Engineering Management
Field Project

Project Risk Management in New Product Development Projects

By

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Executive Summary

New product development (NPD) projects are efforts of cross-functional teams conducted in organizations by following a set of processes to achieve set goals for features, cost, performance, and at the right time. NPD efforts involve uncertainties that cross-functional teams categorize as technical risks and non-technical risks.

The focus of the NPD teams is more towards the technical risks associated with a product and less on non- technical risks, which threaten attainment of the target cost, scope, and time constraints. Focusing on non-technical risk management enables teams to employ strategies to effectively counter them. The field project undertaken studies the NPD project stages, project management procedures and non-technical risk management procedures defined by guiding bodies and compares them with the procedures written by companies known for their NPD efforts.

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List of Principal Symbols and Nomenclature

AHP – Analytic Hierarchy Process

BN – Bayesian Networks

BS – British Standards

CE - Concurrent Engineering

CPM - Critical Path Method

DFMEA – Design Failure Mode and Effect Analysis

FMEA – Failure Mode and Effect Analysis

FTA - Fault tree analysis

GERT- Graphical Evaluation and Review Technique

IEC – International Electrotechnical Commission

IPMA- International Project Management Association

NASA - The National Aerospace and Space Admission

P- Diagram - Parameter Diagram

PDMA – Product Development Management Association

PERT - Program Evaluation and Review Technique

PEST - Political, Economic, Social and Technological

PFMEA – Process Failure Mode and Effect Analysis

PMBOK- Project Management Book of Knowledge

PRINCE II - Projects in Controlled Environment, Version 2

RFMEA- Risk Failure Mode and Effect Analysis

RPN – Risk Priority Number

SFMEA – System Failure Mode and Effect Analysis

SWOT - Strengths Weaknesses Opportunities and Threats

VDI - Verein Deutscher Ingenieure

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Chapter 1 - Introduction

New products cater to ever-changing business demands, such as innovations, new solutions, environmental standards, new safety standards, and end of product life cycle. “Bringing new products to market is crucial in today's competitive business environment as market leadership, healthy market share, and sustained growth are all enabled through the process of developing and launching successful new products and services” (Barczak & Kahn, 2012, p. 293). At an organizational level, efforts of functions such as marketing, product design engineering, operations, purchasing, quality, and logistics are required to create a product, in line with these demands. Organizations form cross-functional teams consisting of all these functions and adopt a process termed as “new product development” (NPD). Industry defines the start and end of an NPD activity as idea generation, followed by design, development, prototyping, and stops with first production.

NPD encounters uncertainties that cross-functional teams classify as technical risks and non-technical risks. Technical risks are product-specific and may result in an undesirable consequence, such as functional failure of product. Failures could potentially arise due to tolerances, assembly methods, application of loads, etc. Failures due to the above-mentioned factors are intrinsic. External factors for example, undesired and unintended use of product, can also cause failures. Managing uncertainties to prevent failures is germane, as the impact of a failure can be catastrophic. Product designers build contingencies like “factor of safety” into the design to increase the reliability of the product. Building contingencies into a product helps to manage technical risks but does not minimize them. In a mass production scenario, contingencies lead to an exponential increase in the cost of manufacturing a product. Thus, organizations try to trim down contingencies.

Technical risk management focuses on limiting the use of contingencies. Tools such as Failure Mode and Effect Analysis (FMEA) emerged as proactive tools prompting team members to predict, counter, and define responses to address failures, and hence reduce contingencies and manage technical risks. “The major objective of the application of FMEA is the identification of potential failure modes of the system components, evaluating their causes and their subsequent effects on the system” (Mandal & Maiti, 2014, p. 3527). FMEA workshops are typically conducted by the cross functional team, along with experts. FMEA is a one of the risk management tools that minimizes planning with contingencies.

Technical risk management is inbuilt in the mission of an NPD activity. However, cross-functional teams place less emphasis in identifying and managing non-technical risks, such as meeting cost targets, time to market, branding, etc. Intrinsic factors that contribute to non-technical risks are lack of a systematic approach to NPD, low team commitment, lack of a support from the organization, etc. Cross-functional teams can minimize non- technical risks due to intrinsic factors by following a systematic process for NPD. Some of the external factors that contribute to non-technical risks are fluctuating material prices, logistic issues, etc. For external factors, the team may need to plan contingencies.

Organizations view NPD activity as a project with a tangible result. PMI (2013) describes a project as a “temporary endeavor undertaken to create a product, service, or result” (p.3). To manage an NPD, a structured project management process is required. “Project management is defined as the application of knowledge, skills, tools and techniques to meet a project requirement” (PMI, 2013, p. 5). Different fields like software development, manufacturing, construction management, oil and gas applications, and space programs have adopted project management procedures to manage projects and reduce non-technical risks arising due to internal factors.

Project management procedures are relevant for NPD as it groups activities, which are temporary having a definite start and end. The majority of project management standards, methods, and guidelines have emerged employing best practices and tools from operations. Organizations that have implemented project management methods for NPD have seen shorter product development cycles, minimal risks and better-documented projects.

PMI (2013) notes that risks are highest at the beginning of the project. In NPD projects, both the categories of risk are maximum while the product is still subject to conceptual changes and decrease as the NPD cycle reaches a logical conclusion. Non-technical risks reduce with the systematic engagement of planned activities. PMI (2013) defines "The purpose of risk management is to devise strategies to manage identified risks that a project might encounter, positive or negative" (p. 309). It is important to address non- technical risk in NPD projects and focus on its management along with the other areas, such as team management, communication management, and stakeholder management. The context of the risk management for NPD should be both technical risk related to products and systems and non-technical risks for the overall project.

An NPD project is as a transitory venture before mass production. Nonetheless, the documentation of the project will play a vital role in maintaining the versions and providing historical reference for the product. For non-technical risk, documentation becomes part of the organization's documentation libraries and different teams' reference this information at all stages of the product life cycle. The current NPD process has deficiencies in defining risk management processes for non-technical risks. Project management procedures help to reduce non-technical risks due to internal factors. Conversely, adopting a project management procedure increases the amount of documentation of NPD. PMI (2013) prescribes risk management processes and general tools and techniques acceptable for all industries. The recommended risk management tools are elaborate and applied in different contexts, depending on the project phase.

Purpose and Scope

The contribution of this field project will be to see if PMI (2013) recommended risk management procedures are appropriate for non-technical risks in NPD projects. The study will examine if implementing the non-technical risk management procedures can be achieved utilizing minimal tools by the selection of risk management methods based on the existing knowledge of technical risk management. Most of the tools involve two parameters: probability and impact to define the likelihood and consequence of risks respectively. Further, the project will focus on the question of whether or not a modified FMEA tool called Risk FMEA (RFMEA) is beneficial in identifying risks, and planning responses. The FMEA method prescribes three parameters: probability, impact, and detection. Research will examine if building in the detection element could circumvent deficiencies in the current usage of risk management tools.

Chapter 2 - Literature Review

The field project aims to understand standard guidelines for project management procedures, risk management procedures, NPD procedures, and the FMEA method. The literature review examines research papers addressing adoption of project management procedures for NPD, risk management methods for non- technical risks in NPD projects, and FMEA as a risk management tool for non –technical risks in NPD projects.

Project Management Method

Project management procedures, as defined by guiding bodies, provides a framework with best practices for effective project management. The purpose of project management processes is to "Ensure the effective flow of the project throughout its life cycle" (PMI, 2013, p. 47). PMI (2013) defines five phases or Process Groups required for projects:

1. Initiating Process Group
2. Planning Process Group
3. Executing Process Group
4. Monitoring and Controlling Process Group
5. Closing Process Group

The Initiating Process Group consists of processes conducted to set objectives. The Planning Process Group define the required effort to meet the objectives. The Executing Process Group focusses on completing the planned objectives. The Monitoring and Controlling Process Group focuses on the review, track, and measure objectives. The Closing Process Group consists of concluding activities. The project management Process Groups are interdependent and interacting as per project requirements. The five Process Groups are applicable for all industries and can be iterative. Table 1 shows the Process Groups, Knowledge Areas, and processes recommended by PMI (2013).

Knowledge Areas	Project Management Process Group				
	Initiating Process Group	Planning Process Group	Executing Process Group	Monitoring and Controlling Process Group	Closing Process Group
4. Project Integration Management	4.1 Develop Project Charter	4.2 Develop Project Management Plan	4.3 Direct and Manage Project Work	4.4 Monitor and Control Project Work 4.5 Perform Integrated Change Control	4.6 Close Project or Phase
5. Project Scope Management		5.1 Plan Scope Management 5.2 Collect Requirement 5.3 Define Scope 5.4 Create WBS		5.5 Validate Scope 5.6 Control Scope	
6. Project Time Management		6.1 Plan Schedule Management 6.2 Define Activities 6.3 Sequence Activities 6.4 Estimate Activity Resources 6.5 Estimate Activity Duration 6.6 Develop Schedule		6.7 Control Schedule	
7. Project Cost Management		7.1 Plan Cost Management 7.2 Estimate Costs 7.3 Determine Budget		7.4 Control Costs	
8. Project Quality Management		8.1 Plan Quality Management	8.2 Perform Quality Assurance	8.3 Control Quality	
9. Project Human Resource Management		9.1 Plan Human Resource Management	9.2 Acquire Project Team 9.3 Develop Project Team 9.4 Manage Project Team		
10. Project Communication Management		10.1 Plan Communication Management	10.2 Manage communication	10.3 Control Communications	
11. Project Risk Management		11.1 Plan Risk Management 11.2 Identify Risks 11.3 Perform Qualitative Risk Analysis 11.4 Perform Quantitative Risk Analysis 11.5 Plan Risk Responses process		11.6 Control Risks process	
12. Project Procurement Management		12.1 Plan Procurement Management	12.2 Conduct Procurements		12.4 Close Procurement
13. Project Stake Management	13.1 Identify Stakeholders	13.2 Plan Stakeholder Management	13.3 Management Stakeholder Engagement	13.4 Control Stakeholder Engagement	

Table 1. PMI Process Groups and Knowledge Area Mapping.

Note. Adapted from "A Guide To The Project Management Body Of Knowledge" (PMBOK Guides). Project Management Institute, 2013, p. 57.

PMI (2013) describes Process Groups to be more than life cycle phases as they can all occur in one phase of a project or can occur recurrently as subprocesses.

NPD Process

Stage-Gate and Concurrent Engineering are the two most widely followed procedures for NPD. The Stage-Gate process evolved in the late 1990s and a large number of organizations have adapted it to expedite NPD projects from idea to launch (Kahn, 2004). Figure 1 shows the Stage-Gate process of NPD, consisting of the following stages:

1. Idea Generation
2. Scoping
3. Build Business Case
4. Development
5. Testing and Validation
6. Launch

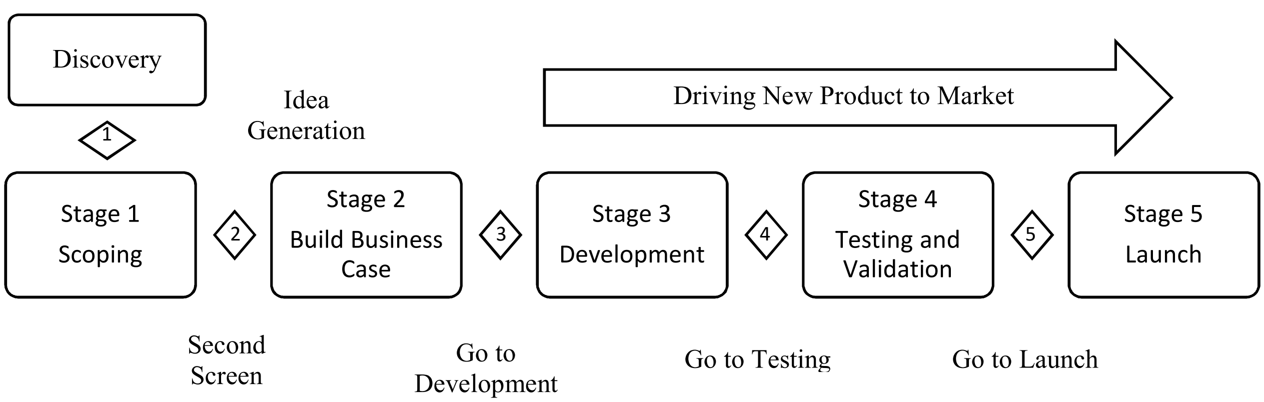


Figure 1. An Overview of a Typical Stage-Gate Process.
Adapted from "PDMA Handbook of New Product Development", by K.B.Kahn, 2004, PDMA. p. 25

Kahn (2004) observes that each stage has a gate before the beginning of the next that determines the Go/No-Go decision. A gate is a checkpoint for quality, cost, and the worthiness of the overall project.

Concurrent Engineering (CE) procedures consist of product design and development running in parallel, rather than sequential stages as in the Stage-Gate process. The focus is to simultaneously design the product, undertake product development, and conduct production trials for each iteration. Advantage of CE procedure is the detection of risks early on, such that the design and production of product evades the organization's deficiencies.

Figure 2 shows typical engineering disciplines in CE, based on the client, user or customer requirements. A fully integrated design follows, Process Engineering, Production, and Operations (NASA, 1999).

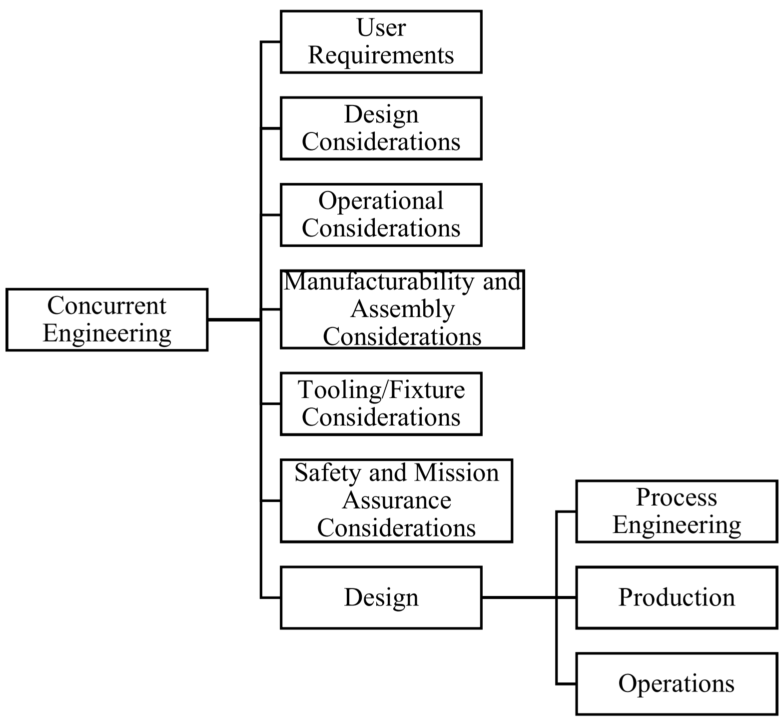


Figure 2. Concurrent Engineering Flow Diagram.
Adapted from lesson learnt based on Reliability guideline number from National Aeronautics and Space Administration, 1999, Lesson Number. 681

Stage-Gate Process and PMI's Procedure for NPD Projects

The project management procedure defined by PMI (2013) is comprehensive and structured. Many organizations have adopted it for their projects. The phases recommended by PMI (2013) are comparable with the Stage-Gate process. Figure 3 shows the comparable Stages and corresponding Process Groups defined by PMI (2013). The beginning of the project, generally called the Initiation Process Group is equivalent to the Idea generation and Scoping stage, where a preliminary market, technical, business, and financial feasibility is studied.

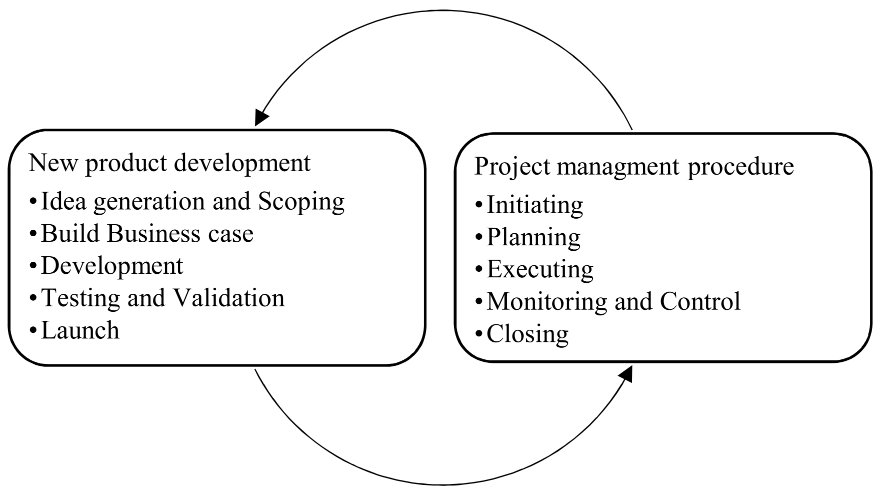


Figure 3. Comparing Stage-Gate Process to PMI Process Groups

The Planning Process Group can be compared to the Build Business case stage, where an analysis of user requirements, concept testing, and a detailed technical and financial feasibility is presented as a "business case" to the stakeholders. The Development stage of NPD involves activities or processes, which are similar to those conducted under the Executing Process Group. It involves implementation of the development plan to produce a functional prototype of the product tested under laboratory conditions.

The Testing and Validation stage can draw parallels with the Monitoring and Control Process Group. The Emphasis is on auditing the technical deliverables with beta testing, field-testing, and production trial runs. A review of the entire project with financial justification is analyzed before launch. Although activities of the Launch stage can be similar to the Closing Process Group, Launch is not exactly the close of a NPD project. It involves activities like monitoring problems during full production launch of variants, launches in different markets and continuous improvement (Kahn, 2004) . The project management approach becomes all the more relevant for Concurrent Engineering NPD projects. Since the process of CE is iterative, each iteration of CE NPD will contain all the Process Groups.

Tools in Stage-Gate Process

Bhuiyan (2011) proposes a successful NPD framework by defining Critical Success Factors, metrics, and tools and techniques as shown in Table 2.

Stage	Critical Success Factor	Metrics	Tools and Techniques
New Product Strategy	Clear Strategy Well Communicated Strategy	Return on Investment Degree of Communication	Financial Analysis
Idea Generation	Customer Focused Idea Generation	Number of Customer Focused Ideas Generated	Balanced-scorecard as a Communication Tool Lead User Method Ethnographic Approach
Screening and Business case	Up-Front Homework	Expected Commercial Value (ECV) Net Present Value (NPV) Internal Rate of Return (IRR) Productivity Index (PI)	Financial Method of Evaluation
Development	Speed Customer Feedback	Development time Degree of functional integration Degree of team commitment Concurrency of activities Degree of design effort on real customer priorities	Team Cohesiveness Dynamic Time to Market Degree of Parallelism
Testing	Product Functionality Customer Acceptance Customer	Product Performance Customer-Perceived Value	Validation Testing User and Field Testing

Table 2. Critical Success Factors and Metrics for NPD Process
Note: Adapted from “A framework for successful new product development” by Nadia Bhuiyan, Journal of Industrial Engineering and Management, Vol 4, No 4 (2011), p. 766.

The framework provided in Table 2 suggests generic Critical Success Factors that organizations need to build into the process of NPD. Adopting the PMI (2013) procedure or the framework suggested by Bhuiyan (2011), requires emphasis on NPD project management and documentation.

The PMI (2013) procedure is a universal procedure defined to suit all industries by defining best practices. However, the procedure might not be suited for NPD projects without modifications. Pons (2008) studied the application of PMI (2013) procedure for NPD project management and concluded that the method is generally useful for managing NPD projects, except in projects characterized by complex interrelated activities and large uncertainties. This suggests an NPD framework needs to focus on internal processes by identifying the gaps in the current system and customize a procedure that integrates the NPD process with PMI (2013) procedures.

Risk Management

Risk management in NPD projects gains importance, as changes at the later stage are undesirable, and can hurt the achievement of scope the timeline of the project, and the development costs. Figure 4 shows the increase in cost of changes and decrease in degree of risk and uncertainty with the progress of project.

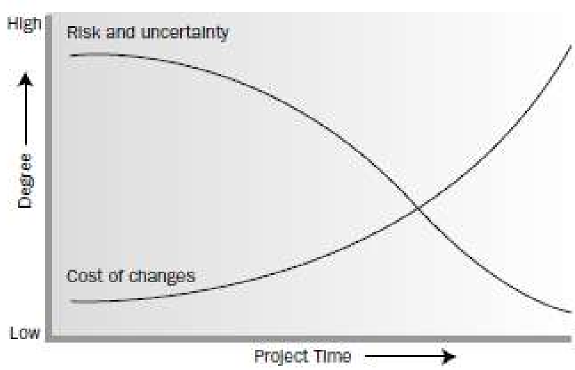


Figure 4. Impact of Variable Based on Project Time.
Adapted from "A Guide To The Project Management Body Of Knowledge" (PMBOK Guides). Project Management Institute, 2013, p. 40.

Non- technical risk management for NPD projects should address uncertainties in meeting triple constraints: cost, time and scope. Cost refers to direct measurable factors, such as project budget and product cost. Time refers to meeting milestones, such as the target date for completing various stage or gates, launch dates, etc. Scope as a constraint means meeting all the functional requirements of the product, characteristics, and quality parameters.

It is important to a have a procedure to systematically address and reduce the effect of non-technical risks in a project. PMI (2013) defines Risk Management Knowledge Area, consists of the following processes:

1. Plan Risk Management
2. Identify Risks
3. Perform Qualitative Risk Analysis
4. Perform Quantitative Risk Analysis
5. Plan Risk Responses
6. Control Risks

PMI (2013) suggests the Plan Risk Management process to document risk management practices, in an organization. The project team documents the identified risks through the Identify Risks process. The Perform Qualitative Risk Analysis process aims at prioritizing risks and defining their probability and impact. The Perform Quantitative Risk Analysis process analyzes the effect of risk on the project, based on the derived numerical values. The project team decides the actions to reduce threats and enhance the opportunities with the Plan Risk Responses process. The Control Risks process focuses on applying the planned risk responses, tracking the indicators and evaluating the process of risk management throughout the project.

Figure 5 gives an outline of recommended Inputs, Tools and Techniques and Output for each of the six processes applied.

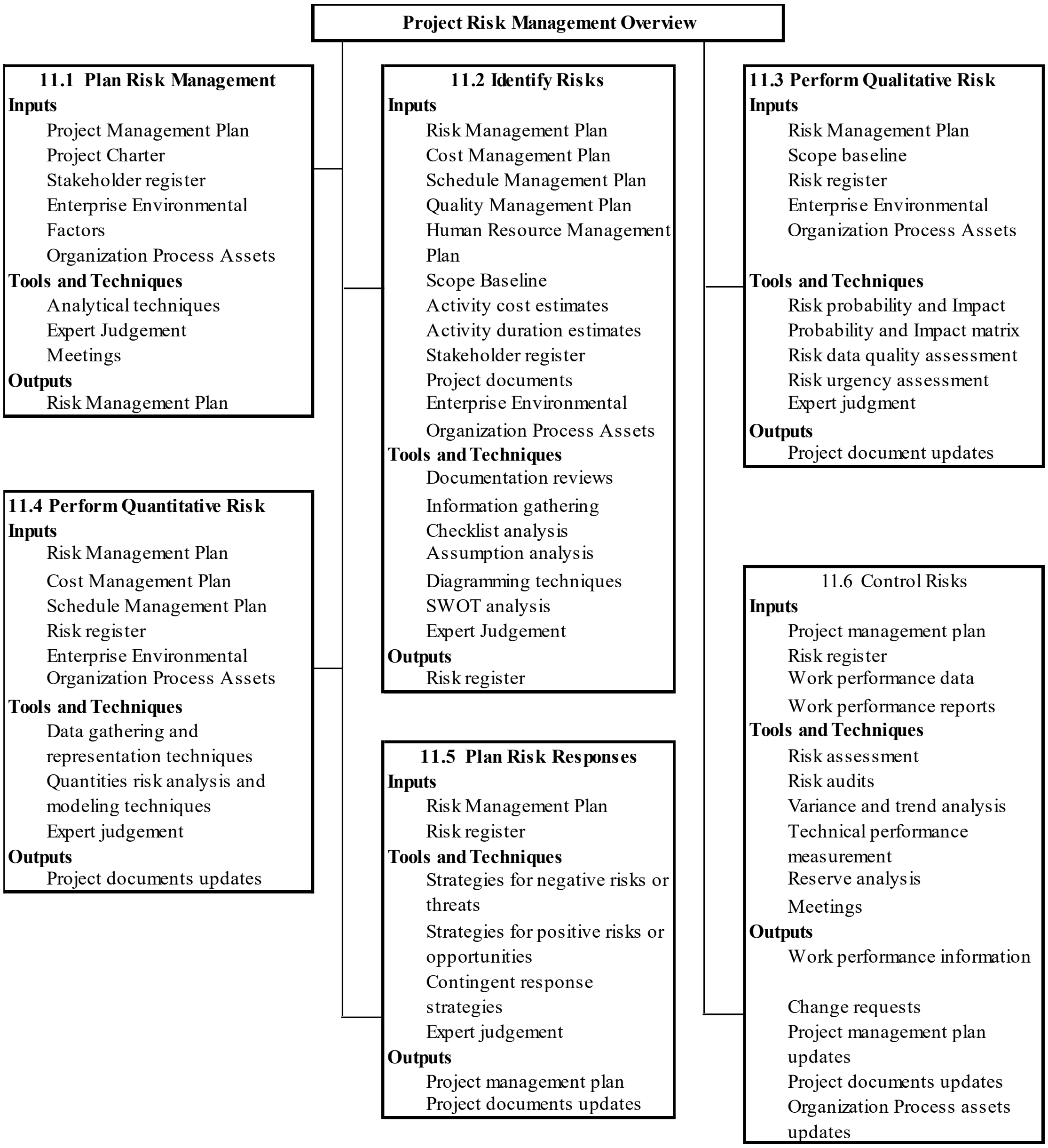


Figure 5. Risk Management Overview.
Adapted from "A Guide To The Project Management Body Of Knowledge" (PMBOK Guides). Project Management Institute, 2013, p. 312.

Berg (2010) recommends a framework for risk management, which includes:

1. Basis for risk management established by company

2. Establishing context

3. Risk identification

4. Risk analysis

5. Risk assessment
6. Risk control and coverage
7. Risk monitoring and review

Figure 6 shows the risk management process suggested by Berg (2010).

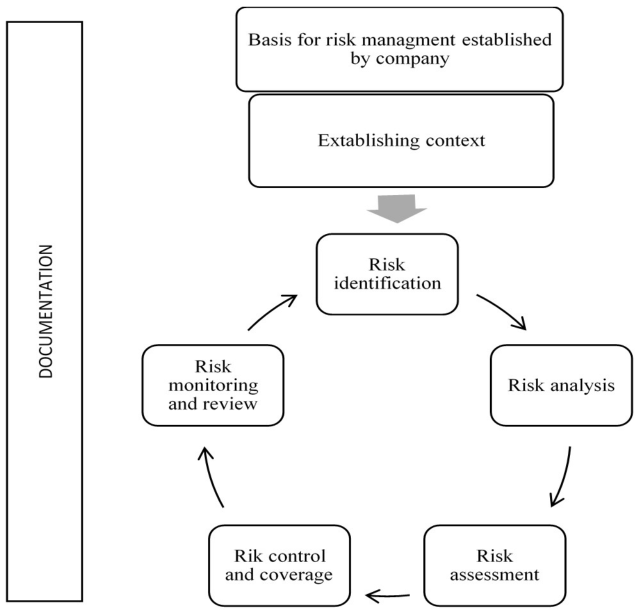


Figure 6. Risk Management Process.
Note: Adapted from "Risk Management: Procedures, Methods and Experiences" by Heinz-Peter, Berg, RT&A # 2(17), 2010, p. 5

Perusing the definition of the processes recommended by Berg (2010) the identification, analysis; assessment, control and coverage, and monitoring and review processes for risks are the same as the PMI (2013) procedure. Both the procedures are appropriate for addressing non-technical risks in an NPD project. While it is desirable to use processes recommended by PMI (2013), or the procedure suggested by Berg (2004), it is desirable to have fewer tools for risk management.

Risk Management Tools

PMI (2013) recommends specific tools for processes in risk management. Table 3 shows risk management techniques recommended by PMI (2013).

Process Group	Process	Tools and Techniques	Tools
Planning Process Group	Plan Risk Management	Analytical techniques	
		Expert Judgement	
		Meetings	
	Identify Risks	Documentation reviews	
		Information gathering techniques	Brainstorming
			Delphi technique
			Interviewing
			Root cause analysis
		Checklist analysis	
		Assumption analysis	
		Diagramming techniques	Cause and effect diagram
			System or process flow charts
			Influence diagrams
		SWOT analysis	
		Expert Judgement	
	Perform Qualitative Risk Analysis	Risk probability and Impact	
		Probability and Impact matrix	
		Risk data quality assessment	
		Risk urgency assessment	
		Expert judgment	
	Perform Quantitative Risk Analysis	Data gathering and representation techniques	Interviewing
			Probability distribution
		Quantities risk analysis and modeling techniques	Sensitivity analysis
			Expected Monetary value analysis
		Expert judgment	Modelling and simulation
	Plan Risk Responses	Strategies for negative risks or threats	Avoid
			Transfer
			Mitigate
			Accept
		Strategies for positive risks or opportunities	Exploit
			Enhance
			Share
			Accept
		Contingent response strategies	
		Expert judgment	
Monitoring and Controlling Process Group	Control Risks	Risk assessment	
		Risk audits	
		Variance and trend analysis	
		Technical performance measurement	
		Reserve analysis	
		Meetings	

Table 3. Overview of Risk Management Tools and Techniques (PMI 2013).

Organizations apply risk management processes, utilizing appropriate tools, depending on the phase, stage or Process Group of the project. Idea generation and scoping stage employs a variety of risk management tools that aide in the selection of a product for NPD.

Porananond & Thawesaengskulthai (2014) suggest the list of most frequently used risk management tools:

1. Analytic Hierarchy Process (AHP)
2. Bayesian Network (BN)
3. FMEA
4. Fuzzy Set
5. Expected Utility Theory
6. Game Theory
7. Monte Carlo Simulation
8. Bubble Diagrams
9. Control Charts

NPD Risk Management for Non- Technical Risks

Applying the PMI (2013) procedure for NPD risk management, Pons (2008) suggests the use of tools such as, Hazard and Operability study, Zonal analysis, FMEA, and Fault Tree Analysis (FTA) in the Identify Risks process for NPD projects. The Quantitative and Qualitative Risk Analysis processes yield a probability and impact, or consequence to explain the likelihood and effect of the risk. Pons (2008) explains that the purpose of planning a risk response is for the treatment of risk, to select a risk strategy, depending on the tolerable level of risk. This level will be variable between individuals and organizations. However, the risks discussed in this context are not distinguished as technical or non- technical risks.

NPD Stage-Gate procedure employs Gates as decision points for managers to make a Go/No-go decision, and serve as checkpoints for the risk monitoring and review process for both technical and non-technical risks. Kahn (2004) observes that the gate decisions are often poorly undertaken. He conjectures that gate decisions are the least proficiently conducted component of the NPD process. Kahn (2004) terms risk management as “risk analysis” and recommends the use of techniques such as Hazard Analysis to analyze risks in the beginning stage. Hazard Analysis helps in the identification of potential risks, indicating if the risk exists or not with a binary scale (0 or 1), and helps in arriving at preliminary risk levels. Teams use hazard analysis specifically to identify risks, which affect the safety aspect of a product. In other words a technical risk.

Kahn (2004) suggests the use of the Hazard analysis for the Idea generation, Scoping, and Build Business case stages, followed by FMEA for the Development, Testing and Validation, and Launch stages. To analyze technical risks, Pons (2008) and Kahn (2004) suggest tools with a perspective of analyzing the potential risks that a product poses to the external environment or users. PMI (2013) does not distinguish between technical and non-technical risks and suggests the tools for both the realms. Project risks or non-technical risks in an NPD project context are defined using probability or likelihood on an ordinal scale, converting probability and impact between a scale of zero and one. This helps in defining “risk rating”, a measurable product of probability and impact, which quantifies the level of risk a project organization, users, or clients accept.

Pons (2008) observes ranking of a risk rating is easier if both the consequence and probability are quantitative. In the more general cases where probability and impact are on a nominal scale, it is difficult to defend or interpret the risk. Mapping probability and consequence using a probability and impact matrix does not establish the priority or urgency to the risk. It is desirable to have an approach that quantifies risks and defines a numeric value that represents a threshold value of risk acceptability as well as a factor to help prioritization of risk.

FMEA for Non-Technical Risks

"FMEA is a procedure during the product design and development phase used for identifying potential failure risks at the right point in time to correct any faults as well as introduce corrective actions (Standard Volvo Group, 2009)". The essential part of FMEA is collection of data and documents for conducting a workshop, referenced for identifying potential risks.

Standard Volvo Group (2009) suggest tools such as Screening to identify functional risks, the Dependability Analysis for new and complex functions, and the FTA for effect of combination of failures to make FMEA more effective. An FMEA workshop at the beginning of the product concept development forms the basis for Design FMEA (DFMEA). Prototype and production trials help to derive supplier FMEA, and process FMEA. Design team updates DFMEA, along with modification made to correct deficiencies, changes in customer requirements, or governmental regulations while Process FMEA (PFMEA) becomes an active document reflecting the process improvements. Table 4 shows a typical FMEA form. `

Main System			Name	Drawing part no.	Machine No.					Functional specification		Supplier					
Main function			Date	Updated	Status					Issued by		Project				Issue	
Part		Characteristics of failure				1st Rating				Action Status			2nd Rating				
No.	Function	Failure mode	Cause	Effect	Testing	O	S	D	RPN	Action	Responsible	Date	O	S	D	RPN	Sign

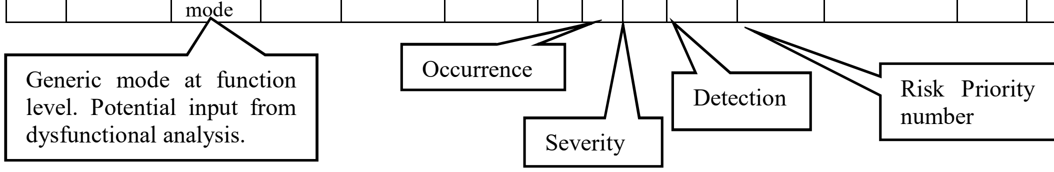


Table 4. Extract of an FMEA Template.
Note: Adapted from "STD 105-005- Failure Mode and Effect Analysis" by Standard Volvo Group, 2009, p. 6

Standards like IEC 60812 and BS 5760–5 provide basic guidelines for conducting FMEA workshop. (The definitions of the components of FMEA columns and the quantitative scale ratings are in Appendix – 1). Standard Volvo Group (2009) suggests that FMEA is a tool that emphasizes a systematic working procedure.

FMEA method is versatile and applicable with modifications to other processes such as, logistics, software, and project management. Risk FMEA (RFMEA) is a modified version of FMEA for computing and analyzing non-technical NPD risks. Carbone & Tippet (2004) note that the effects considered are mainly on project deliverables and the triple constraints of schedule, cost, and scope.

Table 5 explains the relationship between traditional FMEA and RFMEA, and suggests a quantitative scale for arriving at Likelihood or Probability and Impact for risk management.

FMEA Column	Failure Mode	Occurrence	Severity		Detection	RPN
RFMEA Column	Risk Event	Likelihood	Impact	Risk Score	Detection	RPN

Table 5. Comparison of Simplified FMEA and RFMEA Forms
Note. Adapted from "Project Risk Management Using the Project Risk FMEA" by Thomas Carbone & Donald Tippet (2004), Engineering management journal, Volume: 16; Issue: 4, p. 28

Tables 6, 7, and 8 give an example of likelihood, impact, and detection guidelines used to determine the quantitative scale for the parameters.

Value	Likelihood
9 or 10	Very Likely to occur
7 or 8	Will Probably occur
5 or 6	Equal chance of occurring or not
3 or 4	Probably will not occur
1 or 2	Very unlikely

Table 6. Likelihood Value Guidelines
Note. Adapted from "Project Risk Management Using the Project Risk FMEA" by Thomas Carbone & Donald Tippet (2004), Engineering management journal, Volume: 16; Issue: 4, p. 28

Value	Impact
9 or 10	Schedule – Major milestone impact and > 20% to critical path Cost – Total project cost increase > 20% Technical – The effect on the scope renders end item unusable
7 or 8	Schedule – Major milestone impact and > 10% - 20% to critical path Cost – Total project cost increase > 10% - 20% Technical – The effect on the scope changes the output of the project and may not be usable to client
5 or 6	Schedule – Major milestone impact and > 5% - 10% to critical path Cost – Total project cost increase > 5% - 10% Technical – The effect on the scope changes the output of the project and requires client approval
3 or 4	Schedule – Major milestone impact and < 5% ;Cost – Total project cost increase < 5% ; Technical – The effect on the scope is minor but requires approved scope changes.
1 or 2	Schedule , Cost - Impact is insignificant , Technical – Changes are not noticeable

Table 7. Impact Value Guidelines
Note. Adapted from "Project Risk Management Using the Project Risk FMEA" by Thomas Carbone & Donald Tippet (2004), Engineering management journal, Volume: 16; Issue: 4, p. 28

Value	Detection
9 or 10	There is no detection method available or known that will provide an alert with enough time to plan for a contingency
7 or 8	Detection method is unproven or unreliable ; or effectiveness of detection method is unknown to detect in time
5 or 6	Detection method has medium effectiveness
3 or 4	Detection method is moderately high effectiveness.
1 or 2	Detection method is highly effective and it is almost certain that the risk will be detected with adequate time

Table 8. The Detection Value Guidelines
Note. Adapted from "Project Risk Management Using the Project Risk FMEA" by Thomas Carbone & Donald Tippet (2004), Engineering management journal, Volume: 16; Issue: 4, p. 28

Communication between stages of NPD or Process Groups is essential for a product, and the FMEA tool imbibes this in its procedure. This makes RFMEA a holistic tool for documenting non-technical risks. RFMEA is effective due to the inclusion of three parameters: probability, impact, and detection to define risk. Based on the three parameters the limits of acceptance of a risk are set with "risk score", or the product of probability and impact, and Risk Priority Number (RPN), the product of probability, impact, and detection.

Carbone & Tippet (2004) further explain the benefits of the RFMEA in the reduction of time spent doing up-front risk contingency planning. With RFMEA, the team does not need to address every risk at an early stage. The detection values included in the RPN provides an additional measure to prepare the timing of the risk response. The team gets an operative procedure for determining the risk planning for activities by having more time to focus on the most critical risks and deferring the others. The merits of including a detection factor, when evaluating risks that are unknown or whose potential is speculative. Assigning the highest value of detection gives the identified risk a priority. By including a detection factor, RPN is calculated. It seems plausible to assume a situation where the risk does not require addressing immediately, and project team can fix the risk as it occurs.

In agreement with the using FMEA as a tool for non-technical risks, Gomes, et al. (2012) recommend adopting the PMI (2013) procedure for risk management process, and observes the interaction of Process Groups. However, Gomes, et al. (2012) explain the use of FMEA for generic non-technical risks, such like "lack of interaction between the five project management processes" which do not consider the advantages of implementing a project management procedure. The non-technical risks identified question the judgment, experience, and influence of a project manager and a functional manager, rather than identifying gaps in an organization's process. The research does not bring out the benefits of using FMEA as a risk management technique.

Wu, et al. (2010) articulate the risks and the challenges in NPD in the Concurrent Engineering environment. They recommend FMEA as the risk analysis method and the use of Graphical Evaluation and Review Technique (GERT) for further interpretation. GERT is a tool used to estimate project activity duration with a probabilistic approach. GERT is widely used as a network analysis tool, employed as an alternative to scheduling tools, such Program Evaluation and Review technique (commonly called as PERT) and Critical Path Method (called as CPM). GERT is a complex stochastic network tool, used for complex networks.

Wu, et al. (2010) suggest that for arbitrary RPN values above threshold value (set based on the risk appetite of organization or team) risk reduction activities are needed. Since most of the risk impact in a Concurrent Engineering NPD is on the schedule, or the project cost, a set of activities need to be done, in order to reduce the risk. These networks of activities are addressed with a GERT model. Resolving a GERT model will indicate the realistic values for second rating (refer Table 2). Wu, et al. (2010) work indicates that for complex CE projects, prescribing activities for risk reduction requires additional analysis. The literature review conducted leads to the following conclusions:

1. PMI (2013) procedure are appropriate for managing NPD projects with low complexities and fixed requirements.
2. NPD projects that follow the Stage-Gate process contain phases that can be equivalent to PMI (2013) procedures. Concurrent Engineering, on the other hand, may follow PMI method of project management in one cycle, or have the all the Process Groups repetitively for each phase of Concurrent NPD.
3. The PMI (2013) procedure for risk management is comprehensive. It helps in the documentation, planning and monitoring of risks with different tools applicable at different phases.
4. Establishing context should be the first step in risk management, which helps in distinguishing external, internal, known, and unknown risks.

5. The FMEA or RFMEA can be a tool for non- technical risk management in a single template.
6. The FMEA method includes the detection element, which enables prioritizing risks.
7. Using quantitative scale for probability, impact, and detection helps in gauging "risk appetite" by calculating a "risk score" and prioritizing risk using the RPN number.

Chapter 3 - Research Procedure

The field project will examine the literature discussing FMEA for NPD projects. Then the research will focus on document review of the NPD processes and risk management processes of three organizations. Finally, the application of non- technical risk management in NPD will be examined via three case studies. The research process applied will be analysis, synthesis, and verification.

Analysis

Guiding bodies have derived project management practices from best practices in terms of processes, tools, and structure. Risk management is not new to projects, and hence many sources are available on the broader subject of tools and processes. Risk management procedures set by various institutes like PMI, Projects in Controlled Environment, Version 2 (PRINCE II), and the International Project Management Association (IPMA), etc. are available for reference. PMI (2013) procedure is chosen as reference, as PMI is one of the most widely accepted accreditation bodies in the United States. The procedure is reputed to be “knowledge based”, emphasizing theoretical knowledge, tools, and processes, by giving the required emphasis on different Process Groups.

NPD standards are often product-, industry-, and organization-specific. However, guiding bodies, such as the Product Development Management Association (PDMA), the Association of International Product Marketing and Management, the International Society for Professional Innovation Management, and the Society for Concurrent Product Development are playing active roles in defining standards and presenting case studies identifying areas of improvement. The PDMA operates 22 chapters in the United States. It has published guidelines, case studies, and best practices for NPD projects. Hence, bibliographical references are included from PDMA publications.

Automotive and defense equipment manufacturers were pioneers in adopting the FMEA method. All the standards describe the FMEA tool with the same notations and definitions. Industries use modified versions of FMEA to suit other applications such as system FMEA, RFMEA, etc.

Synthesis

To lend further support to findings, this field project identified organizations known for innovation and setting industry standards through continuous improvement efforts.

The first organization known as “BG Company” in this project provides solutions to automotive, packaging, tools, and systems to a variety of industrial customers. The company follows strict adherence to internal quality procedures set according to ISO standards, such as ISO – TS 16949, which mandate defining processes for product development, manufacturing and quality management. The company represents automotive manufacturers at various international forums and sets global standards with its patents and innovative customer-centric solutions.

The second organization, Battelle Memorial Institute, is a non-profit applied science and technology development company serving industries such as energy & environment, consumer & industrial products, and health and analytics. The organization designs and develops products critical for the United States government as well as commercial consumers. The Institute manages reputed national laboratories, setting standards in product development and risk management processes.

The third organization known as “AG Transportation Solutions” in this project is a multinational company offering solutions for the railway sector. Customers recognize the organization for its sustainable solutions, and for setting a benchmark in the industry with its products, quality standards, and procedures.

Here, research compares the preceding organizations' procedures to the recommended NPD and risk management guidelines prescribed by guiding bodies to identify similarities and differences in the procedures and tools.

Verification

The case studies discussed will help in assessing the organizations' NPD efforts and the gap between defining non-technical risk management procedures and implementing them.

The first case study focuses on NPD and risk management processes of Goan Merin Engineering, analyzing potential risks defined. The case study presents realistic problems and gives an insight into the adequacy of the organization's non - technical risk management process.

The second case study for this project addresses the development of project risk metrics for Concurrent Product Development. The case helps in deriving a suitable risk index for CE NPD, and gives insights into whether the detection element of FMEA is indeed an advantage and other alternative approaches to arriving at risk metrics.

The third case study reviewed presents a specific framework for non-technical risks studying of reduced fat Lanna pork sausage as an NPD project. The case study presents a "house of risk" framework.

Following the above structure, the analysis and the results of this field project are in the next chapter.

Chapter 4 - Results

A review of NPD procedures and non-technical risk management procedures suggests that modified and many versions may exist within the organization for different product lines in their portfolio. The procedures reviewed in this section belongs to a specific product line of AG Transportation Solutions and a product line of BG Company. Battelle's NPD procedure from Kahn (2004) does not mention any specific product line. The case studies reviewed do not refer to any procedure and instead use different tools based on the discretion of the authors.

AG Transportation Solutions and the BG Company's NPD Processes

The NPD processes of the AG Transportation Solutions (2014a) and the BG Company (2015) are similar to the Stage-Gate process. A comparison of the Process Groups as per PMI (2013), the Stage-Gate process discussed by Kahn (2004), and the NPD processes of the two organizations is shown in Table 9.

PMI Process Groups	Stage-Gate Process	AG Transportation Solutions Manage R&D & Product Plan	BG Company Product Development Process
Initiating	Innovation	Innovation Process	Project Preparation
Planning	Scoping	Product & R & D Plan Update	Product/Process Conception
	Build Business Case	Program Approval / Technology Program Execution	Product /Process Engineering
Executing	Development	Product Development	Product /Process Realization
Monitoring and Control	Testing and Validation	Product Development	Product /Process Realization
Closing	Launch	Product Management Process	Release

Table 9. Comparison of Stage-Gate Processes of Organizations

Described NPD processes of the AG Transportation Solutions and the BG Company classify the type of the project and the complexity of the project as the first step of product development. Design teams subsequently determine the best approaches and tools required for projects. Both organizations have adopted project management processes for the Development stage, with the repetitive activities, such as risk management, lessons learned, and project review document management. The BG Company specifies a “maturity level indicator” to ensure structured, target- oriented project management. The maturity level of a platform, an invention, or product developed for a customer requirement based on the guidelines described in “Verein Deutscher Ingenieure”, popularly known as VDI guidelines. Table 2 below gives a summary of the approaches and the tools of these organizations.

Stage-Gate Process	**Stage-Gate Process approaches and tools**	**AG transport Solutions Manage r & d plan approaches and tools**	**BG Company NPD approaches and tools**
Innovation	Brainstorming , Open innovation methods , Strategic methods , Patent methods, Internal idea Capture	Idea approval by Product approval board. Funding strategy	Project type based on Innovation (platform), Acquisition, Customer and Service. Innovation – Customer requirements only.
Scoping	Voice of Customer, Ethnographic research, Focus groups, First draft of objectives. Quality Function Deployment, Pugh Matrix.	Ethnographic Approach, Customer need review, Product, Price, Place, Positioning	Concept development, Voice of customer, Design For Manufacturing and assembly.
Build Business Case	Product canvas , Financial analysis tools Net Present Value(NPV) , Return On Investment, Productivity index, Benefit cost ratio	Financial Validation, Go/No Go decision, Design for Quality , Contractual commitments	Quality Gate 0 – Stage 1 , NPV calculation, Profitability % , Internal Rate of Return etc.
Development	Design for factors speed, ease of manufacture, differentiation , customer needs, for environment, Rapid prototyping ,Lean methods	Project Management Process Groups	A, B, C, D samples, Detailed design, production and project planning. Project Management approach.
Testing and Validation	Subjective testing and validation techniques based on product, platform, and industry.	Validation and Quality techniques as per Customer need review	Testing for Serial production , process capability
Launch	Pre- launch and post- launch. NPD ramp up for full production	Product evolution versions, Key Performance Indicator (KPI)’s, Payback and ROI	Release for full production.

Table 10. Approaches and Tools Defined in Stage- Gate Process Compared to AG Transportation Solutions and BG Company NPD.

Salient points in NPD Stage-Gate process

The objectives defined by Kahn (2004) and the tools recommended Bhuiyan (2011) for the Innovation, the Scoping, the Build Business Case, and the Product Development Stages of an NPD project are similar to the prevalent procedures in both the organizations. The BG Company suggests the production of A, B, C, D samples during the development process. It is understood that A samples are rapid prototypes , B samples are functional prototypes , C are Pre-pilot lot of accepted size , and D samples are the pilot lot used for the Testing and Validation Stage.

1. The Innovation stage - AG Transportation Solutions defines the sources of idea generation, such as individuals, experts, platforms, and regional businesses. The process filters ideas based on funding strategy with a formal approval from the innovation board, the process integrates the rejected ideas into the technology cycle. BG Company emphasizes on identifying the ideas, selecting the concept, and assessing the product and process as part of the Innovation stage. The development team verifies the innovation process with a gate that validates the concept, cost, and required new processes to manufacture the product.
2. The Scoping stage - AG Transportation Solutions achieves the objectives of this stage by a process called "product r & d plan update", where alignment of an idea is done with regions, platforms and markets. A preliminary scope with project plan is prepared for approval. BG Company calls this stage a "project conception stage" that proceeds with the building of A-Samples or a mockup of the product for evaluation.
3. The Build Business Case stage -AG Transportation Solutions and the BG Company do not specify the template or tool used for evaluation of a business case. The former suggests a product approval board and the latter a reference to a technical committee and stakeholders. Anecdotal evidence by the organization's employees suggests the use of tools, such as the Net present value, the Internal Rate of Return, the Productivity Index, and the Profitability percentage to evaluate the project and accept them based on defined minimum values set by the organizations. Design of

the product commences after the approval of the business case and is concluded by the building and evaluation of B- Samples to complete the gate requirements.

4. The Development stage – Both organizations prescribe project management procedures for development of the product. This suggests that the development stage could have selected processes the five process groups as described in PMI (2013), excluding processes addressed in the earlier phases. BG Company concludes the stage with the production of C and D samples and their evaluation.
5. Testing and Validation - The gates and reviews cover the technical as well as project monitoring and control activities. The product is tested and validated under laboratory, field and other tests recommended as per the test plan. Both the organizations describe a similar process for this stage.
6. The Launch stage - As discussed in the literature review, the launch stage contains activities, which might stretch beyond the launch of all versions. AG Transportation Solutions (2014a) defines the Launch stage as "product management process", suggesting that the activities pertaining to launch of the product versions and monitoring of the project metrics are undertaken at this stage. The BG Company (2015) terms this stage as "ramp up" and "release" stage with the successful completion of the testing and validation of the product and the proof of capability under serial conditions.

Risk Management Processes

AG Transportation Solutions defines risk management process with the "Guidelines for Risk Management" document and is similar to the PMI (2013) procedure for risk management. BG Company's risk management procedure is identical to the procedure defined by Berg (2010). The organization separates technical risks from non-technical risks and provides separate guidelines for both aspects. A tabulation of non- technical risk management techniques of both the organizations vis-à-vis PMI (2013) is shown in Table 11.

PMI (2013) Risk Management processes	**AG transport Solutions – Guidelines for Risk Management**	**BG Company Non- Technical Risk Management**
Plan Risk Management		Establishing the Risk context
Identify Risks	Identification	Risk Identification
Perform Qualitative and Quantitative Risk Analysis	Assessment	Risk Analysis
Plan Risk Responses	Mitigation	Risk Communication and Consultation
		Risk Treatment
Control Risks	Monitoring	Risk Monitoring and Review

Table 11. Comparison of Risk Management Processes by PMI Guidelines with the AG Transportation Solutions and BG Company's Risk Management Processes.

The activities and tools of both the organizations is shown in Table 12.

PMI (2013) Risk management	**AG transport Solutions RM activities**	**AG transport Solutions RM tools**	**BG Company RM activities**	**BG Company RM tools**
Plan Risk Management	Project characteristics , risk classes, sub classes from the Guideline	Predefined list.	Establishing RM procedure	8D , Sorting
Identify Risks	Identification, Recording, Classification , Qualification	Brainstorming	Identification of potential risk	FMEA, Quality gate list, Brainstorming.
Perform Qualitative and Quantitative Risk Analysis	Assessment Risk analysis Risk allocation Assessment of risks for quality, cost , and delivery impact,	Problem Solving, Fish bone diagram, 5 Why techniques. Gate Review, FMEA, Design Review, Risk Urgency	Risk analysis and liability analysis.	FMEA, FTA, Cause and Effect, Modelling, Field monitoring.
Plan Risk Responses	Execution plan for mitigation	Mitigation techniques, such as Contingency, change request , negotiation, Project Single List of Issues	Risk reduction	Minimization, Prevention, Transfer, and Acceptance.
Control Risks	Tracking and measuring mitigation action plan Risk reporting	PDCA, ADEL, Risk Review	Risk monitoring ,communication,	Consult. Review, Escalation, Horizontal communication, and Monitoring

Table 12. Risk Management Activities and Tools presented Process wise for AG Transportation Solutions and BG Company.

<u>Comparison of Risk Management Processes</u>

AG transport Solutions describes its risk management procedures to conduct risk reviews and recording a risk register whereas BG Company describes similar risk management processes for automotive and non-automotive projects. Reviewing this information, the salient points are as follows:

1. The Plan Risk Management process - AG Transportation Solutions does not document a specific procedure for the Plan Risk Management process as the initial step for risk management. BG Company defines the Establishing the Risk Context process to describe the range and marginal conditions of the process.
2. The Identify Risks process - AG Transportation Solutions' procedure highlights the differentiation of risk that are within and outside the control of the organization.BG Company guides project managers to separate known and unknown risks with the context and use of specific tools. The organization emphasizes the use of tools, such as 8D for unknown risks, and the Sorting techniques for considering applicable known risks described in the organization's risk register.
3. The Perform Qualitative and Quantitative Risk Analysis process - AG Transportation Solutions recommends quantitative and qualitative tools to analyze the impact of the risk on quality, cost, and delivery. It recommends prioritization and ranking of risks and then allocating the risk to a relevant risk owner. BG Company recommends prescribed tools for risk analysis, such as FMEA, and re-identification of risks with Gate filters that are appropriate to the particular stage.
4. The Plan Risk Responses process - AG Transportation Solutions suggests mitigation as a risk response as opposed to the four recommended risk responses in

the PMI (2013) i.e. Avoid, Transfer, Mitigate, and Accept. AG Transportation Solutions specify three levels of risks, at the project, the project review committee, and the organization level. The procedure calls for reporting the top-level risks in the separate system. This ensure the risks get the right amount of attention, much before the review BG Company recommends actions to minimize, prevent, transfer, and accept risks.

5. The Control Risks process - AG Transportation Solutions accentuates on tracking and measuring in a mitigation action plan. The guideline suggests use of “ADEL”, a customized risk communication tool. The template requires the project team to specify the class, type, expected closure date, probability, impact, scoring, description, root cause, assumption, rational, quality impact, cost impact, delivery impact, and the mitigation plan. BG Company recommends the monitoring and review of risks with the milestones and the rule deadlines. The procedure recommends the review committee / management to fix risks based on urgency and priority. The process emphasizes that the “Effectiveness and status of the measures have to be ensured and should the situation arise necessary steps must be initiated” (BG Company, 2013, p. 9).

FMEA in Risk Management Guidelines

AG Transportation Solutions recommends a risk review format that follows the FMEA template, with probability, impact, and urgency specified. The guideline defines risk urgency as the product of probability and impact of a risk and the implied criticality of the risk. Figure 7 below shows the risk urgency matrix.

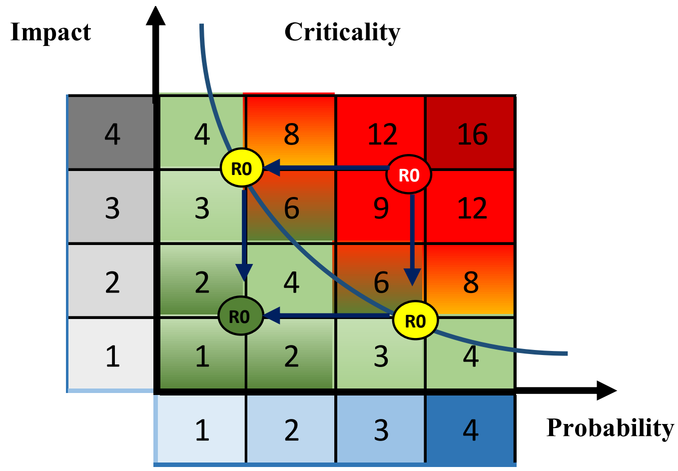


Figure 7. Risk Scoring Matrix.
Adapted from "Guidelines for Risk Management", by AG Transportation Solutions, 2014, p.7

The matrix gives a visual indication of criticality of the risk that prompts the project team to define required action based on risk urgency. Table 13 gives an overview of the recommended action for the urgency score.

Risk Urgency	Inference and Action
16	Intolerable – Task force mitigation plan
12	In desirable – Mitigation Plan
8	Moderate – Adequate monitoring /controlling
4	Acceptable – Ordinary management
8-12 (Probability of 2*impact 4) – (Probability 3 * Impact 4)	Preventive actions
5-4, 9-6	Evaluation and monitoring
8-12 (Probability of 4*impact 2) – (Probability 4 * Impact 2)	Corrective actions

Table 13. Risk Urgency Score and Inference
Adapted from "Guidelines for Risk Management", by AG Transportation Solutions, 2014, p.6

AG Transportation Solutions also recommends a risk-reporting tool that is similar to the FMEA template, with the exception of a detection factor. Table 14 shows the risk-reporting template.

Risk reference	Risk Title	Risk Description	Root Cause	Impact	Assumptions	Risk Owner	P	I	P x I	U	Risk Score	P	I	P x I	U

Table 14. Risk Review Format of AG Transportation Solutions
Adapted from "Guidelines for Risk Management", by AG Transportation Solutions, 2014, p. 6

BG Company directs the project team to plot risks on a risk matrix to determine the probability and impact values. The risk matrix helps to interpret number of risks that are in red zone with a high probability and impact. The risk matrix is shown in Figure 8.

Probability of Occurrence

very high	5	6	7	8	9
high	4	5	6	7	8
average	3	4	5	6	7
low	2	3	4	5	6
very low	1	2	3	4	5
	very low	low	average	severe	very severe

Severity of Consequence

Figure 8. Risk Matrix
Adapted from "Risk Management", by BG Company, 2013, p.10

BG Company recommends a risk management tool also similar to the FMEA template. Table 15 shows the template with probability, impact and trigger point for risk.

Risk Management Tool														
General Project Risk			Project									Date		
			Project Manager											
Risk	Risk label	Implication of Risk	Impact before risk	Probability of occurrence	Risk Factor	Risk Response	Responsible	Due date	Impact after risk response	Probability of Occurrence after Risk Response	Risk Factor	Status	Trigger Point	Expiration date

Table 15. Risk Management Tool of BG Company
Adapted from "Risk Management", by BG Company, 2013, p.10

The risk label indicates the effect of risk specifically on the project objectives, the quality, the time, and the cost. The evaluation of the probability and impact values before and after describing the risk response. The procedure suggests that appropriate corrective action can reduce the probability of the risk, while a preventive action can be a risk elimination strategy. The unique element of the tool is the description of the trigger point for risk response. The detection parameter for a risk evaluates if risk is detectable, whereas the trigger point' suggests looking at when and how the team can detect risks. However, the guideline does not provide any further explanation for trigger point. It directs the project team to identify a risk as well as its trigger point. The review indicates that the organizations prefer the FMEA approach for risk review.

Battelle Memorial Institute's NPD and Risk Management Processes

The product development process of Battelle Memorial Institute suggests a CE approach as shown in Figure 9.

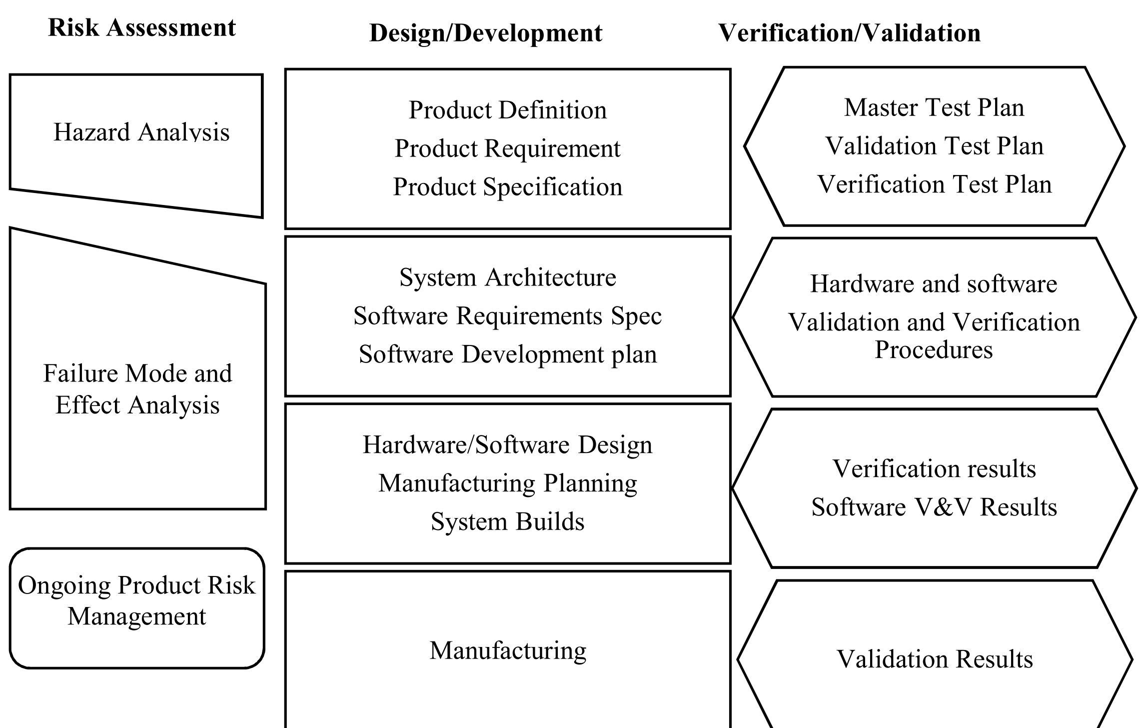
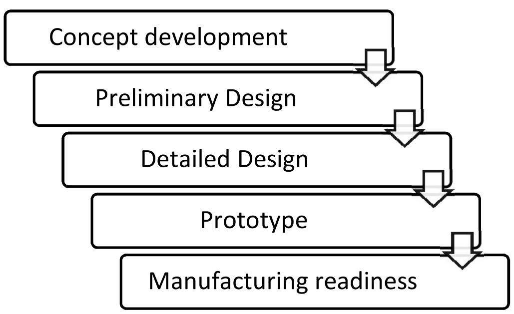


Figure 9. Battelle Product Development and Risk Assessment Procedure
Adapted from "PDMA Handbook of New Product Development ", by K.B.Kahn, 2004, PDMA. p. 431

Kahn (2004) documents the product development and risk management procedure for Battelle Memorial Institute to demonstrate the role of risk assessment. The three broad categories of the product development activities are the risk assessment, design /development, and the testing and validation. The CE approach ensures simultaneous occurrence of the design /development and the testing and validation activities preceded by risk assessment. Chambers (1996) suggests a phase wise development in Battelle Memorial Institute that consists of the Concept development, the Preliminary Design, the Detailed Design, the Prototype, and the Manufacturing readiness phases as shown in Figure 10



- Are initial objectives are still met?
- Technical risk characterized and minimized?
- Do we need to modify the plan?
- Do we need to kill the project?

Figure 10. Phases of Product Development in Battelle Memorial Institute.
Adapted from "PDMA Handbook of New Product Development ", by K.B.Kahn, 2004, PDMA. p. 431

Following the CE approach, the NPD project focuses on rapid time-to-market concept. Chambers (1996) emphasizes on examining the major milestones with relevant questions at the end of each phase. It is assumed that Battelle Memorial Institute has a gate system between the phases.

Chambers (1996) discusses the challenges that lie in implementing team practices, in a functional environment emphasizing a rapid time-to-market approach. Kahn (2004) lists Hazard Analysis and FMEA as the tools for risk assessment. However, the literature does not distinguish between technical risks and non-technical risks. A U. S. Department of Energy (1996) document drafted by Battelle Memorial Institute recommends risk management tools for projects including Hazard and Operability Study, Checklist Analysis, What-If Analysis, FTA, and FMEA.

Case Study: Goan Meiren Engineering NPD Risk Management

Susterova, et al.(2012) discuss risk assessment for Goan Meiren Engineering following a process of identifying risks, assessing risks, and mapping them with a risk matrix grid. The case study identifies thirteen potential risks then assigns them to a risk matrix, derives the probability and the impact values and lists strategies to eliminate the risks. The identified risks, the risk elimination strategies, and the risks mapped to the risk matrix grid is in Appendix-2

<u>Merits and Demerits in the Case</u>

Susterova, et.al (2012) identified risks that question the judgment of the organization and its ability to carry out the NPD projects. The case study does specify a context, or the tools applied to arrive at the probability, impact, and the elimination strategies. The elimination strategies for potential risks are generic and contain recommended actions any organization should apply, in order to have a successful NPD project. It is pertinent to address them, by setting a context and categorizing these risks.

<u>Alternative Approach for Risk Review in the Case</u>

The Berg (2010) procedure with the FMEA method applied for the identified risks will be helpful to demonstrate the risk management process and provide a framework to document, analyze, and address the risks.

1. Establishing context - The field project infers that the risks identified are the current deficiencies in the organization and risks arising in the process of an NPD.
2. Risk identification - Susterova, et al. (2012) have identified risks that this field project analyzes for the purpose of the field project.

3. Risk assessment - The field project uses the format proposed by BG Company (2013) with the probability, impact, and detection values based on the Carbone & Tippet (2004) to analyze the risks.

Risk Management Tool																
Project			**Project Manager**									**Version**				
			Before risk response					**Date**				**After risk response**				
Risk	Risk label	Implication of Risk	Impact	Probability	Risk rating	Detection	Risk Factor	Risk Response	Strategy	Responsible	Due date	Impact	Probability	Risk rating	Risk Factor	Status
Technical capability of the product does not meet the expectations.	P	The product does not succeed in the market	9	5	45	9	405	E	Define and signoff product requirements	EG		7	4	28	252	
Complicated design of product for manufacturing	P	Exceeded the limits and budget forecast.	9	7	63	5	315	M	Use design for manufacturability approach	PM		7	6	42	210	
		Increases product cost	9	5	45	5	225	M	Track product cost	PM		7	4	28	140	
		The product development process is longer.	7	5	35	7	245	M	Track product cost schedule	EG		5	4	20	140	
Critical people leave the project	Q	Delay in project and launch time	7	5	35	7	245	E	Sign off resource agreements and alternative members	PM		5	4	20	140	
Introduction of new tools, technology, or processes during the project.	T	The subcontractors and supplies do not fulfill the schedule.	9	5	45	7	315	M	Analysis of internal and external environment	PM		7	4	28	196	
The competence of the product development team is not to expected level.	Q	The NPDt process is longer.	7	5	35	5	175	A	Measure competence level of assigned resources before start of project	PM		5	4	20	100	
The project management team don´t follow the best practices	P	Does not meet project objectives.	9	5	45	3	135	E	Set ground rules and procedures at the beginning of product	PM		7	4	28	84	
Design errors	Q	Cost increase due to redesign.	7	4	28	3	84	M	Involvement of an experts at concept and rapid prototype stage	EG		5	3	15	45	

Figure 11. Example of Risk Assessment Using an FMEA Template.

4. Risk control and coverage - Susterova, et al. (2012) recommend the risk control action is "eliminate", while the present analysis provides other strategies or actions for risk response.
5. Risk monitoring and review

   PMI (2013) recommends the project team to decide on an appropriate risk management process at the beginning of a project. The Plan Risk Management process would define the frequency and metrics used in the project, which would help at deciding the appropriate monitoring method for the risks. The case study lacks a review process.

Case Study: Risk Management Framework

Chompoonoot et.al (2014) discuss the risk management framework with the study of reduced fat Lanna pork sausage as an NPD project. The proposed risk management process consists of the risk identification, the risk assessment, and the risk mitigation. The case study uses tools such as the SWOT and the PEST to identify the risks, a "house of risk" framework is used to analyze the risks, sort high impact risks, and define preventive actions to mitigate these risks.

Merits and Demerits in the Case

As the first step, the case study defines risk agents from Porter's five forces: the threat of substitute products and services, the threat of established rivals, the threat of new products or services, the bargaining power of suppliers and customers. The case study derives risk events for each of these forces using SWOT analysis as a tool to address weakness and threats that result from the analysis. Since the case study deals with the overall NPD effort from a supply chain perspective, the approach and the use of risk identification tools is justified.

The second step of risk evaluation is done with the house of risk model is built on the concept of aggregate risk potential (AGP) derived from risk agent probability, the risk event impact score, and a correlative score derived for risk agent and risk event score. The correlative score is derived for a combination of risk agents and risk events. An example for a risk agent is “failure to identify customer needs” and the risk event is “failed product launches”. While the concept looks novel, this is similar to cause and effect relationship analysis. The FMEA framework provides more benefits in this scenario, forcing the team members to focus on the relevant risks, their sources, the causes, and its effects.

The framework proposes risk mitigation as the third step and recommends prioritizing the risks based on the aggregate risk score, designing preventive actions, evaluating preventive action, and then choosing the most effective preventive action. The preventive actions are chosen from a preemptive list, limiting the scope of identified risks and their preventive actions from a known source of risks.

Case Study: Risk Metrics for CE NPD

Esterman & Kosuke (2005) discuss risk management of an NPD project in a CE environment to aid in the managers’ decision-making process. The case study recommends aligning the Voice of Customer into the risk assessment process for analyzing risks at four levels:

1. Product Development Program
2. Supplier Subsystems Level
3. Engineering Metric Level
4. Component Level

Merits and Demerits in the Case

Esterman & Kosuke (2005) describe risk at the overall product level involving design teams at the product level, the design team of the suppliers of major subsystems, the supplier of components level. The applicability of the risk assessment procedure called the Advanced FMEA technique that analyzes complex process failures similar to the System FMEA technique referred to in The Standard Volvo Group (2009). The other alternative risk management strategies proposed are Construction Management Practice and Design Structure Matrix. The construction management practice proposes CE NPD to adopt a design-build set up, where the ownership of the design as well as manufacturing of sub systems are the responsibility of a sub-contractor to ease the communication between the original equipment manufacturer and supplier. The design structure matrix method uses networking concept, identifying sequential and parallel tasks to determine dependencies between activities.

Esterman & Kosuke (2005) contend that the above-mentioned procedures are not effective to meet the required level of communication and knowledge sharing that is required in a CE environment. Esterman & Kosuke (2005) demonstrate in the example of an NPD project in CE environment of Hewlett- Packard the techniques might not be effective in the risk assessment of dependent downstream activities and the associated risks in the overall product and the major subsystems. The case study signifies that for complex projects with multiple dependencies and a CE environment, a simple FMEA based risk management are not be effective.

Conclusions

The research in this field project indicates:

1. Organizations that have achieved the status of being “world class companies” follow a structured process for NPD.

2. The companies have adopted project management approach to manage repetitive activities, such as risk management, lessons learned, and project reviews document management.
3. The project management procedures described in PMI (2013) is widely recognized and organizations have adopted several processes coined by this guideline.
4. The NPD process of organizations following the Stage-Gate process recommend similar tools for the NPD stages. The overview of the NPD tools used by the organizations are also similar.
5. The risk management process is structured in these companies where the procedure prescribed by Berg (2010) and PMI (2013) are widely used.
6. The FMEA template and procedure is adapted as a method, tool, or reporting format for risks, making it effective for risk management for products with fixed requirements.
7. Though teams use the FMEA format as a tool or a risk reporting method, the detection parameter is not in used. The closest resemblance is the trigger point, which indicates the detection factor and not detectability of the risk.
8. With the example of the Goan Meiren Engineering, the field project demonstrates the ease of the FMEA method.
9. The NPD projects are subjected to complex dependencies between activities, which limits the usage the FMEA as a risk management tool
10. For CE environment a simple FMEA might not be sufficient for risk management. Alternatives such as system FMEA or combining FMEA with tools such as DSM can be used to address risks pertaining an to NPD project duration. Using tools such as

GERT would help to derive the 2nd rating for risks based on the risk response is recommended by experts.

11. The document review as well as overview of case studies brought highlighted different aspects of the risk management process, such as the levels of risk management and escalation, importance of the Cause and Effect relationship, and treatment of known and unknown risks.

The results of this field project establishes the advantages of RFMEA as a holistic tool for NPD project risk management. Since FMEA as a tool and procedure is widely accepted in the automotive, industrial and aerospace, and design and manufacturing industries, technical and project personnel are familiar with the requirements of this procedure and will accept its advantages for use as a risk management tool for NPD.

Chapter 5 - Suggestions for Additional Work and Recommendations

The research in the field project presented an overview of NPD processes, project management procedures and the risk management procedure for non- technical risks. A review of procedures recommended by guiding bodies, compared to procedures in organizations and case studies suggests areas for further work.

Limitation in Literature Review

There is limited literature focusing on a NPD project management, as well as risk management. Organizations are currently applying the FMEA method in different fields and hence there is experience in conducting and utilizing the advantages provided in the framework. The literature supporting the use of FMEA tool does not document examples, which are relatable in the context of project risk management. The FMEA method has a structure that can greatly benefit the NPD risk management process. However, the current literature does not convey it effectively.

Further Work in NPD and Risk Management

The literature review showed that, while there are articles written by experts citing the advantages of following the PMI (2013) approach for NPD, there are very few papers with collaborative research along with industries looking at the complexity of products and advantages and disadvantages of a hybrid process combining the NPD process and PMI (2013) procedures. Organizations can counter the risks due to lack of processes and the disadvantages of having floating gates in Stage-Gate process with the PMI approach. To explore the topics in detail, real time case studies are required in analyzing the effectiveness of NPD project management and the gaps identified in applying the method. Since many global organizations have implemented a hybrid method and are constantly upgrading their processes it is evident that they are following the FMEA tool for risk management however, they do not substantiate the advantages of having a quantitative scale or the reasons for omitting the "detection" factor. A further study of these two aspects will be beneficial for small and medium size companies, to adopt the procedure to streamline the NPD process.

Recommendations

The emphasis of risk management process and tools is emerging in the field of NPD. Organizations need to categorize their development process and project management process to look at NPD as a formal project. A process that includes NPD activities, with a project management procedure will ensure that organizations give equal importance to all the knowledge areas creates valuable documentation and aids in traceability of the product. Focusing on risk management in NPD projects can be easier with known tools like the FMEA.

A project management framework should start with a relevant NPD process and applicable tools. Utilizing the frameworks suggested by Kahn (2004) for a Stage-Gate process and by PMI (2013), organizations can choose the best approach or process for NPD. With a project management framework for NPD, organizations will focus on the other knowledge areas including risk management to define a robust NPD process. The Berg (2010) framework of risk management is easy to implement, while PMI (2013) defines the summary of possible risk management tools. The FMEA tool recommended in this field project is definitely one of the simplest, yet most effective tools to conduct risk management. While the framework is versatile, organization can customize the values of probability, impact and detection, to suit the risk appetite of the organization. Carbone (2004) have suggested the guide values for the three parameters that can be easily adapted by organizations as per their scale of operation.

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Appendix -1 Definitions of FMEA Columns

Failure mode - The ways in which the functions may be disturbed or fail totally.

Cause - The possible reasons for the failure.

Effects of failure - Consequence of each failure.

Testing - The test form(s) where the corresponding failure modes are detected.

Probability of occurrence -Estimate of at what frequency the cause of failure can occur.

Severity - The effect of failure for the system/customer or environment.

Probability of detection - The likelihood of discovering a failure.

Risk priority number (RPN) - The measure of the risks, obtained by multiplying the probability of occurrence, severity and probability of detection ratings.

Risk rating- the factor obtained by multiplying the probability of occurrence, severity.

Recommended actions- Action in order to eliminate/reduce failure risks and effects.

Decided actions - Actions taken in the project with a time schedule and a responsible person.

Criteria for estimation of probability of occurrence (Po) (Operating time, the equivalent mileage/time: e.g. X km/5 years)	**Frequency**	**Rating**
Remote probability of occurrence, i.e. fool-proof design	<1/100000	1
Very low probability of occurrence. No previous complaints	<1/10000	2-3
Low probability of occurrence	<1/1000	4-5
Moderate probability of occurrence	<1/100	6-7
High probability of occurrence	<1/10	8-9
Very high probability of occurrence	<1/1	10

Table 16. Probability of Occurrence Rating Scale (O)
Note: Adapted from “STD 105-005- Failure Mode and Effect Analysis” by Standard Volvo Group, 2009 , p. 9

Rating	Effect on function	Type of impact	Accidents / injuries	Legal non complian ce	Repair	Image effect	Enviro n-ment effect	Cost impact for the customer
1	Small, may be noticed only by high demanding customers	Not noticeable	No	No	Can wait	Non	No	None
2-3	Noticed by average customers	Effective but still OK	No	No	At next scheduled maintenance	Minor	Minor	Low
4-6	Reduced functional performance Potential mission delay for the end customer	Effective and very noticeable	No	No	Repair ASAP needed	Obvious	Moder ate	Moderat e
7-9	Interrupted product function (vehicle, system or subsystem breakdown). Unplanned stop with or without warning	Effective and mission stop Limp home	No	Yes	Need towing Immediate repair before continuing mission	High	Consid er-able	High
10	Risk of accident and injuries with or without warning	Accident may occur	Yes	No		Catastrophic	Severe	Very high

Table 17. Criteria for Estimation of Severity (S)
Note: Adapted from "STD 105-005- Failure Mode and Effect Analysis" by Standard Volvo Group, 2009, p. 9

Criteria for estimation of probability of detection (Related to development phase (review also the verification/validation plan) including any supplementary computer simulations)	Rating
Failure which will always be detected	1
Failure detection is almost certain for potential causes and failure mode	2
Very high probability to detect the failure mode	3
High probability to detect the failure mode	4
Moderately high probability to detect the failure mode	5
Moderate probability to detect the failure mode	6
Low probability to detect the failure mode	7
Very low probability of detection	8
Remote chance to detect or not included directly in the test program	9
Failure will not be found - cannot be tested	10

Table 18. Criteria for Estimation of Probability of Detection (D)
Note: Adapted from "STD 105-005- Failure Mode and Effect Analysis" by Standard Volvo Group, 2009, p. 9

Appendix-2 Goan Merin Engineering Case Study

Potential risks		Elimination of potential risk	Risk in matrix grid
1	Technical capability of the product does not meet the expectations. The product does not have assumption that will succeed in the market	The risks of the project are clearly defined in advance, before beginning through market research	Medium risk
2	Complicated design of product for manufacturing exceeded the limits and budget forecast.	Project managers must achieve balance among these resource constraints: time, funds, and required quality	High risk
3	The durability of the product development process is longer. The product could not enter to the market in a right time.	Anticipating changes in technology and estimating the product life cycle	Low risk
4	Manufacturing problems increase complexity of the product and the cost	Set a limit on the amount of risk, that will be accepted	Low risk
5	Critical people left the project	Improved communications, Increased motivation, Change the project manager in project management	High risk
6	Critical resources needed for the project was not available at the right times.	Developing plans and practices that notify the most serious risks. Introducing standardized risk management processes, enabling quick respond to changes.	Medium risk
7	The project missed critical milestones.	Compliance methods at each stage in process of product development. Improve the process to be more accurate.	Medium risk
8	Cost of the product exceeded the market expectations, exceeded budget.	Anticipating and responding to expected competitor reaction. Inclusion of managers with experience in audits and inspections.	Low risk
9	Introduction of new tools, technology, or processes during the project.	Testing of new tools, technology or processes for a specified period. Analysis of internal and external environment.	Medium risk
10	The competence of the product development team is not to expected level.	Involvement of an experienced project manager to team.	Medium risk
11	The project management team don´t follow the best practices and rules in project management	Review the decision to accept best alternative.	Low risk
12	The subcontractors and supplies do not fulfill the schedule.	Effective communication, regular exchange of information between subcontractors and supply.	Low risk
13	The mistakes in design cause problems in manufacturing. There are misunderstandings between designers and manufacture. Redesign is expensive and takes additional time.	Optimizing the cost of risk management and reducing losses due to incorrect decisions.	High risk

Table 19. Potential Risks and Elimination Strategies from Goan Meiren Engineering
Adapted from "Risk Management in Product Development Process" by Monika Susterova, Jaak Lavin and Jueri Riives, 2012, Annals of DAAAM & Proceedings, Vol. 23 Issue 1, p.227

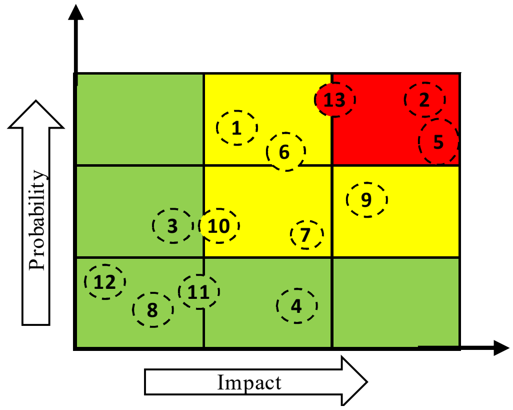

Figure 12. Risks Identified in Goan Meiren Engineering Mapped in a Matrix Grid.
Adapted from "Risk Management in Product Development Process" by Monika Susterova, Jaak Lavin and Jueri Riives, 2012, Annals of DAAAM & Proceedings, Vol. 23 Issue 1, p.228

Risk #	Probability of risk	Impact of risk
1	12	5
2	14,5	14,5
3	5,5	4
4	2	9
5	10,5	14,8
6	9,8	7
7	5	9
8	1	3,5
9	7	12,5
10	6	6
11	3,5	4,8
12	3,5	2
13	12	10

Table 20. Probability and Impact Values for Identified Risks in Goan Meiren Engineering.
Adapted from "Risk Management in Product Development Process" by Monika Susterova, Jaak Lavin and Jueri Riives, 2012, Annals of DAAAM & Proceedings, Vol. 23 Issue 1, p.228