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General Risks of CRM&N Product Development Process: A Case Study of a Medical Device Manufacturing Company

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Abstract: Nowadays, every new product development process is bound to have certain risks. This study will analyze the identification and control risks in the Cardiac Rhythm Management & Neuromodulation (CRM&N) product development process of a medical device manufacturing company in the United States and summarize and analyze the common risks during New Product Development Process (PDP). CRM&N system of medical industry product and service institutions, namely the CRM&N system used by medical devices, medical equipment, medical consumables, biotechnology and other medical products/services enterprises. The medical industry is facing many problems in transportation and terminal sales. This study adopts the case analysis method, through the analysis of a new product development case of a company, the research results of this study are obtained: (1) Risk should be controlled at every step of a new product from the preparation before production to the end of production. Therefore, the company needs to establish a complete risk management system to reduce the existence of some risks as far as possible. (2) Large sample size and heavy testing workload in the process of new product development led to increased costs. Therefore, companies need to use new statistical methods to analyze large sample data and reduce development costs. This study makes an in-depth analysis of the risks that may occur in the process of the company's new product development and draws some useful conclusions and strategies.

Keywords: cardiac rhythm management & neuromodulation (CRM&N), product development process (PDP), medical device manufacturing, risk analysis

1. Introduction

1.1. Importance and Necessity of Production Development

Product development is important for enterprises to win in market competition and earn market advantages, especially for the New Product Development (NPD). However, due to the development of science and technology and the rapid changes in consumer needs, the life cycle of products is getting shorter day by day. The time, profitability and production transformation ability of new product development have become important criteria for evaluating the success of a new product development process. Inspired by the Covid-19 pandemic, the medical industry has developed rapidly. How to

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develop and produce vaccine, medical drugs and medical equipment in a shorter time has become an urgent need. Compared with drugs and general medical supplies, the Research and Development (R&D) and manufacture of medical equipment or device is often more complicated. Moreover, the medical device Product Development Process (PDP) should be complied with Regulatory & ISO 13485 requirements, Food and Drug Administration (FDA) Design Control Guidance, and Product Development materials from CDRH (Center for Devices and Radiological Health), etc. for medical device manufacturer in United States. For the new product development department of the medical device manufacturing industry, shorter R&D time and efficient production efficiency will make medical device manufacturing enterprises more competitive in the industry. From a more profound point of view, improving PDP at Medical Device field also has positive significance for human life and health.

1.2. Nature and Significance of the Problem

In the PDP of medical devices, engineers usually encounter this kind of problem: in the face of numerous complicated project requirements, some project risks are hidden in the initial phase. If engineers cannot identify these potential problems in time, these problems will definitely bring huge risks for production stage. In order to avoid these potential risks and control the cost, it is necessary for designers and engineers to use appropriate methods and strategies to identify and control these risks during the PDP.

1.3. Research Objective

The main aim of this study is to summarize and analyze the common risks during PDP for the Cardiac Rhythm Management & Neuromodulation (CRM&N) products. Moreover, exploring the mitigation strategies for these risks through literature review and a case study of a company in the medical device manufacturing industry in the United States. The study validated reliability and efficiency of the current product development process of the company. This research has implications for the new product development process of similar medical device manufacturer.

The second chapter will summarize recent research on PDP, PDP risks and risk strategies; The third chapter will analyze PDP of a specific case; The fourth chapter will evaluate the potential risks of this case; and the fifth chapter will conclude the corresponding mitigation strategies. The last chapter is the summary of the whole research.

2. Literature Review

Over the past few decades, many researchers and practitioners have conducted research to address Risk Assessment Challenging during product development process. The purpose of this section is to provide an up-to-date review of research in the field of Project Management, Product Development, Risk Assessment and Risk Management. We systematically analyzed relevant papers published by researchers and practitioners and reported their observations.

2.1. New Product Development Theories

NPD is one of the most valuable areas of business. A scientific, efficient, and systematic new product development process is crucial. There are multiple mainstream management models for NPD: Product and Cycle-time Excellence, Integrated Product Development, Stage-gate System, agile methodology and Product Value Management. However, a single product development management model can no longer meet the growing requirements of contemporary enterprises [1,2]. More and more companies are making improvements to their Product Development Processes with hybrid and dynamic

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models [1,2]. Most NPD projects are facing sustainable decisions about resource allocation. This causes NPD project selection that ignore underlying political dynamics and lack empirical descriptions of real-world processes [3]. At the same time, more scholars are trying to bring the concept of lean six sigma manufacturing into the product development process to reduce product development risks, costs, and waste [4]. A data-driven Lean PDP model could be the trend of the future.

2.2. Risk Analysis of NPD or PDP

During new production development, many risks are likely to arise. First, one significant risk is resources would be wasted, leading to the failure of project [5]. Other risks include that Production takes too long, costs are too high, processes are cumbersome, and methods are used improperly. The definition of risk can be described as "the effect that uncertainties on object project" [6]. Risk management is a way of controlling and adjusting the risk factors [6]. The importance of risk management has been emphasized especially in new production development. However, the status quo is that many companies spend much money on the development of new production and innovation production, their risk management system is not perfected [5]. Overall, risk assessment system needs to be built and risk management is essential in every phase of production. In this case study, the risks of every phase of new production development are assessed, risk management strategies are made.

2.3. Strategies to Mitigate Risk of NPD or PDP

In the process of new product development, there are many strategies to reduce or avoid risks. For example, Subramanian uses a combination of life cycle thinking (LCT) or life cycle assessment (LCA) and risk assessment (RA) to address early product risk and design risk [7]. In order to reduce the design risk, Ewing adopted the method of building a better organizational framework structure [8]. Huang uses data analysis to analyze the company's risks in a data-based way to better visualize risks [9]. Yao has proposed four risk control methods: risk transfer, risk avoidance, risk retention and risk sharing [10]. These four methods are effective for current risk analysis. By using index analysis, Zhang made tables to analyze the intensity of each risk in an indexed way, so that each risk could be marked more accurately [11]. Based on the methods and strategies in the past, this paper also puts forward some strategies.

3. CRM&N Product Development Process (PDP) Analysis

3.1. Background Introduction of Case

The subject of this study is a medical device manufacturing company located in the central region of the United States. The company's main business is to manufact titanium and stainless-steel CRM&N category medical device through multiple sheet metal forming manufacturing operations, such as Annealing, Drawing, Rolling, Bending. The PDP in this company is a stage-gated review process used to manage the execution of new product and process developments.

3.2. CRM&N Product Development Process (PDP)

The PDP outlines the requirements for the successful completion of product design, development and transfer to the manufacturing phase of a new product or process development project in accordance with regulatory and quality system requirements, which includes five phases: Feasibility and Initiation, Design and Development, Design Verification and Validation, Transfer to Production and Process Validation and Product Launch and Key Performance Indicators (KPIs) Assessment (See Fig. 1).

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3.2.1. Phase 1: Feasibility and Initiation

This is the initial evaluation of possible development of a commercial product and/or early feasibility of a "make-to-print" request. The primary objective of this phase is to evaluate the opportunity and decide to either proceed or stop. If the decision is to proceed, then project planning begins:

1) Opportunity evaluation for product, which includes financial, legal, market & competitive, early regulatory or clinical path.
2) Quote evaluation, review, and final acceptance.
3) Initial Project Risk Assessment.
4) Project Leader Selection or Project Scope and Project Charter.
5) Initial Design and Development Planning or Resource planning.

3.2.2. Phase 2: Design and Development

This and the next phase are primarily the recursive and iterative phases where new inputs may be incorporated into prior outputs and prototyping. Significant technical communication takes place with the client.

1) User needs, design inputs, applicable regulatory standards or plan for environmental health and safety are defined.
2) Customer requirements are broken down and adopted into the internal documentation systems. Specification concurrence is completed.
3) Early prototypes, models, and/or engineering evaluation units are planned and developed.
4) Planned design outputs and verification methods are confirmed and documented. Some design outputs begin to emerge. The Device History File (DHF) and Design Risk Management (dFMEAs or equivalent) are initiated.
5) Design For Manufacturability (DFM) and update the Environment, health and safety (EH&S) plan are part of this phase.
6) Design Assurance takes on a more involved role and drives compliance and design quality. Regulatory design reviews begin.

3.2.3. Phase 3: Design Verification and Validation

At this phase of the project, additional functional participants are required as the scope and complexity of the activities escalate. While the Design team is progressing through the Design Outputs matrix and Design Verification protocols and executions, other functions join to start collecting documentation from this phase to compile draft regulatory filings.

This Phase is likely to be the most time consuming and complex since many aspects of the design and development project are reaching conclusions and pivotal Design Reviews take place, while preparations for mass production ramp up.

1) Design Input / Design Output traceability matrix.
2) Design verification builds.
3) Design verification / validation protocols and reports.
4) Design Reviews.
5) Risk Management file updates.
6) Process Development / Process Characterization.
7) Operational Qualification (OQ) protocols / reports.
8) Complete clinical evaluations.
9) Test method validation protocols.
10) Supplier selection / Sourced Item Qualifications.

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3.2.4. Phase 4: Transfer to Production and Process Validation

In this phase, all functions complete their corresponding assignments and tasks. This Phase is also likely to be time consuming and complex. since many aspects of the design and development project are at the technical transfer points between R&D and commercial operations.

1) Complete Process Validation builds and Process Validation Reports.
2) Complete technical transfer plan from design to manufacturing.
3) Complete supply chain implementation and qualify suppliers.
4) Complete all validations and file approved validation reports.
5) Complete EH&S reports.
6) Post-market clinical follow-up, surveillance, and vigilance plan, as required.
7) Complete risk management report.
8) Complete manufacturing readiness activities including the release of the Bill of Materials.
9) Complete training.
10) Complete Sales forecast and production planning.

3.2.5. Phase 5: Product Launch and Key Performance Indicators (KPIs) Assessment.

This phase begins with the launch of the product. It is early commercial life that will continue thorough the product Lifecycle.

1) Verify fulfillment of project charter / plan and close out project.
2) Commercial launch and marketing checklist complete.
3) Quality supply agreements in place.
4) Post-market surveillance established.
5) File regulatory authorizations / clearances.
6) Manufacturing process KPIs reviewed and maintained.
7) Product quality monitoring metrics (complaint, NCRs, yields) deployed.
8) Quality audits established.

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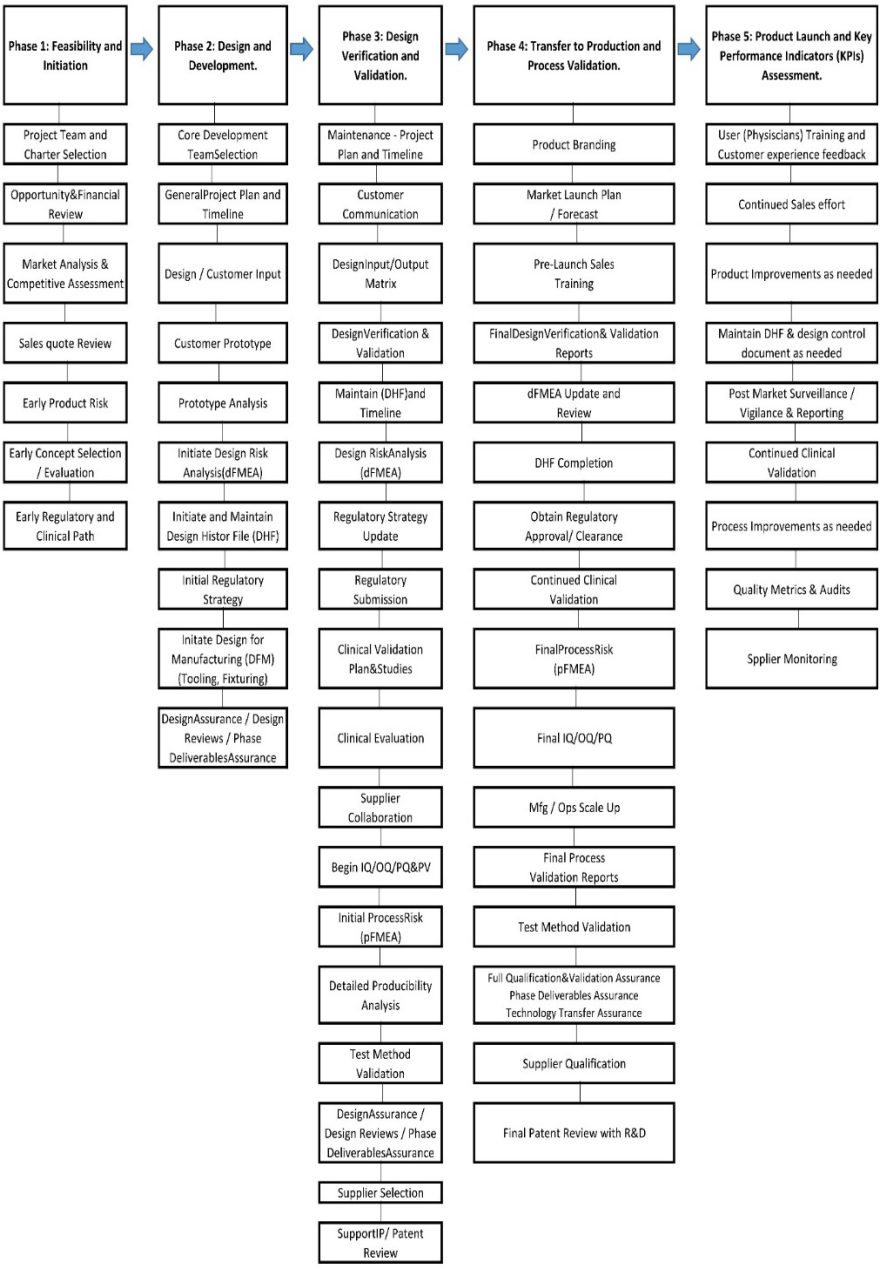

Figure 1: High-Level CRM&N product development process flow. (Photo credit: Original)

4. Risk Analysis during PDP

In the flow chart of PDP, five risks are to be considered. The first risk is the early product risk which appears in the phase 1: feasibility and initiation. In phase 1, early development work is conducted to determine design feasibility, evaluate the business opportunity and the project scope. One of reason why the evaluation of designing and producing new product is more challenging is because the environment of new products is hard to predict without past data [7]. As a result, the process of evaluation might cost too much time and money, the evaluation might not be accurate, and the product safety cannot be guaranteed.

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The second risk is initiate design risk that appears in phase 2. This phase conducts a series of activities including prototype builds, procurement planning, process characterization, supplier development, and risk management activities under customer concurrence. During this phase, one possible risk is the time cost lost due to improper sequencing of activities. To mitigate this risk, Ewing and Cudney's idea can be applied that a well-organized and planned framework is needed [8].

In phase 3, two important processes are to complete. Design verification testing is completed, design inputs are finalized and shown to the customers until they are satisfied. In addition, production specifications begin to develop. There are two risks as well, one is design risk, another is initial process risk. When the design plan is being verified, the design risk emerges. A lot of methods can be used in verification and validation whether the design meets customer requirements. For example, Maropoulos and Ceglarek mentioned a method to test the probability that a product can be assembled and function under a given set of tolerances called modelling assembly tolerances [12]. However, when using such methods, there would be risks. The range of tolerances becomes a challenge when using this method. Tolerances that are too tight can increase costs, while tolerances that are not wide enough can result in poor quality or even costly rework [12]. Another risk in this phase, initial process risk can also be due to wrong choice of estimation method, inappropriate sample size, and communication errors with customers (especially when the customer decides the sample size).

In phase 4, product design is completed and is transferred to production. The challenges are to guarantee that the plan is ready and appropriate so that product design has been correctly translated into Production Specifications. Select suppliers and form a supply chain. Determine whether the communication with upstream and downstream enterprises is smooth, whether the number of suppliers is appropriate, whether the upstream raw material supply cost can be guaranteed to be the lowest and the quality is qualified, and whether the products provided by the suppliers can allow Integer to produce products with guaranteed quality and quantity to meet customer needs. In all, with all the risks mentioned above, risk management and mitigation face many challenges.

5. Strategy and Suggestion for CRM&N PDP

5.1. Risk Introduction

In the previous article, we have detailed several types of risk: early product risk and initial design risk leading to high time and cost, design risk leading to high cost, initial process risk leading to poor product quality.

In addition, there are a few other obstacles:

1) The sample size is generally large or defined by customers. The sample size used in the design verification and verification process generally needs to meet the standards of statistical validity, so in order to meet the standards of the final product, the sample size should not be small. Some customers go to extremes and order a very large sample size. Therefore, the time required for this process is also large.

2) The inspection, identification and verification process are very complicated. This process includes updating and finalizing design inputs, alignment matrices, process validation, completing relevant checklists, design validation, and so on, none of which is easy and therefore takes a long time.

5.2. Suggested Policies

1) Use a combination of Life Cycle Thinking (LCT) or Life Cycle Assessment (LCA) and Risk Assessment (RA) to address early product risk and design risk [7]. According to the research findings, the combined use of life cycle assessment (LCA) and risk assessment (RA) is considered suitable for implementing safety design (SD) throughout the entire life cycle of a product. Applying these simplified methods aims to avoid some obvious sources of risk and impact at an early stage.

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2) Build a well-organized and well-planned framework to reduce or avoid initial design risks [8]. The second stage is a series of complex activities, and if the sequence of activities is not well arranged, then this stage will naturally take longer. We need to make a reasonable plan before we start, so as to reduce the time cost.

3) Improve the data collection method and use the data collection platform. For the problem of statistical sample size, although we cannot easily reduce the sample size, but we can improve the process and way of collecting samples. There are many sample data collection platforms that can help us collect a large amount of sample data quickly and accurately. We should use these platforms as smartly as possible to save time.

4) Develop an appropriate sample size to address initial process risks. In order to ensure quality and quantity and meet customer requirements, the sample size must be large enough and the sample data must be as accurate as possible. As mentioned above, this stage can be improved by leveraging big data platforms.

5) Rearrange the planning stage and make reasonable and flexible use of time cost. We recommend that companies develop products in several phases simultaneously to reduce the time required. In this stage, some stage activities do not interfere with each other and can be carried out simultaneously to speed up the progress of the whole stage.

6. Conclusion

This paper takes a American medical device manufactured company as an example to analyze the company's CRM&N PDP, with the purpose of finding out the possible risks in the process and finding countermeasures. After studying the various phases of PDP, the risks mainly appear in the third phase. In this phase, due to large sample size and huge amount of inspection work, the cost increase. Such that, it is important to use new statistical methods and data collection platforms to analyze large sample data, organize every step more efficiently. However, the risks in every process of CRM&N NPD cannot be ignored. Risk detection should be provided at every stage. From pre-production preparations to official production, to the end of production and product testing, risks should be controlled in every step. It is necessary to pay attention to the connection between the various stages, the risk of this stage may affect the progress of the next stage. Therefore, it is crucial to establish a complete risk management system so that every phase of production can relate to each other. To evaluate early risks, certain methods are essential to use such as combination of LCT, LCA and RA. New data collection methods need to be used to collect sample with appropriate size. Overall planning and organize all stages to shorten the time consuming of the PDP.

This conclusion can provide reference for other companies' new product production and risk management. Nevertheless, there are also shortcomings. This case study only analyzes the case of one company, the conclusions drawn from this analysis are difficult to generalize to other companies around the world. However, this article includes literature summary and case analysis, which is meaningful to future meta-analysis. In the future, it is expected to collect more companies, more comprehensive data and summarize the risk mitigation pattern that applicable to more companies.

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