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# Navigating challenges in new product development: Strategies for reducing failure rates in the medical device industry

Nirali P Shah *

*Research and Development Department, Nobel Biocare, USA.*

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## Abstract

New product development (NPD) in the medical device industry is critical for advancing healthcare technology and improving patient outcomes. Due to high usage of automated processes and applications in healthcare, the medical devices are not limited to products but have expanded to software as medical device. However, the failure rate of NPD projects in this sector remains high due to various challenges. This article explores the complex NPD process, which includes concept development, feasibility studies, design, and development, verification and validation, regulatory approval, and commercialization. Major reasons for project failures are identified, such as regulatory challenges, Change Management issues, market misalignment, communication failures, and insufficient risk management. Addressing these failure points requires a multifaceted approach. Regulatory pathways should be navigated with careful planning and compliance, and market needs must be thoroughly understood through comprehensive research. Resource allocation should be optimized to avoid constraints, and effective communication channels should be established to align all project participants. Finally, implementing rigorous risk management strategies, such as Failure Modes and Effects Analysis (FMEA), can help mitigate potential risks early in the development process. By adopting these strategies, medical device companies can improve their NPD processes, reduce the failure rate of projects, and bring innovative and effective medical devices to market successfully.

**Keywords:** Healthcare technology; Medical Device Industry; New Product Development; Project Management; Risk Analysis

## 1. Introduction

The medical device industry is an essential component of the global healthcare system, responsible for developing innovative products that improve patient outcomes, enhance diagnostic capabilities, and streamline therapeutic procedures. This sector encompasses a wide range of products, from simple devices like bandages and thermometers to complex instruments such as MRI machines and implantable defibrillators. The industry is also expanding to include software as a medical device (SaMD), reflecting the growing importance of digital health solutions. Despite its critical role, the industry faces significant challenges in the new product development (NPD) process, which often result in high failure rates.

NPD in the medical device sector is driven by the need to address emerging healthcare challenges, adapt to technological advancements, and meet the evolving demands of healthcare providers and patients. Innovations in medical devices can lead to improved diagnostic accuracy, minimally invasive surgical techniques, and better patient monitoring, ultimately enhancing the quality of care [1,2].

* Corresponding author: Nirali Shah

## 2. Medical Device Classification

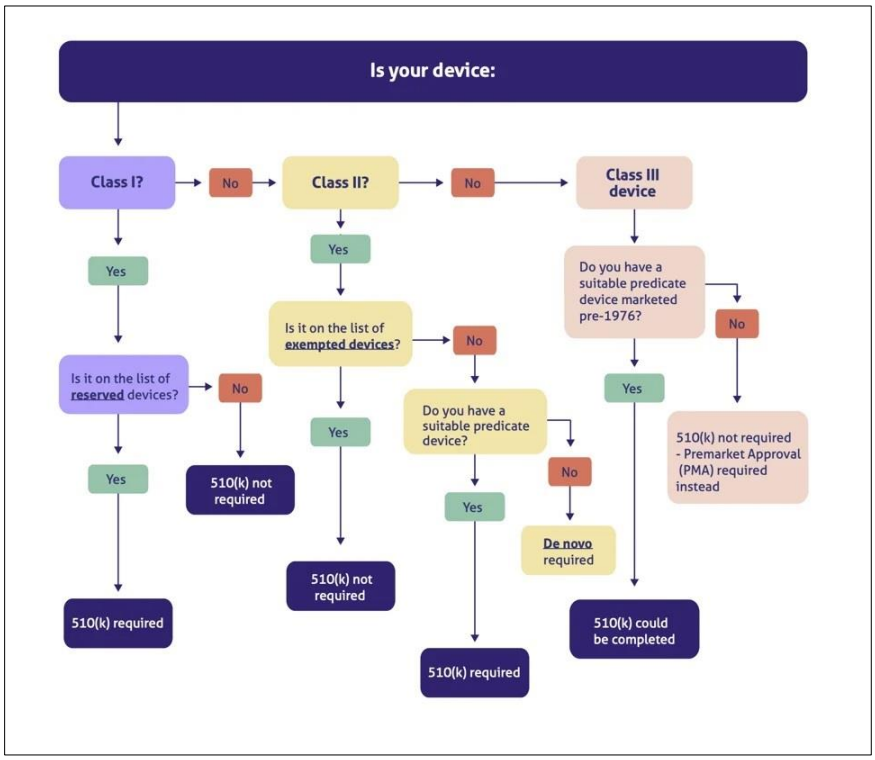


**Figure 1** Medical Device Classification Decision Tree [3,4]

### 2.1. New Product Development Design Control process

The design control process for medical devices is a critical framework that ensures products are safe, effective, and meet both user needs and regulatory requirements. This process is outlined by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and is a fundamental part of the Quality System Regulation (QSR) for medical devices covered under 21 CFR Part 820.30. Here's a detailed overview of each phase of the design control process.

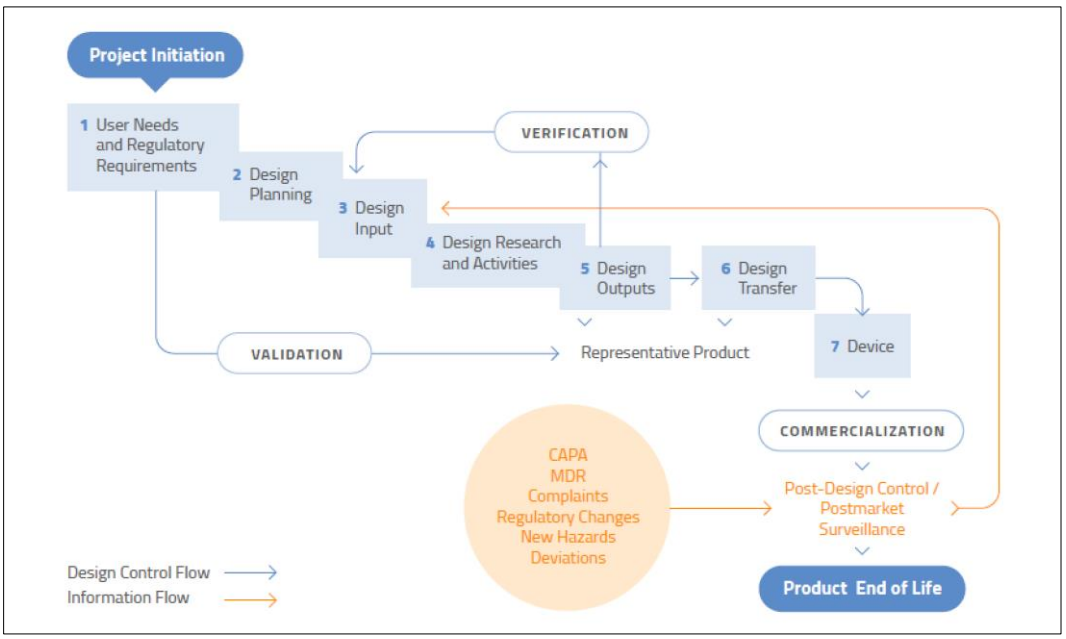


**Figure 2** Representation of Design Control Model [17]

#### *2.1.1. Design and Development Planning*

At this initial stage, a detailed design and development plan is created, outlining the design project's structure, tasks, schedules, and responsibilities. [5,6,18]

#### *2.1.2. Design Inputs*

Design inputs establish the requirements that are essential for designing the medical device. These are based on user needs, intended use, and must include any regulatory requirements. [7,8,18].

#### *2.1.3. Design Outputs*

Develop specifications and descriptions that translate design inputs into a tangible form.

Design outputs are the results of the design effort at each phase and are necessary for building a device that conforms to design inputs. [8,9]

#### *2.1.4. Design Review*

Design review is a formal, structured process within the design control framework of medical device development that evaluates the design at various stages of the product lifecycle to ensure it meets all specified requirements. This process is essential to ensure that the product is developed according to plan, is safe, and meets user needs and regulatory compliance requirements. The no of the design review to be conducted depends on the organization. However, typically there is 1 design review conducted for each phase i.e., Design input, Design output, Verification and Validation. [8,10,18]

#### *2.1.5. Design Verification*

Design verification in the design control process is a critical step that ensures a medical device meets all specified design requirements laid out during the design input phase. It is primarily focused on confirming that the design outputs align with the design inputs through objective evidence, which typically involves conducting a series of tests, analyses, inspections, and reviews. [11,12]

#### *2.1.6. Design Validation*

Design validation in the design control process is an essential step that focuses on ensuring the final medical device meets the intended user needs and specified application requirements. Unlike design verification, which checks whether the product was built right (i.e., if it meets the specifications derived from the design inputs), design validation confirms that the right product was built for the end user's actual needs and uses. Design validation ensures that devices conform to defined user needs and intended uses and must be completed using initial production units or their equivalents. [12,13,18]

#### *2.1.7. Design Transfer*

Design transfer in the design control process is a critical phase that ensures the design outputs developed during the product design stages can be successfully manufactured while maintaining compliance with all quality requirements. It involves the formal transfer of all design documentation and knowledge from the design team to the manufacturing team, ensuring that the product can be produced consistently and reliably in a production environment. [14,15,18]

#### *2.1.8. Design Changes*

Design changes within the design control process of medical device development refer to the alterations made to the design of a medical device after initial approvals have been obtained. These changes can stem from new regulatory requirements, technological advancements, feedback from clinical practice, or manufacturing considerations. Managing these changes effectively is crucial to ensure the device remains safe and effective and continues to meet regulatory compliance. [14,15,18]

#### *2.1.9. Design History File (DHF)*

The Design History File (DHF) is a comprehensive compilation of documentation that describes the design history of a medical device. It is required by regulatory bodies, such as the U.S. Food and Drug Administration (FDA), to ensure that medical devices are designed and developed according to approved procedures and regulatory standards. The DHF provides a detailed, chronological record of the design process, capturing all significant steps from the initial conception through to market release. [16,18].

There are multiple regulations by international standardization of Organization (ISO) and Food and Drug Administration (FDA) to guide how to develop the medical device of any classification to ensure their safety and efficacy for the users.

**Table 1** Design Control Related Processes in ISO 13485:2016 and FDA 21 CFR Part 820 [17]

| Topic | ISO 13485:2016 | FDA 21 CFR Part 820 |
|---|---|---|
| Design Control | 7.3 | 820.3 |
| Design Reviews | 7.3.1 | 820.30 (e) |
| Design Planning | 7.3.2 | 820.30 (a), 820.30 (b) |
| Design Change | 7.3.9 | 820.30 (i), 820.70 (b) |
| Design Input | 7.2.3 | 820.30 (c) |
| Design output | 7.3.4 | 820.30 (d) |
| Design Verification | 7.3.6 | 820.30 (f) |
| Risk Analysis and Management | 7.1. ISO 14971:2012 | 820.30 (g) |
| Design Validation | 7.3.7 | 820.30 (g), 820.70 (l) |
| Design Transfer | 7.3.8 | 820.30 (h) |
| Design History File | 7.3.10 | 820.30 (j) |
| Device Master Record | - | 820.181 |
| MDR & Complaints | 7.2.3, 8.2.2 | 803, 820.198 |
| CAPA | 8.5.2, 8.5.3 | 820.100 |
| Post Market Surveillance | 8.2.1 ISO 14971:2012 | 822 |

## 3. Role of Project Management in New Medical Device development

Project management in the development of new medical devices is a critical function that ensures projects meet specified objectives within the constraints of time, budget, and quality, all while complying with rigorous ISO and FDA standards [19,20]

- Project Planning: Developing a comprehensive project plan that includes scope definition, resource allocation, timelines, and budgeting. This plan aligns with the rigorous milestones and documentation required by both ISO and FDA standards.
- Resource Management: Efficiently managing both human and material resources to ensure that the project team has access to the necessary tools, information, and personnel to meet development and regulatory milestones [22]
- Quality Assurance: Implementing quality assurance practices throughout the development process to ensure that the medical device will meet both the regulatory standards and the high quality expected by end-users.
- Stakeholder Communication: Maintaining clear and continuous communication with all stakeholders, including regulatory bodies, to ensure transparency and address any compliance issues promptly [22]
- Risk Management: Conducting ongoing risk assessments as per ISO 14971 to identify potential issues that could impact the safety and effectiveness of the medical device or the project's compliance with regulatory standards [21,22]
- Change Management: Managing changes in project scope, design, process, or systems while ensuring continuous compliance with established guidelines and regulations. This includes documentation and approval of changes as per the structured process required by the FDA and ISO standards [19,20,21]
- Project Monitoring and Control: Continuously monitoring project progress against the plan, adjusting strategies as necessary to handle deviations, and implementing corrective actions to address any issues that arise [22]
- Project Closure: Ensuring that all project deliverables are completed, and all regulatory approvals are obtained. Finalizing all project documentation to ensure that everything is for audits and future reference.

Effective project management in medical device development not only drives the project to completion within the established constraints but also ensures rigorous adherence to quality and regulatory standards. The integration of project management practices with ISO and FDA requirements is essential for the successful launch of safe, effective, and compliant medical devices. This approach minimizes risks and enhances the efficiency and outcomes of medical device development projects.

## 4. New Medical Device Development Project Failure Rate

The failure rate for new medical device development projects is notably high, reflecting the complexities and challenges associated with bringing a new device to market.

The medical device development process is complex and requires navigating both technical and regulatory hurdles that contribute to these failure rates. About 75% of US-based medical device startups fail [23]. These failures can be attributed to various factors including financial burdens, regulatory hurdles, and technical challenges in development. Reliability in medical devices is difficult to measure due to the need for large sample sizes and lengthy testing. Failures often result from product flaws or surgical/installation errors, and the consequences of these failures prompt increased regulatory scrutiny, which in turn can slow innovation and market entry. [24,25]

## 5. Major reasons why NPD projects fail and how to overcome

The major reasons for failure in new medical device development projects encompass a range of technical, managerial, and regulatory challenges. Below are the 5 main reasons for such a high rate of failures for Medical Device New Product development projects and the strategy to overcome those shortfalls.

### 5.1. Inadequate Risk Management

Effective management of risks associated with new product development is crucial. Failures often arise due to the inability to foresee and mitigate various risks early in the development stages, including technical uncertainties and regulatory challenges [26].

- *Early Identification and Analysis of Risks*: Risk management should start early in the medical device development process. Failure to identify and analyze potential risks during the initial stages of development can lead to more significant problems later on. [26]
- *Integration of Risk Management with Design and Development:* Risk management must be integrated with the product design and development processes. Often, development teams engage in risk management activities too late in the process, which limits their ability to influence design inputs and user needs meaningfully. [27]
- *Compliance with Regulatory Standards:* Effective risk management ensures that all aspects of the device, from its functionality and usability to its manufacturing process, meet regulatory requirements. [28]
- *Ongoing Risk Monitoring and Review*: Development teams must continually monitor, review, and control identified risks, adapting their strategies as new information becomes available or as project circumstances change. [26,28]
- *Stakeholder Involvement and Communication:* Ensuring that all stakeholders have a clear understanding of potential risks and their roles in managing those risks is crucial for the success of the project [29, 30]

In summary, inadequate risk management in medical device development can result from failures at multiple levels, including poor early risk identification, lack of integration with other development processes, insufficient regulatory compliance, inadequate ongoing monitoring, and poor stakeholder communication. Addressing these challenges requires a proactive, integrated, and well-communicated risk management strategy.

By addressing risk management comprehensively and proactively, medical device development projects can significantly improve their chances of success, ensuring not only compliance with regulatory standards but also the safety and efficacy of the medical devices produced.

### 5.2. Regulatory Hurdles

Regulatory hurdles are a significant and often cited reason for the failure of new product development projects in the medical device industry. The complexity of regulatory requirements, combined with the high costs of compliance and the risks of not gaining approval, can severely impact the success of a project.

- Complexity of Regulatory Requirements: Different countries have different regulatory bodies with their own sets of regulations, which can vary significantly. The complexity of these regulations means that companies must navigate a labyrinth of compliance issues, which can include extensive documentation, rigorous testing protocols, and detailed risk assessment procedures. Misunderstanding or underestimating these requirements can lead to significant delays [31,32]
- Cost of Regulatory Compliance: The costs associated with achieving regulatory compliance are substantial and can be prohibitive. According to a study cited by the Regulatory Affairs Professionals Society (RAPS) [33], the cost to bring a medical device from concept to market can vary widely but is typically in the millions of dollars, depending on the device's classification and complexity.
- Time Delays and Market Dynamics: The time required to navigate the regulatory approval process can also contribute to project failure [34].
- Risk of Non-Approval: A failure to meet the regulatory criteria for safety and effectiveness can result in a refusal to approve the device, necessitating either significant modifications or, in some cases, abandonment of the project altogether.[35]
- Adaptation to Regulatory Changes: Regulatory environments are not static, and changes in regulations can have a profound impact on ongoing development projects. [36]

Understanding and navigating these regulatory hurdles is critical for the success of medical device development projects. By engaging with these resources, companies can better navigate the regulatory challenges that frequently contribute to project delays or failures in the medical device industry. Investing in regulatory expertise and maintaining a proactive stance on compliance are essential strategies for success.

### 5.3. Change Management Issues

Change management issues are a critical and often overlooked reason for the failure of new product development projects in the medical device industry. Effective change management involves managing the human, technical, and organizational aspects of change to ensure that new developments are implemented smoothly and effectively.

- *Stakeholder Engagement and Communication:* In medical device projects, engaging stakeholders at all stages—from concept through development and deployment—is crucial. [29]
- *Resistance to Change:* Resistance from both individuals and organizational units can severely impede the adoption of new technologies or processes. Overcoming resistance requires careful planning, transparent communication, and inclusive decision-making [37]
- *Adaptability to Regulatory and Market Changes:* Projects that fail to adapt to these changes can quickly become obsolete or non-compliant. Effective change management must include mechanisms to monitor external changes and adapt the project scope and objectives accordingly. [38]
- *Strategies to Mitigate Change Management Issues*: Proactive Planning: Develop a detailed change management plan at the project's inception, outlining strategies for communication, stakeholder engagement, and training.

By addressing these change management issues effectively, medical device companies can enhance their ability to successfully introduce new products, ensuring they are both accepted by users and compliant with regulatory standards.

### 5.4. Market Misalignment

Market Misalignment is a significant challenge in the development of new medical devices, often leading to project failures. This issue arises when there is a disconnect between the developed product and the market's needs, preferences, or conditions.

- *Understanding Market Needs:* Failure to conduct comprehensive market research before and during the development process can result in a product that does not adequately address any specific market need, leading to poor adoption [39]
- *Competitive Analysis:* Insufficient competitive analysis can also lead to market misalignment. Developers must understand not only current competitors but also anticipate future market entries. A product might meet current market needs but could become obsolete or less desirable upon the launch of more advanced or cost-effective alternatives [40]
- *Adaptability to Market Changes:* The inability to adapt to changes in market trends, technology, and customer preferences can result in a product becoming irrelevant by the time it reaches the market. Rapid technological advancements and shifts in healthcare practices require a proactive approach to product development and iteration.

Market misalignment can be a devastating pitfall for new medical device projects, but it can be mitigated through rigorous market research, continuous stakeholder engagement, comprehensive competitive and regulatory analysis, adaptable pricing strategies, and proactive monitoring of market trends. Addressing these areas effectively requires a multidisciplinary approach involving marketing professionals, industry analysts, regulatory experts, and strategic planners from the outset of the product development process.

### 5.5. Communication breakdown

Communication breakdowns are a prevalent and critical factor leading to the failure of medical device new product development projects. Ensuring effective communication throughout the development lifecycle is essential for success.

- *Cross-Functional Team Dynamics:* The integration of diverse professional backgrounds in a medical device project team often leads to miscommunication. Effective collaboration between engineers, regulatory experts, and marketers is crucial but often hampered by differing terminologies, priorities, and objectives [41].
- *Regulatory Communication:* Misunderstandings or miscommunications with regulatory bodies like the FDA can lead to incorrect submissions, resulting in delays or rejections. Precise and proactive communication is required to navigate the complex regulatory landscape effectively [42]
- *Stakeholder Engagement:* Inadequate communication with stakeholders, including investors, clinical advisors, and potential users, can lead to misaligned expectations and insufficient support. Ensuring that all stakeholders are regularly updated and engaged is crucial [43]
- *User-Centric Communication:* Engaging with end-users throughout the development process is essential but often overlooked. Failure to incorporate ongoing user feedback can result in a product that does not fully meet market needs [44]

Communication breakdowns can be systematically addressed by implementing structured communication strategies, using modern tools, and ensuring regular engagement with all stakeholders involved in the development of medical devices. By prioritizing clear and effective communication, organizations can significantly reduce the risk of project failure due to misunderstandings or information silos.

## 6. Conclusion

The challenges of new product development (NPD) in the medical device industry are numerous and multifaceted, directly impacting the high failure rates observed in this sector. Our review highlights the critical areas where improvements are necessary to enhance success rates and drive innovation forward. Regulatory hurdles, change management complexities, technological uncertainties, market misalignment, resource constraints, communication breakdowns, and inadequate risk management have all been identified as significant contributors to project failures.

Strategic enhancements in project management practices are essential. Implementing rigorous project management methodologies can provide the structured approach necessary to navigate the complexities of medical device development effectively. Furthermore, stakeholder engagement must be prioritized to ensure that all parties, from developers to end-users, are aligned and committed to the project's goals. This engagement is crucial for adapting to changes and overcoming resistance that might arise during the development process.

Technological integration must be managed with an emphasis on aligning with current market and healthcare trends to ensure relevance and applicability. Regulatory pathways, particularly, require careful navigation and continuous compliance to prevent costly delays and ensure market entry. Thorough market research is indispensable for aligning product development with real-world needs and expectations, thereby enhancing the likelihood of commercial success.

Resource allocation should be optimized to support all stages of development, ensuring that projects are not only well-funded but also well-staffed with the necessary expertise. Effective communication channels are critical to maintaining project alignment and momentum, preventing misunderstandings that could derail development efforts.

Finally, implementing comprehensive risk management strategies, such as Failure Modes and Effects Analysis (FMEA), is crucial. These strategies help identify potential risks early in the development process, allowing for timely mitigation and reducing the likelihood of project failure.

By adopting these strategies and fostering an environment of continuous improvement and rigorous oversight, medical device companies can reduce the failure rate of NPD projects. This shift not only promises to bring innovative medical

devices to market more reliably but also significantly enhances patient care by introducing safer, more effective technologies.

## Compliance with ethical standards

*Disclosure of conflict of interest*

No conflict of interest to be disclosed.

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