R_{STG2_4}	Delayed nomination / PO issuance	Risk that supplier nomination and purchase order issuance are delayed	Organisational factors and governance
R_{STG2_5}	Unrealistic / unconfirmed project timing	Risk that the tooling project timing is not available, unrealistic, or not confirmed by all stakeholders	Organisational factors and governance
R_{STG3_1}	Late design delivery	Risk that the tooling design is not prepared and delivered on time	Quality of engineering information
R_{STG3_2}	Design–spec nonconformity	Risk that the tooling design does not comply with the agreed specification and standards	Quality of engineering information
R_{STG3_3}	Insufficient design review	Risk that the tooling design has not been properly reviewed and confirmed by the project team	Quality of engineering information
R_{STG3_4}	Documentation archival gap (design)	Risk that the approved tooling design has not been correctly stored in the documentation system	Organisational factors and governance
R_{STG4_1}	Toolmaker capacity constraint	Risk that the toolmaker does not have sufficient capacity to execute manufacturing	Supplier capabilities

R_{STG4_2}	Shortage of manufacturing materials/components	Risk that required raw materials and components are not available for manufacturing	Availability of critical resources
R_{STG4_3}	Manufacturing–design nonconformity	Risk that the tooling is not being manufactured in accordance with the validated design and specifications	Quality of engineering information
R_{STG4_4}	Schedule slippage (manufacturing)	Risk that the tool manufacturing does not progress according to the planned schedule	Organisational factors and governance
R_{STG5_1}	Spec conformity of manufactured tool	Risk that the manufactured tool is not fully consistent with the approved specification	Quality of engineering information
R_{STG5_2}	Trial material unavailability at supplier	Risk that the required raw materials are not available for performing tool trials	Availability of critical resources
R_{STG5_3}	Incomplete handover documentation	Risk that the tooling documentation is not complete and ready for handover	Quality of engineering information
R_{STG6_1}	Suppliers start-up support unavailable	Risk that the toolmaker's representative is not available during the tool start-up at the production plant	Supplier capabilities
R_{STG6_2}	BOM material unavailability at plant	Risk that the required material is not available at the production plant according to the BOM	Availability of critical resources
R_{STG6_3}	Production equipment not prepared for start-up	Risk that the production equipment is not fully prepared for tooling start-up	Plant readiness
R_{STG6_4}	Project team not ready for start-up support	Risk that the project team is not available or ready to support the tooling start-up activities	Competence and availability of project roles

Each named risk factor (R_{Im} and R_{STGs}) is then operationalised into a single, scorable assessment question (AQ) that preserves the factor's intent and scope. For traceability, the risk factor number accompanies the assessment question (AQ) in the matrices, and each AQ is aligned with its risk category (RC) and the applicable risk limitations (RL). The complete AQ sets are presented in Table 78 and Table 79.

Table 78 Input risk assessment matrix for project Proj_1

Input Risk (R_I)	Assessment Question (AQ)	Risk Category (RC)	Risk Limitation (RL)		
			Cost (C)	Quality (Q)	Timing (T)
R_{I1}	How do you assess this customer's reliability and stability in the context of the tooling-development process?	TECH			
R_{I2}	How do you assess the experience and operational reliability of the selected process engineer in projects of a similar type?	ORG			
R_{I3}	How do you assess the competence and oversight capability of the Project Manufacturing Leader in tooling-related activities?	ORG			
R_{I4}	How do you assess the effectiveness and project-management maturity of Project Manager leading the project?	ORG			
R_{I5}	How do you assess the competence and experience relevant to the production plant?	ORG			
R_{I6}	How do you assess the maturity and predictability of this production technology?	TECH			

Table 79 Stage risk assessment matrix for project Proj_1

Stage Risk (R_{STG})	Assessment Question (AQ)	Risk Category (RC)	Risk Limitation (RL)		
			Cost (C)	Quality (Q)	Timing (T)
R_{STG1_1}	Are the requirements for the production tools clearly defined and aligned with the customer's expectations?	TECH			
R_{STG1_2}	Are the organisational standards properly incorporated into the tooling specification?	ORG			

R_{STG1_3}	Have the necessary consultations with the technical team been completed before finalizing the specification?	ORG			
R_{STG1_4}	Does the specification accurately reflect the technological capabilities of the production plant?	TECH			
R_{STG1_5}	Has the specification been properly reviewed, approved, and archived in the documentation system?	ORG			
R_{STG2_1}	Is an adequate supplier panel available for the technology required by this tooling project?	ORG			
R_{STG2_2}	Is the selected supplier appropriate for the scope and complexity of the tooling?	ORG			
R_{STG2_3}	Does the supplier fully understand the tooling specification and confirm it in their offer?	TECH			
R_{STG2_4}	Has the supplier been officially nominated and has the purchase order been issued without delays?	ORG			
R_{STG2_5}	Is the tooling project timing available, realistic, and confirmed by all stakeholders?	ORG			
R_{STG3_1}	Is the tooling design prepared and delivered on time?	TECH			
R_{STG3_2}	Does the tooling design comply with the agreed specification and standards?	TECH			
R_{STG3_3}	Has the tooling design been properly reviewed and confirmed by the project team?	TECH			
R_{STG3_4}	Has the approved tooling design been correctly stored in the PLM/documentation system?	ORG			
R_{STG4_1}	Does the toolmaker have sufficient capacity to execute the manufacturing?	TECH			
R_{STG4_2}	Are all required raw materials and components available for manufacturing?	TECH			
R_{STG4_3}	Is the tooling being manufactured in accordance with the validated design and specifications?	TECH			

R_{STG4_4}	Is the tool manufacturing progressing according to the planned schedule?	ORG			
R_{STG5_1}	Is the manufactured tool fully consistent with the approved specification?	TECH			
R_{STG5_2}	Are the required raw materials available for performing the tool trials?	TECH			
R_{STG5_3}	Is the tooling documentation complete and prepared for handover?	TECH			
R_{STG6_1}	Is the toolmaker's representative available during the tool startup at the production plant?	ORG			
R_{STG6_2}	Is the required material available at the production plant according to the BOM?	TECH			
R_{STG6_3}	Is the production equipment fully prepared for tooling startup?	ORG			
R_{STG6_4}	Is the project team available and ready to support the tooling startup activities?	ORG			

The unified set of assessment questions (AQ) provides a consistent and operational basis for the subsequent risk calculation process.

5.2.3 Validation of Phase 3 – Risk calculation

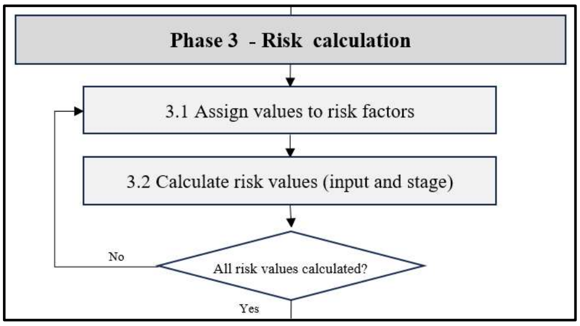


Figure 18 Phase 3 of the methodology of assessing and reducing the risk of development of tooling in automotive industry - risk calculation (recap of Figure 14)

5.2.3.1 Assign values to risk factors (Phase 3, Point 3.1)

At this stage of the methodology of assessing and reducing the risk of development of tooling in automotive industry, the examined process was analysed from the perspective of risk occurrence. As a first step it was assumed that the risk level was measured using fuzzy logic, in accordance with the risk limitation guidelines presented in Table 75 and the linguistic definitions provided by the experts in Table 80.

Table 80 Linguistic scale for risk limitations (RL)

Linguistic term	Risk Limitation (RL)		
	Cost (C)	Timing (T)	Quality (Q)
very low - VL	C < 3% of budget	Delay < 1 day	No impact on tool quality
low - L	3% ≤ C < 5% of budget	1 ≤ Delay < 3 days	Small impact on tool quality; easily corrected on site
medium - M	5% ≤ C < 10% of budget	3 ≤ Delay < 5 days	Noticeable quality impact; repairable on site (no tool return)
high - H	10% ≤ C ≤ 50% of budget	5 ≤ Delay ≤ 10 days	Major quality impact, tool may require transport to supplier
very high - VH	C > 50 % of budget	Delay > 10 days	Critical quality impact, tool must be transported to supplier

In the next step membership function values were assigned and results presented in Table 81 together with their graphical interpretation presented in Figure 19.

Table 81 Membership functions used for project Proj_1 risk assessment

Linguistic Value	Membership function values for the input data (C, T, Q)	Membership function values for the output (RPN)
1	2	3
Very low (VL)	(0;1;3)	(0;0;200)
Low (L)	(1;3;5)	(0;200;400)
Medium (M)	(3;5;7)	(200;500;800)
High (H)	(5;7;9)	(600;800;1000)
Very high (VH)	(7;9;10)	(800;1000;1000)

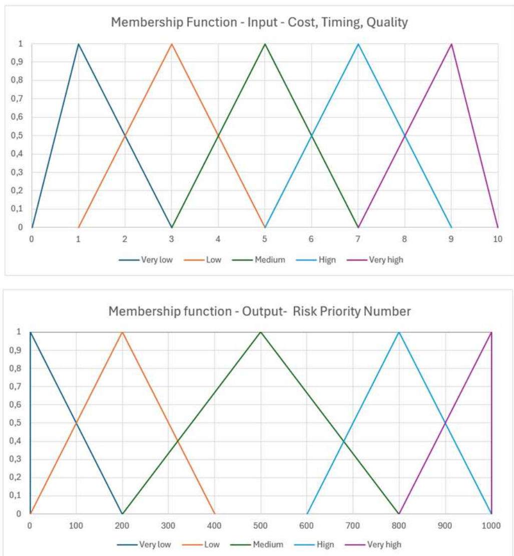


Figure 19 Membership functions used in the process of Proj_1 project risk assessment

Although cost (C), timing (T) and quality (Q) are expressed on different physical scales, the defined membership functions transform these heterogeneous inputs into a unified fuzzy space, ensuring their comparability and enabling consistent aggregation.

Input Risk (R_I) evaluation

In the next step the expert group defined in Phase 1, Point 5 evaluated each input risk factor (R_{Ii}) using the assessment questions presented in Table 78. For each input risk (RI_i), each expert independently provided a linguistic assessment consistent with the cost, timing and quality limitations defined in Table 80 and taking into account the project specific information listed in Table 72. The evaluations were performed with reference to the organisational and technical risk categories established in Table 74, ensuring that each judgement reflected both the contextual conditions of the project and the nature of the identified risk factor. The individual expert ratings for all input risks (R_{Ii}) are summarised in Table 82.

Table 82 Project Proj_1 input risk (R_I) assessment

Input Risk (RI)	Assesment Question (AQ)	Project information	Risk Category (RC)	E1			E2			E3			E4			E5			Average		
				Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)		
				C	T	Q	C	T	Q	C	T	Q	C	T	Q	C	T	Q	C	T	Q
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
RI_1	How do you assess the reliability and stability of this customer in the context of the tooling development	OEM 1	TECH	L	M	L	M	M	L	M	M	M	L	L	L	L	L	M	3.80	4.20	3.80
				3.00	5.00	3.00	5.00	5.00	3.00	5.00	5.00	5.00	3.00	3.00	3.00	3.00	3.00	5.00			
RI_2	How do you assess the experience and operational reliability of selected process engineer in projects of similar	PPE 2	ORG	H	H	M	M	M	M	H	M	M	M	L	L	M	M	M	5.80	5.00	4.60
				7.00	7.00	5.00	5.00	5.00	5.00	7.00	5.00	5.00	5.00	3.00	3.00	5.00	5.00	5.00			
RI_3	How do you assess the competence and oversight capability of this Project Manufacturing Leader in	PML 1	ORG	VL	L	L	VL	L	L	L	L	L	L	L	L	VL	L	L	2.00	3.00	3.00
				1.33	3.00	3.00	1.33	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	1.33	3.00	3.00			
RI_4	How do you assess the effectiveness and project-management maturity of Project Manager leading the	PM 3	ORG	L	L	VL	L	L	L	VL	VL	VL	VL	VL	L	VL	VL	L	2.00	2.00	2.33
				3.00	3.00	1.33	3.00	3.00	3.00	1.33	1.33	1.33	1.33	1.33	3.00	1.33	1.33	3.00			
RI_5	How do you assess the competence end experience in relation the production plant?	PP 4	ORG	L	L	VL	L	L	L	VL	VL	VL	VL	VL	L	VL	VL	L	2.00	2.00	2.33
				3.00	3.00	1.33	3.00	3.00	3.00	1.33	1.33	1.33	1.33	1.33	3.00	1.33	1.33	3.00			
RI_6	How do you assess the maturity and predictability of this production technology?	Foaming	TECH	L	L	M	L	L	L	L	L	L	L	L	M	L	L	M	3.00	3.00	4.20
				3.00	3.00	5.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	5.00	3.00	3.00	5.00			

To perform the evaluation, experts rated the assessment question (column 2) with reference to the project-specific information (column 3) and the corresponding risk category (column 4). The linguistic ratings provided by the experts (columns 5 –19) in were averaged (columns 20 – 22). The average values were subsequently processed using MATLAB R2024a with the Fuzzy Logic Designer module. The linguistic terms were defuzzified using the Mamdani triangular membership functions as defined in Table 81 and illustrated in Figure 19.

Input risk (R_{I_i}) values were then aggregated across the three risk limitations - cost, timing, and quality - as defined in Table 75, resulting in the final consolidated input risk (R_I) value for project Proj_1. The numerical and linguistic fuzzy-RPN results derived from this process are summarised in Table 83.

Table 83 Input Risk level for project Proj_1

Input risk	Cost (C)	Timing (T)	Quality (Q)	Fuzzy RPN
R_I	3.10	3.20	3.38	326

Stage Risk (R_{STG}) evaluation

The expert group defined in Phase 1, Point 1.5 evaluated each stage risk (R_{STGs}) factor using the assessment questions presented in Table 79, following their order of occurrence in the analysed project. For each stage risk (R_{STGs}), every expert independently provided a linguistic rating based on:

- The cost, quality and timing risk limitations specified in Table 80.
- The project-specific information listed in Table 72.
- The overall status of the project Proj_1, supported by expert knowledge and experience from previous projects.

All with reference to organisational and technical risk categories defined in Table 74. The individual expert assessments for each stage risk (R_{STGs}) are presented in Table 84.

Table 84 Project Proj_1 stage risk (R_{STG}) assessment

Stage (STG)	Stage Risk (R_{STG})	Assessment Question (AQ)	Risk Category (RC)	E1 Risk limitation (RL)			E2 Risk Limitation (RL)			E3 Risk Limitation (RL)			E4 Risk Limitation (RL)			E5 Risk Limitation (RL)			Average Risk Limitation (RL)		
				C	T	Q	C	T	Q	C	T	Q	C	T	Q	C	T	Q	C	T	Q
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
STG1	RSTG1_1	Are the requirements for the production tools clearly defined and aligned with customer expectations?	TECH	M	M	L	VL	L	L	VL	L	L	L	M	L	L	L	L	5.57	5.23	4.91
				5.00	5.00	3.00	1.33	3.00	3.00	1.33	3.00	3.00	3.00	5.00	3.00	3.00	3.00	3.00			
	RSTG1_2	Are the organizational standards properly incorporated into the tooling specification?	ORG	H	M	M	H	M	M	H	M	M	H	M	M	M	M	M			
				7.00	5.00	5.00	7.00	5.00	5.00	7.00	5.00	5.00	7.00	5.00	5.00	5.00	5.00	5.00			
	RSTG1_3	Have the necessary consultations with the technical team been carried out before finalizing the specification?	ORG	VH	M	M	M	M	M	M	M	M	M	L	L	M	L	L			
				8.67	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	3.00	3.00	5.00	3.00	3.00			
	RSTG1_4	Does the specification reflect the technological capabilities of the production plant?	TECH	H	H	M	H	H	M	M	M	M	M	M	M	M	M	M			
				7.00	7.00	5.00	7.00	7.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00			
	RSTG1_5	Has the specification been properly reviewed, approved, and stored in the documentation system?	ORG	H	H	H	H	H	H	H	H	H	H	H	H	H	VH	VH			
				7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	8.67	8.67			
STG2	RSTG2_1	Is an adequate supplier panel available for the technology required by this tooling project?	ORG	M	M	L	VL	L	L	M	L	L	L	M	L	M	L	M	5.65	5.23	4.75
				5.00	5.00	3.00	1.33	3.00	3.00	5.00	3.00	3.00	3.00	5.00	3.00	5.00	3.00	5.00			
	RSTG2_2	Is the selected supplier appropriate for the scope and complexity of the tooling?	ORG	H	M	M	H	M	M	H	M	M	H	M	M	M	M	M			
				7.00	5.00	5.00	7.00	5.00	5.00	7.00	5.00	5.00	7.00	5.00	5.00	5.00	5.00	5.00			
	RSTG2_3	Does the supplier fully understand the tooling specification and confirm it in their offer?	TECH	M	M	M	M	M	M	M	M	M	M	L	L	M	L	L			
				5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	3.00	3.00	5.00	3.00	3.00			
	RSTG2_4	Has the supplier been officially nominated and has the purchase order been issued without delays?	ORG	H	H	M	H	H	M	M	M	M	M	M	M	M	M	M			
				7.00	7.00	5.00	7.00	7.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00			
	RSTG2_5	Is the tooling project timing available, realistic, and confirmed by all stakeholders?	ORG	H	H	M	H	H	M	H	H	M	H	H	H	H	VH	VH			
				7.00	7.00	5.00	7.00	7.00	5.00	7.00	7.00	5.00	7.00	7.00	7.00	7.00	8.67	8.67			
STG3	RSTG3_1	Is the tooling design prepared and provided on time?	TECH	L	M	M	VL	L	L	VL	L	L	VL	VL	VL	VL	L	L	1.93	2.75	2.55
				3.00	5.00	5.00	1.33	3.00	3.00	1.33	3.00	3.00	1.33	1.33	1.33	1.33	3.00	3.00			
	RSTG3_2	Does the tooling design comply with the agreed specification and standards?	TECH	VL	VL	VL	VL	VL	VL	VL	VL	VL	VL	VL	VL	VL	VL	VL			
				1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33			
	RSTG3_3	Has the tooling design been properly reviewed and confirmed by the project team?	TECH	M	M	L	VL	L	L	VL	L	L	L	M	L	L	L	L			
				5.00	5.00	3.00	1.33	3.00	3.00	1.33	3.00	3.00	3.00	5.00	3.00	3.00	3.00	3.00			
	RSTG3_4	Has the approved tooling design been correctly stored in the PLM/documentation system?	ORG	L	M	M	L	M	M	VL	VL	VL	VL	VL	VL	VL	VL	VL			
				3.00	5.00	5.00	3.00	5.00	5.00	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33			

Table 84 continuation

Stage (STG)	Stage Risk (RSTG)	Assessment Question (AQ)	Risk Category (RC)	E1			E2			E3			E4			E5			Average		
				Risk limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)			Risk Limitation (RL)		
				C	T	Q	C	T	Q	C	T	Q	C	T	Q	C	T	Q	C	T	Q
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
STG4	RSTG4_1	Does the toolmaker have sufficient capacity to execute the manufacturing according to plan?	TECH	L	VL	M	L	VL	M	VL	VL	M	VL	VL	M	VL	VL	M	2.08	1.67	2.95
				3.00	1.33	5.00	3.00	1.33	5.00	1.33	1.33	5.00	1.33	1.33	5.00	1.33	1.33	5.00			
	RSTG4_2	Are all required raw materials and components available for manufacturing as planned?	TECH	VL	L	VL	VL	VL	M	VL	VL	M	VL	VL	VL	VL	L	L			
				1.33	3.00	1.33	1.33	1.33	5.00	1.33	1.33	5.00	1.33	1.33	1.33	1.33	3.00	3.00			
	RSTG4_3	Is the tooling being manufactured in accordance with the validated design and specifications?	TECH	L	VL	VL	L	L	VL	L	L	L	VL	VL	VL	L	VL	L			
				3.00	1.33	1.33	3.00	3.00	1.33	3.00	3.00	3.00	1.33	1.33	1.33	3.00	1.33	3.00			
	RSTG4_4	Is the tool manufacturing progressing according to the planned schedule?	ORG	L	VL	L	L	VL	VL	L	VL	VL	VL	VL	VL	VL	VL	VL			
				3.00	1.33	3.00	3.00	1.33	1.33	3.00	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33			
STG5	RST51_1	Is the manufactured tool fully consistent with the approved specification?	TECH	L	VL	VL	L	VL	VL	L	M	VL	L	VL	VL	VL	VL	VL	1.78	2.73	2.67
				3.00	1.33	1.33	3.00	1.33	1.33	3.00	5.00	1.33	3.00	1.33	1.33	1.33	1.33	1.33			
	RST51_2	Are the required raw materials available for performing the tool trials?	TECH	VL	L	L	VL	L	VL	VL	VL	VL	VL	VL	VL	VL	L	VL			
				1.33	3.00	3.00	1.33	3.00	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	3.00	1.33			
	RST51_3	Is the tooling documentation complete and prepared for handover?	TECH	VL	L	M	VL	L	M	VL	L	M	VL	M	M	VL	M	M			
				1.33	3.00	5.00	1.33	3.00	5.00	1.33	3.00	5.00	1.33	5.00	5.00	1.33	5.00	5.00			
STG6	RSTG6_1	Is the toolmaker's representative available during the tool startup at the production plant?	ORG	L	VL	H	L	L	M	L	VL	M	L	VL	H	L	L	M	3.40	5.02	5.30
				3.00	1.33	7.00	3.00	3.00	5.00	3.00	1.33	5.00	3.00	1.33	7.00	3.00	3.00	5.00			
	RSTG6_2	Is the required material available at the production plant according to the BOM?	TECH	L	M	M	L	M	L	L	M	M	L	M	M	L	L	M			
				3.00	5.00	5.00	3.00	5.00	3.00	3.00	5.00	5.00	3.00	5.00	5.00	3.00	3.00	5.00			
	RSTG6_3	Is the production equipment fully prepared for tooling startup?	ORG	L	H	M	L	M	M	L	M	M	L	M	M	L	H	H			
				3.00	7.00	5.00	3.00	5.00	5.00	3.00	5.00	5.00	3.00	5.00	5.00	3.00	7.00	7.00			
	RSTG6_4	Is the project team available and ready to support the tooling startup activities?	ORG	M	H	M	L	H	M	M	VH	M	M	VH	M	M	H	H			
				5.00	7.00	5.00	3.00	7.00	5.00	5.00	8.67	5.00	5.00	8.67	5.00	5.00	7.00	7.00			

To perform the evaluation, experts rated each assessment question (column 3 of Table 84) with reference to the corresponding risk category (column 4) and overall status of the project Proj_1 supported by expert knowledge and prior project experience. The linguistic ratings provided by experts (columns 5 –19 in Table 84) were averaged for each stage of the project and summarised in columns 20-22. The average values were subsequently processed using MATLAB R2024a with the Fuzzy Logic Designer module. The linguistic terms were defuzzified using the Mamdani triangular membership functions defined in Table 81 and illustrated in Figure 19. The stage risk (R_{STG_i}) values were then aggregated across the three risk limitations (RL) – cost (C), timing (T) and quality (Q) - as defined in Table 75, producing the final stage risk (R_{STGs}) value for each stage of the project Proj_1. The numerical and linguistic fuzzy-RPN results obtained from this process are summarised in Table 85.

Table 85 Stage risk level for project Proj_1

Stage risk	**Cost (C)**	**Timing (T)**	**Quality (Q)**	**Fuzzy RPN**
R_{STG1}	5.57	5.23	4.91	772
R_{STG2}	5.65	5.23	4.75	717
R_{STG3}	1.93	2.75	2.55	193
R_{STG4}	2.08	1.67	2.95	178
R_{STG5}	1.78	2.73	2.67	196
R_{STG6}	3.40	5.02	5.30	548

5.2.3.2 Calculate risk values (Phase 3, Point 3.2)

The total stage risk (R_{TSTG}) of the project Proj_1 was calculated in accordance with the Eq. (6). In this step, the defuzzified input-risk (R_I) and the defuzzified stage-specific risk (R_{TSTG}) are both normalized to the [0,1] scale and combined multiplicatively.

Numerical example for STG2:

$$R_{TSTG_2} = \left(\frac{R_I}{1000}\right) \cdot \left(\frac{R_{ST\ 2}}{1000}\right) = \frac{326}{1000} \cdot \frac{717}{1000} = 0.2339 \approx 0.23$$

Accordingly, the total stage risk (R_{TSTGs}) values for project Proj_1 are presented in Table 86.

Table 86 Risk value for each stage of the tooling development process Proj_1

Total risk	Project stage	Risk value
R_{TSTG1}	Tooling specification creation and acceptance	0.25
R_{TSTG2}	Tooling supplier nomination	0.23
R_{TSTG3}	Tooling design creation and acceptance	0.06
R_{TSTG4}	Tooling manufacturing	0.06
R_{TSTG5}	Tooling commissioning at supplier	0.06
R_{TSTG6}	Tooling startup at production plant and preliminary handover	0.18

These results indicate that the highest exposure occurs in the early stages (STG1 - STG2), while the middle stages (STG3 - STG5) remain low-risk and the exposure increases again during start-up (STG6). A detailed interpretation of these findings is provided in the following section.

5.2.4 Validation of Phase 4 – Risk values analysis and minimization

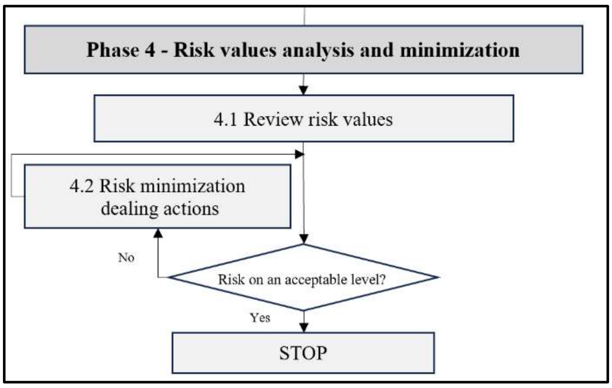


Figure 20 Phase 4 of the methodology of assessing and reducing the risk of development of tooling in automotive industry - risk values analysis and minimization recap of Figure 15

5.2.4.1 Review risk values (Phase 4, Point 4.1)

All calculated risk values for project Proj_1 were reviewed to ensure that the expert assessments were consistent and that no contradictory or abnormal results appeared. As no irregularities were identified, the results were accepted without correction and used for further interpretation in the following subsections.

Structural analysis of risk distribution

The distribution of risk across the defined risk categories (RC) and risk limitations (RL) was analysed to identify how organisational and technical factors, as well as cost-, timing- and quality-related constraints, contributed to the calculated risk values at each stage of the tooling development process. The results of this analysis are presented in Table 87 and Table 88.

Table 87 Project Proj_1 risk category ratio

Risk category (RC)	Risk step						
	R_I	**R_{STG1}**	**R_{STG2}**	**R_{STG3}**	**R_{STG4}**	**R_{STG5}**	**R_{STG6}**
1	2	3	4	5	6	7	8
Org	68%	61%	83%	26%	20%	0%	46%
Tech	32%	39%	17%	74%	80%	100%	54%

Table 88 Project Proj_1 risk limitations ratio

Risk limitation (RL)	Risk step						
	R_I	**R_{STG1}**	**R_{STG2}**	**R_{STG3}**	**R_{STG4}**	**R_{STG5}**	**R_{STG6}**
1	3	4	5	6	7	8	9
Cost (C)	32%	35%	36%	27%	31%	25%	25%
Timing (T)	33%	33%	33%	38%	25%	38%	37%
Quality (Q)	35%	31%	31%	35%	44%	37%	39%

In Proj_1, risk category ratios (Table 87) show input risk is predominantly organizational (ORG 68% - TECH 32%) remains constant across the entire project, so it requires sustained attention. The stage level split shows ORG dominance at the process early phases (specification acceptance (STG1 - 61%) and supplier nomination (STG2 - 83%), whereas the middle stages (tooling design acceptance, manufacturing, supplier handover and startup) call for a stronger technical focus. This pattern suggests clear ownership for organizational mitigations up front and at handover, and engineering technical actions in the central part of the process.

In Proj_1, risk limitation ratios (Table 88) show balance in remains constant across the entire project (R_I - C 32% / T 33% / Q 35%), means that – if needed - there is no obvious single "lever" for immediate risk reduction at baseline. From the stage level view perspective, the middle and late stages, shifts in the limitation mix become visible. Timing (T) is relatively more pronounced during design and commissioning (STG3 ≈ 38% T, STG5 ≈ 38% T), while Quality (Q) increases notably during manufacturing (STG4 ≈ 44% Q) and remains elevated at supplier handover (STG5 ≈ 37% Q). In practice, this means that - if needed – risk reduction priorities should be set at the stage level: enforce schedule discipline for STG3- STG5 (T) (e.g., closing tooling design acceptance on time or even quicker) and apply quality (Q) conformance for STG4- STG5 (e.g., process inspections of tooling manufacturing at the supplier, documented acceptance checks).

Evaluation through decision thresholds

Once the input risk (R_I), stage risk (R_{STG}), and total stage risk (R_{TSTG}) values have been calculated, they must be interpreted using predefined decision thresholds. These decision thresholds make it possible to determine whether a given process step requires preventive or corrective action, or whether the risk level remains acceptable. For the project Proj_1, the decision thresholds were adopted as specified in Table 89.

Table 89 Input risk (R_I), stage risk (R_{STG}), and total stage risk (R_{TSTG}) thresholds

Risk priority level	Input risk (R_I) range	Stage risk (R_{STG}) range	Total stage risk (R_{TSTG}) range
Low	$R_I < 0.40$	$R_{STG} < 0.40$	$R_{TSTG} < 0.10$
Medium	$0.40 \leq R_I < 0.60$	$0.40 \leq R_{STG} < 0.60$	$0.10 \leq R_{TSTG} < 0.20$
High	$R_I \geq 0.60$	$R_{STG} \geq 0.60$	$R_{TSTG} \geq 0.20$

The decision thresholds were defined by the expert group appointed in Phase 1.

Recording and communicating results

Using the decision thresholds, the total stage risk values calculated for project Proj_1 were consolidated and recorded as shown in Table 90.

Table 90 Total stage risk level for individual stage for project Proj_1

Total risk	Project stage	Risk value	Risk level
R_{TSTG1}	Tooling specification creation and acceptance	0.25	High
R_{TSTG2}	Tooling supplier nomination	0.23	High
R_{TSTG3}	Tooling design creation and acceptance	0.06	Low
R_{TSTG4}	Tooling manufacturing	0.06	Low
R_{TSTG5}	Tooling commissioning at supplier	0.06	Low
R_{TSTG6}	Tooling startup at production plant and preliminary handover	0.18	Medium

This table constitutes the formal outcome of the risk evaluation step and is communicated to project stakeholders to ensure a common understanding of risk exposure at each stage of the tooling-development process. These results are archived as part of the project documentation and serve as the basis for subsequent mitigation planning presented in the following section.

5.2.4.2 Risk minimization (Phase 4, Point 4.2)

Identification of stages requiring action

Based on the decision thresholds in Table 89 and the total stage risk (R_{TSTG}) values recorded in Table 90, three stages require mitigation: STG1 (R_{TSTG1} = 0.25, High), STG2 (R_{TSTG2} = 0.23, High) and STG6 (R_{TSTG6} = 0.18, Medium). The remaining stages (STG3–STG5) fall within the low-risk range and do not require additional actions.

Selection of mitigation measures

Applying the methodology of assessing and reducing the risk of development of tooling in automotive industry to project Proj_1 requires combining the evaluated input risk (R_I), total stage risk (R_{TSTG}) and the dominant risk category (RC) and limitation (RL) at each stage. Based on this combined assessment, Table 91 presents the project-specific mitigation recommendations for the project Proj_1.

Table 91 Project Proj_1 decision matrix for selecting mitigation actions based on R_I, R_{TSTG}, RC and RL dominance

Input risk (R_I) level	Total stage risk (R_{TSTG}) level	Risk category (RC) dominant?	Risk limitation (RL) dominant?	Mitigation action recommendations
High	High	Yes	Yes	Full stop of stage progression; mandatory corrective actions; immediate alignment of responsible functions
			No	Stop of stage; corrective actions focused on RC; RL requires clarification
		No	Yes	Stop of stage; corrective actions aimed at reducing dominant RL
			No	Rapid session to structure risk, assign ownership, clarify RC/RL, and define exit criteria before gate release
	Medium	Yes		Preventive measures executed ahead of other projects; increased oversight and early resource engagement
		No	No	Short alignment session to identify RC/RL dominance; then targeted preventive measures
	Low			Actions focused directly on R_I categories and limitations mitigation or identification
Medium	High	Yes	Yes	Full stop of stage progression; mandatory corrective actions;

				immediate alignment of responsible functions
			No	Stop of stage; corrective actions focused on RC; RL requires clarification
		No	Yes	Stop of stage; corrective actions aimed at reducing dominant RL
			No	Rapid session to structure risk, assign ownership, clarify RC/RL, and define exit criteria before gate release
	Medium	Yes	Yes	Targeted preventive measures to reduce risk aligned with dominant RC/RL
			No	
		No	Yes	
			No	Short alignment session to identify dominant RC/RL, followed by preventive actions
	Low			Standard monitoring cadence with additional focus on RL and RC stability
Low	High	Yes	Yes	Full stop of stage progression; mandatory corrective actions; immediate alignment of responsible functions
			No	Stop of stage; corrective actions focused on technical/organisational RC; RL requires clarification
		No	Yes	Stop of stage; corrective actions aimed at reducing dominant RL
			No	Rapid session to structure risk, assign ownership, clarify RC/RL, and define exit criteria before gate release
	Medium	Yes	Yes	Targeted preventive measures to reduce risk aligned with dominant RC/RL
			No	
		No	Yes	
			No	
	Low			Proceed as planned; no additional risk-driven actions required

Table 92 presents the stage-level mitigation actions for project Proj_1, derived directly from the dominant risk categories and limitations identified for each stage.

Table 92 Project Proj_1 stage-level mitigation planning based on dominant risk limitations and risk categories.

Process Stage (STG)	Risc level	Dominant Risc Category	Dominant Risk Limitation	Selected mitigation actions	Responsible role	Planned completion date
STG1	High (0.25)	ORG (61%)	balanced	1.Finalise & freeze tooling specification 1 week prior to order	TE_1	1 week before STG1 end
STG1	High (0.25)	ORG (61%)	balanced	2. Mandatory cross-functional review of the specifications with minutes - weekly	TE_1; PML_1; PPE_2	3 weeks before STG1 end
STG1	High (0.25)	ORG (61%)	balanced	3. Cross check machine interfaces with maintenance manager	TE_1; PML_1	2 weeks before STG1 end
STG1	High (0.25)	ORG (61%)	balanced	4. Checklist-based verification of spec before release	TE_1	1 week before STG1 end
STG1	High (0.25)	ORG (61%)	balanced	5. Weekly status of cost, timing and tooling quality alignment prior to tool order	PM_1	3 weeks before STG1 end
STG2	High (0.23)	ORG (83%)	C 36%	1. Re-validate supplier panel (technical capacity + financial)	TB_2; TE_1	3 weeks before STG2
STG2	High (0.23)	ORG (83%)	C 36%	2. Align quotation to final scope (BOM, tolerances, trials)	TE_1	1week before STG2
STG2	High (0.23)	ORG (83%)	C 36%	3. Define change-cost handling & escalation	TB_2; PM_1	1week before STG2
STG2	High (0.23)	ORG (83%)	C 36%	4. Weekly cost-deviation review with Technical Buyer	TE_1	From STG2 to STG5
STG2	High (0.23)	ORG (83%)	C 36%	5. Confirm detailed schedule after order	TB_2	1week after STG2 latest
STG6	Medium (0.18)	TECH (54%)	Q 39% T 37%	1. Plant readiness check (machines, gauges, utilities)	PML_1	1 week before STG6
STG6	Medium (0.18)	TECH (54%)	Q 39% T 37%	2. BOM/material availability & conformity	PPE_2	1 week before STG6
STG6	Medium (0.18)	TECH (54%)	Q 39% T 37%	3. Startup run-book with acceptance criteria (TFOT, scrap cap, cycle time)	PML_1	1 week before STG6
STG6	Medium (0.18)	TECH (54%)	Q 39% T 37%	4. Supplier on-site support confirmation	TE_1	1 week before STG6
STG6	Medium (0.18)	TECH (54%)	Q 39% T 37%	5. Pre-PPAP param check	PPE_2	1 week before STG6

Based on the total stage risk (R_{TSTG}) results, together with the thresholds presented in Table 89, in project Proj_1 mitigation actions are triggered for R_{TSTG1} and R_{TSTG2}, (high) and for R_{TSTG6} (medium). For each of the stages requiring action, the dominant risk category (organisational or technical) and the prevailing risk limitations (cost, timing, quality) were identified using the distributions presented in Table 87 and Table 88.

In stage STG1 ($R_{TSTG1} = 0.25$), the organisational category clearly dominates (ORG = 61%), indicating that risk steams primarily from procedural, communication-related or coordination-based factors. This indicates the need for corrective actions focused on improving specification governance, strengthening coordination routines and ensuring thorough verification before releasing documentation. Accordingly, actions include weekly status reviews prior to tool order, mandatory cross-functional specification reviews, interface checks with maintenance and checklist-based verification before specification release.

In stage STG2 ($R_{TSTG2} = 0.23$), the risk structure is again predominantly organisational (ORG = 83%). pointing to supplier-related uncertainties and the financial impact of scope deviations. Corrective actions therefore prioritise re-validating the supplier panel, aligning the quotation to the final scope, defining change-cost handling rules and introducing frequent cost-deviation reviews with the commercial department.

For stage STG6 ($R_{TSTG6} = 0.18$), which falls within the medium-risk range, the dominant category is technical (TECH = 54%), typical for activities performed at the production plant during the startup phase. The risk limitation distribution points to quality as the leading limitation (Q = 39%), followed by timing (T = 37%). This reflects the typical challenges of production startup, where material conformity, process stability and equipment readiness are critical. Preventive actions therefore focus on plant readiness checks, BOM conformity verification, preparation of a startup run-book with acceptance criteria, pre-PPAP parameter checks and confirmation of supplier on-site support.

This structured interpretation of risk limitations and risk categories distributions ensures that mitigation actions applied in Phase 4 are targeted, proportionate, and directly aligned with the dominant sources of risk for each stage of the tooling development process of the project Proj_1.

Summary

The case study confirmed that the developed methodology of assessing and reducing the risk of development of tooling in automotive industry enables a consistent execution of all risk assessment phases - from process preparation, through determining and estimating R_I and R_{STG}, to calculating R_{TSTG}, interpreting the results, and selecting targeted mitigation actions. Importantly, the outcomes of the analysis were directly translated into resource-planning decisions, including adjustments of engineering workload on a stage-by-week basis, which confirms the practical usefulness of the approach in real project conditions. Single project approach concludes functional verification of the methodology of assessing and reducing the risk of development of tooling in automotive industry.

6. Summary and conclusions

The global automotive sector is experiencing intense competitive pressure, shortening development cycles, a growing number of variants, and stricter regulatory and quality requirements. In this environment, the development of production tooling is a key link between product development and serial production, remains area of elevated risk. Stable, repeatable production tool development processes are essential for meeting implementation deadlines, meeting quality requirements, and maintaining cost competitiveness. At the same time, practice shows that classic tools (e.g., FMEA) are fragmented, time-consuming, and subjective, and their results are difficult to translate into coherent, goal-oriented decisions in complex R&D projects.

A literature review reveals the lack in a systematic approach to managing production tooling development, lack of production tooling definition, as well as the lack of a definition of production tooling development, its metrics and direct connection to new product development processes.

In response to these challenges, this work designed and validated a risk assessment and reduction methodology of assessing and reducing the risk of development of tooling in automotive industry specific to production tooling development, integrated with the product development process and supporting step-by-step decisions. The methodology of assessing and reducing the risk of development of tooling in automotive industry consists of four phases: (1) process preparation, (2) risk analysis, (3) risk calculation, and (4) results analysis and risk mitigation. Its core consists of:

- Structural risk model - distinguishing risk categories (RC) and risk constraints (RL).
- Set of standardized assessment questions that allow for the operationalization of development process input risks (R_I) and stage risks (R_{STG}).
- Generalized linguistic scale and fuzzy conversion that unifies expert judgments and allows for comparable values within and across projects.
- Multiplicative aggregation model for total stage risk (R_{TSTG}) and decision thresholds consistent with Stage-Gate logic.
- Critical tooling metrics that ensure link between risk and key business and operational goals.

The work identified and addressed research gaps that have previously hindered practical tooling risk management:

- Lack of an integrated, staged tool development model synchronized with product development - supplemented by a proprietary process model emphasizing steps, supporting tasks, and improvement loops.
- Lack of dedicated metrics and clear decision thresholds - metrics and consistent thresholds were introduced, enabling objective classification of stage risk.
- Subjectivity and dispersion of assessments - addressed by AQ and fuzzy, which allows for the conversion of expert opinions into comparable numerical values and their transfer to gate decisions.
- Decoupling risk assessment from process constraints (time, cost, quality) - addressed by the risk limitation (RL) dimension, which provides risk analysis with a perspective of actual organizational and project feasibility.

Industrial validation of the methodology of assessing and reducing the risk of development of tooling in automotive industry confirmed that:

- The methodology of assessing and reducing the risk of development of tooling in automotive industry enables early identification of higher-risk stages and precise targeting of corrective actions in accordance with the dominant risk categories and limitations.
- In the case study, increased risk exposure was achieved at critical stages (STG1, STG2, STG6), which translated into improved tool readiness and more stable start-up.
- Risk integration with tooling cost, tooling lead time and tooling quality metrics allows for proactive response to schedule, cost, and quality threats.

The most important scientific and methodological achievements of this work include:

- Developing an integrated, phased model for the tooling development related with APQP.
- Defining a universal risk category and risk limitation framework that provides structure, interpretability, and the ability to assign ownership of corrective actions to risk assessments.
- Standardizing expert assessments (linguistic scale + fuzzy) and standardizing decision thresholds in the R_{TSTG} format.
- Identifying and weighting metrics linking risk to business value and operational execution.
- Developing a complete workflow (AQ, spreadsheets, rules, thresholds) that can be implemented in new product development projects involving multiple stakeholders and tool providers.

The most important practical achievements include:

- Ready-to-use "plug-in" methodology of assessing and reducing the risk of development of tooling in automotive industry for existing product development frameworks.
- Templates and criteria enabling quick process launch (AQ, RC×RL matrices, thresholds, interpretation rules).
- Transparent mapping of results to decisions (go/hold/mitigate) with the identification of action owners.
- The ability to scale the methodology of assessing and reducing the risk of development of tooling in automotive industry to multiple projects simultaneously and compare risks between projects (fixed scales, fixed thresholds).

The methodology of assessing and reducing the risk of development of tooling in automotive industry does not replace existing quality standards (e.g., FMEA, PPAP) but rather complements them with a decision-making and prioritization dimension, necessary in complex, multi-stage tool development projects.

Limitations and directions for future work

Several planned and recommended extensions may be considered to further enhance the methodology in future stages of research.

First, it is advisable to explore the automation of data acquisition by integrating the methodology with enterprise resource planning systems and product lifecycle management systems. Such integration could allow selected assessment questions to be completed automatically using existing project and operational records. Additionally, linking the assessment question structure to a "lessons learned" module and enabling automated prioritization of mitigation actions in accordance with project schedules is recommended.

Second, the introduction of adaptive decision thresholds is proposed. These thresholds could learn from historical datasets, allowing dynamic adjustment of metric boundaries such as the Total Stage Gate Risk indicator to the specific characteristics of a given technology or risk portfolio. This approach may also support the development of more precise dominance thresholds for risk likelihood indicators and risk consequence indicators.

Third, it is recommended to conduct extensive cross-sectoral studies, extending beyond tooling development in the automotive industry. Such research would help verify the transferability and broader applicability of the proposed methodology.

Fourth, the methodology could be enhanced through integration with intelligent analytical techniques, particularly machine-learning methods for detecting emerging risk trends. This would support the development of near-real-time decision dashboards that facilitate continuous monitoring and rapid response.

Fifth, it is recommended to introduce a mechanism linking assessed risk levels with the planned workload allocation for project team members. Higher-risk items should be associated with proportionally increased planned mitigation time to ensure that risks with the greatest potential impact are systematically addressed. Such risk-based time allocation would improve resource planning and strengthen the effectiveness of mitigation efforts.

Finally, it is advisable to expand the Assessment Questions Library with variants tailored to key manufacturing domains such as foundry operations, molding processes, injection-molding processes, stamping processes, and composite-material technologies. This would enable more accurate and practical application of the methodology across diverse manufacturing environments.

Conclusion: The proposed methodology of assessing and reducing the risk of development of tooling in automotive industry bridges the gap between general risk management recommendations and the daily practice of tooling development. It provides a measurable, repeatable, and decisive way to manage risk - from early identification to the execution of corrective actions - which directly translates into timeliness, cost-effectiveness, and quality of production tooling development.

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7. Bibliography

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