



# **Optimize the risk of new healthcare product development using Delphi Technique**

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## **Abstract**

*Risk management receives several attentions due to the fact, it is observed as a process to improve the price, agenda, and technological ordinary act of new product improvement packages, but there is a lack of research that observe the powerful combination of unique hazard management practices proposed by using unique requirements with new product introduction programmes and their organization with special scope of risk management accomplishment.*

*Based on experience gained from actual production of new product (Image Guided Therapy Systems). This research describes how the risk in new project development such as production risk, management risk, supplier quality risk, testing risk has been mitigated which resulted in saving the cost, time, resources, and various other factors of the project and effectively contributed to improving the quality of the product by using Delphi Technique.*

**Key Words:** Risk Management, New Product Development, Delphi Technique, Healthcare, Research Method, Research Evaluation, Risk Manual

## **I. INTRODUCTION**

Risk is one of the most critical parts of the task. Its legitimate assessment and treatment increment the possibilities of a task's prosperity. Risk is not only a constant in new product development, but it has also been proven that risk management and mitigation have a superb and significant effect on a company's new product overall performance in maximum industries, making it an important and frequently studied issue in the literature.

### **1.1 Significance of risk management in New Product Development programmes.**

Risk is defined in various forms subjected to the implementation. In decision theory, the various types of risk are related to known probabilities where we have the idea of probabilities of risk which are going to occur and in fiscal theory, when judgment maker assign probabilities to possible outcome risk arise.

A general description of threat provided in the Project Management Body of Knowledge (PMBOK) believes hazard as "An unsure event or situation that, if it takes place, has an advantageous impact or terrible (threat) to the task



goals.” However, for maximum practioner’s venture threat control appears to be approximately identify and supervising risks. Intended for NPD, we comply with the ISO 31000 definition (ISO, 2009) which describes threats because the result of insecurity on accomplishing the New Product Development goals.

New Product Development is fundamentally related to captivating and coping with risks, as maximum activities may be taken as a established reduction of uncertainty, research of client desires and marketplace tendencies decrease the uncertainties ,adjoining necessities, generation progress ,testing and assessment generate reality concerning the skills and price of recent technology , the enhancement and calibration of NPD methods inside the enterprise will increase the reliability of executing the improvement system .Reducingrisks in new product improvement be able to enhancecustomer cost and could be used as a lens system to evaluate and enhance product improvement tactics.

There is also indication that new product improvement suffers from risk, and is liable to critical cost and program overruns, as well as troubles in accomplishing the centered methodological overall routine of the produce within the associated field of software improvement, common price overruns of initiatives are mentioned on the order of 30-40%. Similarly in complicated infrastructure projects, common value invades are estimated within the variety of 27-50%, with up to 77% of tasks experiencing price overruns. Of relevance are findings of the United States authority’s responsibility agency that evaluates the achievement of production packages, amongst the NPD applications, of the US Department of Defense. Even as all manufacturing packages (including those that target production or lifestyles-cycle management) experience an average cost overflow of 26%, those applications that target new producedisplay a standard cost overflow of 42% and schedule setback of 22 months.

In this research paper we are going to analyze the effect of using Delphi technique in new product development to reduce the impact of risks, which will help to deliver the project on fast track and will help to reduce the cost of the project, resources of the project and it will increase the quality of the product which is the main priority.

## **II. LITERATURE REVIEW**

### **Laurent Condamine, Jean-Paul Louisot, Patrick Naim**

This book offers a practical answer for the non-mathematician to all the questions any businessman always wanted to ask about risk quantification, and never dare to ask. Enterprise-wide risk management (ERM) is a key issue for board of directors worldwide. Its proper implementation ensures transparent governance with all stakeholders’ interests integrated into the strategic equation. Furthermore, Risk quantification is the cornerstone of effective risk management at the strategic and tactical level, covering finance as well as ethics considerations. Both downside and upside risks (threats & opportunities) must be assessed to select the most efficient risk control measures and to set up efficient risk financing mechanisms.



**Introduction to monte carlo simulation SamikRaychaudhur**

This is an introductory tutorial on Monte Carlo simulation, a type of simulation that relies on repeated random sampling and statistical analysis to compute the results. In this paper, we will briefly describe the nature and relevance of Monte Carlo simulation, the way to perform these simulations and analyze results, and the underlying mathematical techniques required for performing these simulations. We will present a few examples from various areas where Monte Carlo simulation is used, and also touch on the current state of software in this area

**Risk quantification using qualitative tools (2010) Bryan Maybee**

Measuring the risk and including within the evaluation of the mining the projects has the potential to facilitate better decision making process. By quantifying the risk associated with a particular mining scenario, these uncertain components can influence the projects value. Unfortunately, many of the risk factors that influence a mining project are qualitative in nature, and do not easily lend themselves to numerical evaluation. This paper looks at some of the misapplications of quantitative risk analysis tools in the highly uncertain mining industry. It begins with a review of the progression of valuation techniques that have been used in the mining industry, followed by a look at some of the issues with performing a risk-based evaluation. Using a case study, qualitative risk analysis tools are used to show how these quantitative issues can be alleviated, closing with a brief discussion about possible future research directions.

**Combining Scoring Method and Fuzzy expert system approach to supplier assessment C.K .Kwong**

Fuzzy expert system is an alternative approach from which the heuristics and knowledge of supplier assessment can be captured and the impreciseness and uncertainties due to the human subjectivity, that are common in the process of the supplier assessment, can be handled. In this paper, a combined scoring method with fuzzy expert systems approach is introduced to perform the supplier assessment. With the use of the fuzzy concept, the error due to human judgement in the scoring method could be minimized.

**Sarah Drum, Catriona Bradley, Frank Moriarty (2022)**

In this research paper selections on the layout selections are made at the planning stage to ensure the reliability and validity of Delphi. Advantages of using Delphi consists of it may be completed by respondents in distinct geographical locations in their personal time which permits for mirrored image and it is fee effective.

**Julia Spranger, Angelica Homberg, Marco Sonnberger (2022)**

The content analysis shows that it varies widely, both in terms of criteria and level of detail. Most reporting guidelines explicitly cope with reporting on consensus definition, expert panel, response, feedback design, and wide variety of rounds.



### **III. OBJECTIVE**

- a) Identify and evaluate the risk in ongoing project
- b) Execute process technology development activities.
- c) Reduce the project timeline by implementing Delphi technique
- d) Collect experts-based opinions and use them to resolve observations.

### **IV. DELPHI TECHNIQUE**

Delphi Techniques are group discussion events in which complicated troubles approximately which unsure and imperfect information occurs are evaluated via specialists in an iterative aspect and established method. It may be performed in exclusive subfields of health technology (e.g., medicinal patient care, community fitness and health merchandising, health assistance exploration, clinical learning), specifically to pick out unity. Data-primarily centered learning, realistic experience, and on occasion normal know-how primarily based on existence-global studies are brought together in a structured procedure.

1. Experts with understanding related to the subject are interviewed, normally at the same time as preserving their anonymity.
2. The survey tool is often an identical questionnaire, frequently with public inquiries to seize opinions and reasoning perspectives.
3. From the second one Delphi round onwards, the Experts obtain feedback at the effects of the preceding round similarly to the questionnaire and can rethink or modify their judgements.

### **V. METODOLOGY OF IMPLEMENTING DELPHI TECHNIQUE**

#### **5.1 Design of Delphi Technique**

The Delphi technique was used to implement the new product development of **Image Guided Therapy Systems**. Its miles a way of causing and filtering group judgements and afford a tested systematic approach for fixing compound issues through expert agreement. The procedure includes filing questionnaires to a board of identified experts, in the direction to permit geologically distant and well-versed persons to take part inside the organization consultancy. While the approach can replicate every professional's individual knowledge, it also maximizes their collected understanding by having the discussion with the professionals in the respective departments. The draft plan was dispatched, via email to the experts which were included in the expertise panel, to allow for the modification and formation of hypothetical content with the help of Delphi approach. Inside each round comments from the professionals had been incorporated into the model through study, contrast, and conversation. And an agreement becomes reached after the number of rounds required as per the necessity of the risk.

This project was carried out in the Test Method Validation (TMV) phase of New Product Development.



**Fig 4:** Image Guide Therapy Systems

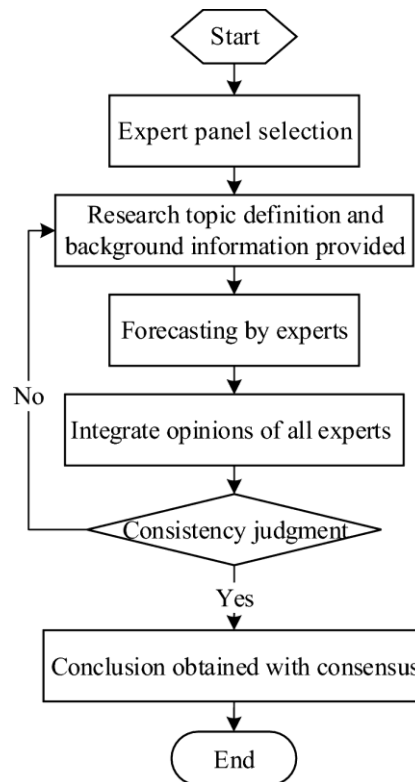
### **5.2 Basics of Test Method Validation (TMV)**

In Test Method Validation Phase five systems of Image Guided Therapy Systems are build and the number of risks coming in production of systems are tracked and tried to reduce as early as possible. This phase takes around six months to complete the milestone.

TMV is carried out to validate the given test method used for testing particular parameter. Any Test method or measuring should give Gauge Repeatability & Reproducibility (GRR%) < 10% to pass the agreed testing method. Motive of TMV is to make sure no defective part due to measurement system error should go to the customer.

Any measurement system consists of three components:

1. Measuring Equipment (Tool) such as Force Gauge, Vernier Calliper, Multimeter contribute to repeatability variation.
2. Appraiser ( person who measures ) contribute to reproducibility variation.
3. Product parts on which measurement is done contribute to design variation which can be within part variation or Actual Process Variation.



**Fig.1:** Process flow of Delphi Technique

### 5.3 Selection of Delphi experts

The experts panel was selected based on following standards: (a)work experience of more than ten years, (b) bachelor’s degree or above, (c)intermediate professional title, (d)expertise in the fields of healthcare production which include Supply chain Management, Production Management, Mechatronics, Electrical, Project Management, Supplier Quality Engineering, Testing, Verification and Validation (e) could complete number of rounds of discussion based on the requirement.

The designation of the experts were :

- 1.Mecanical Designer
- 2.Electrical Designer
3. Product Industrialization Engineer
- 4.Integrated Project Manager
- 5.System Architect
- 6.Procurement Engineer
7. Test Engineer
8. Product Industrialization Project Manager

### 5.4 Developing the questionnaire:

The questionnaire was developed by using tool called Google forms out of total 300 observations in the entire project focus was given on 100 observations which were categorized as (major, moderate, minor, open, and closed). Questions related to each observation were asked to the entire expertise panel. And the solutions of the experts were recorded in the tool to analyze the impact and according to solutions received from the expertise the observation was fixed by taking the necessary action.

The example of questionnaire and the responses is given below:

Q1. Force measurement GRR is more than 10% \*

Change measurement Technique

Continuous Data

Attribute Data

Operators Training

Within system Variation

Q2. French Kit PCBA stud is missing \*

Design Failure

Supplier Quality Issue

System Requirement

Other

Fig 2: Questionnaire

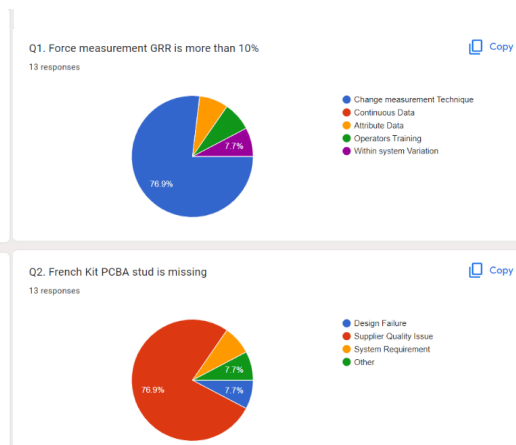


Fig 3 :Responses of experts

### 5.5 Analysis of the risk by experts:

After receiving the questionnaire the analysis of the observations was done by the experts related to relevant fields. Around 100 observations were taken into consideration while developing the prototypes of Image Guided Therapy Systems.

#### 1. Force Measurement GRR is more than 10%.

Force measurement was one of the major risk in the project as GRR (Gauge Repeatability and Reproductivity) value calculated was more than 10% it would have cause the failure of project. So to overcome this issue delphy technique was applied and it was analyzed there are different factors such as horizontal force, vertical force, Angular Force, Force gauge, Operator action, system build which are responsible for failure in force measurement. So the changes were made in operation of Force gage the instrument used for calculating the Force measurement. Work instruction was prepared for operators to major force. The result was GRR dropped down to 8.7% and force measurement was passed.



Sr. No.	Stand/MVS	Observation	Function	Category	Owner	Action Plan or Rationale	Status
1	MVS	MVS column hole mismatch for IR sensor bracket	SQE	Part Quality	Sharan	Conveyed to supplier	Closed
2	Stand	Rotation lock shaft not enteting freely through brake liner	Mech.	Design	Abhijeet	Brake Shaft & Yoke structure hole concentricity added in drawing.	Closed
3	Stand	Surgeon control cable is extra in c-arc cable	R&D	Design	Shashank	DMR modified & Confirmed	Closed
4	Stand	FRONT WHEEL CABLE PUSHER BRKT ASSY-459801796971- depth of hole change for cable pusher	R&D	Design	Abhijeet	Pusher height decreased in drawing , Cable pusher Bracket Modified	Closed
5	Stand	FD Cover not flushing with FD Baseplate	R&D	Design	Sharan	Flushing Criteria given in Gap acceptance , Need to check in Proto9	Closed

**6. RESULTS AND DISCUSSION**

Out of 300 observations around 100 major observation were mainly targeted these hundred observations were of Mechanical, Electrical, Supplier Quality Engineering Mechanical, Supplier Quality Engineering Electrical and Product Industrialization department.

Area of Observation	Status	No. of Risk	Experts
Mechanical	Closed	30	Abhijeet
	Open	0	
	In process	2	
Electrical	Closed	26	Shashank
	Open	0	





	In process	5	
SQE-Mechanical	Closed	11	Sharandeep
	Open	2	
	In process	2	
SQE-Electrical	Closed	10	Seshagri
	Open	2	
	In process	0	
PI	Closed	10	Ram
	Open	0	
	In process	0	

**Table 1:** After applying Delphi Technique

Delphi Technique was applied on the production of Image Guided Therapy Systems, and it was observed that around 80% of the observations were closed on Fastrack mode which effectively resulted in saving the time, cost and resources compared to the conventional production process.

### 7. CONCLUSIONS

This paper has examined the need of Risk Management across the New Product Development system using the Delphi Methodology. The data from this study suggests that ThreatManaging has turn out to be a vital role of companies which try to extend their place in the market by establishing progressive manufactured goods that enhance the health of customer.

By performing the Delphi technique in the production of Image Guided Therapy Systems it has effectively resulted in reducing the timeline of project by 30%.

It has also resulted in saving the cost and resources

of the project and has significantly improved the quality of the Image Guided Therapy Systems.

### 8. ACKNOWLEDGEMENT

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