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FAILURE MANAGEMENT AND ANALYSIS OF MEDICAL DEVICES

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Abstract: Medical device failure management is essential for upholding patient safety and healthcare quality standards. However, existing approaches to analyzing and classifying recalls often lack precision, obstructing the identification of root causes and the implementation of effective mitigation strategies. This study proposes a flowchart to enhance the analysis and classification of medical device recalls, with a specific emphasis on addressing software-related failures. The primary aim is to gather extensive data from the Food and Drug Administration's recall database, encompassing various attributes such as device specifications, recall reasons, severity levels, and manufacturer details. By combining manual review processes with advanced classification techniques, the project aims to develop a vigorous and scalable approach to recall classification. The accuracy and reliability of these techniques will undergo rigorous evaluation, contributing to advancements in recall management practices and regulatory oversight. Through this combined approach, the flowchart ensures that the device undergoes thorough evaluation and risk mitigation measures, thereby minimizing potential risks to patient safety and regulatory compliance. Outcomes include the establishment of an accurate integrated flowchart that enhances the understanding of device safety, facilitates proactive risk mitigation strategies, and improves regulatory compliance. Additionally, study findings will inform the development of engineering standards, quality control processes, and ethical guidelines within the medical device industry, ultimately leading to improved patient safety, environmental sustainability, and economic benefits.

Keywords: Classification, Recall, Software failure, Medical devices

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1. Introduction

Medical devices play a crucial role in modern healthcare, aiding in the diagnosis, treatment, and prevention of diseases and conditions. However, ensuring their safety and efficacy is vital to protect public health. In this study, it's going to delve into the realm of medical device recalls, their classifications, and the vital role biomedical engineers play in this process.

Understanding Medical Device Classifications is fundamental to comprehending the risks associated with different devices. Both the Food and Drug Administration and the European Union have established classifications to categorize devices based on their potential risks to patients. For instance, the Food and Drug Administration's classifications range from Class I to Class III, while the European Union's classifications include Class I to Class III, with varying degrees associated (Anonymous, 2024).

Medical device recalls are voluntary actions by manufacturers, distributors, or other parties to address safety concerns with defective devices that could cause harm, including injury or death. Recalls are triggered by issues such as design flaws, manufacturing defects, labeling errors, or regulatory non-compliance. Regulatory bodies like the Food and Drug Administration and the European Union classify recalls by risk level, from Class I (high risk) to Class III (low risk). Manufacturers are required to notify stakeholders, including healthcare providers and consumers, to ensure timely corrective actions (Dublin et al., 2023). Effective recalls depend on the severity of the defect, distribution reach, and how quickly stakeholders respond. Regulatory agencies oversee recall processes to ensure they reduce risks and protect public health, with ongoing surveillance and collaboration being key to managing recalls efficiently (FDA, 2018).

Ensuring Device Safety through Surveillance and Vigilance is crucial. Market surveillance and vigilance are essential components of maintaining device safety. Within the European Union, the Medical Devices Directives govern market surveillance procedures, allowing authorities to assess device safety and address non-compliant devices. Similarly, the Food and Drug Administration's Medical Device Vigilance System aims to enhance safety by evaluating incidents, disseminating reports, and implementing corrective actions (EU, 2024).

Medical device recalls impose significant financial burdens on both manufacturers and healthcare systems. The cost implications of recalls can be broadly categorized into direct costs and indirect costs.

The cost impact of medical device recalls is classified as classically direct costs and indirect costs. Direct costs refer to the immediate financial expenses incurred by companies during the recall process. These include

production and inventory losses, logistics and return handling, repair or re-manufacturing expenses, re-testing and validation costs, and regulatory fees. Activities such as disposing of recalled devices, halting production lines, collecting and transporting products, and storing defective items are all costly processes. In addition, re-conducting safety and performance testing and managing inspections and approvals with regulatory authorities add further financial strain.

Indirect costs are less visible in the short term but can have far greater long-term consequences. These include reputational damage, loss of trust among healthcare professionals and patients, and market share erosion in favor of competitors. In cases involving patient injury or death, legal liabilities and compensation claims can be substantial. Other impacts include increased product liability insurance premiums, delays in research and development projects due to resource diversion, and a decline in shareholder value for publicly traded companies.

Several factors influence the overall cost of a recall, such as the scope of the recall, the device's risk classification, the underlying reason for the recall, the level of regulatory oversight, and the extent of media coverage. High-risk (Class I) medical devices and urgent recalls tend to incur significantly higher costs (Anonymous, 2023).

For example, in 2019, Medtronic recalled 322,000 insulin pumps due to a software defect. The estimated cost was approximately USD 60 million for production and logistics alone, with total expenses exceeding USD 100 million when legal and compensation costs were included. Additionally, the company experienced an 8% drop in market share and a 6% decline in stock value (FDA, 2021; Seeger Weiss, 2025).

To mitigate the financial impact of recalls, it is essential to implement proactive post-market surveillance systems, utilize AI-based early fault detection mechanisms, adopt modular device designs that enable the replacement of faulty components without recalling entire units, and establish effective crisis management and communication strategy (Xu and Zhang, 2024).

Table 1. Medical device events

Fiscal Year	Medical Device Recall Events Across the U.S.
2023	975
2024	1059 (according to 2023 %8.6 increase

The data indicates in Table 1, a clear upward trend in medical device recall events reported to the U.S. Food and Drug Administration (FDA) over the last two years. In 2023, there were 975 recall events, marking one of the highest figures in recent years. This was followed by a further increase in 2024, with 1,059 recalls, representing an 8.6% year-over-year growth.

One particularly concerning aspect is the rise in Class I recalls — the most serious category, which indicates a reasonable probability of causing serious adverse health consequences or death. Class I recall increased from 33 events in 2020 to 61 events in 2023, nearly doubling in just three years. This escalation suggests not only an increase in the number of faulty or non-compliant devices reaching the market but also a higher proportion of these posing severe safety risks.

This project aims to analyze medical device recalls from 2020 to 2023, focusing on recalls caused by software defects. Using the Food and Drug Administration's recall database, researchers examine critical devices such as implantable medical devices, infusion pumps, drug delivery systems, and diagnostic imaging devices like MRI and CT scanners. The analysis explores the severity of recalls, manufacturer details, device classification, and root causes to identify patterns and trends. The goal is to enhance patient safety, improve device design and manufacturing processes, and strengthen regulatory oversight to prevent future recalls (Sedgwick, 2024).

2. Materials and Methods

To collect the necessary data for the study, the Food and Drug Administration medical recall database will be used. This database contains comprehensive information on medical device recalls, including details on device categories, recall reasons, severity levels, and other relevant data points. Researchers can access the database through the Food and Drug Administration official website or relevant regulatory portals. The FDA dataset is an open-source system, therefore there was no need for an ethical commission decision. For a visual representation of the data collection process, please refer to (Figure 1). In this figure, it's outlined how the data will be accessed and extracted from the Food and Drug Administration medical recall database. This includes navigating the database interface, specifying search criteria, and retrieving relevant recall information. By following this process, data required for the analysis can be efficiently collected and studied (Figure 1) (FDA, 2017).

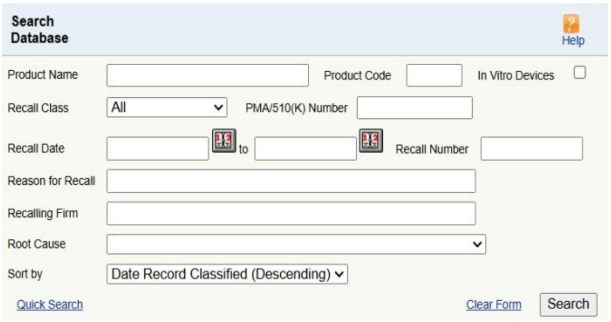

Figure 1. Data collection process from food and drug administration medical recall database (FDA, 2017).

The medical device life cycle, spanning from concept and design to post-market surveillance, ensures safety,

efficacy, and regulatory adherence, mirroring a standard product life cycle (PLC) structure (FDA, 2019). The Food and Drug Administration Center for Devices and Radiological Health (CDRH) adopted a Total Product Life Cycle (TPLC) approach to enable continuous oversight and improved decision- making based on premarket and post market data, accessible through their TPLC database (FDA, 2023).

The method is used to help complete the study and ensure that the medical devices underwent efficient and effective quality control to ensure that products or services meet specified quality standards and requirements. Quality control involves examining individual products or batches to ensure they meet specified standards and are devoid of any flaws or defects (Greenlight Guru, 2024). Two flowcharts have been developed to illustrate the complex processes involved in medical device design, manufacturing, and management within healthcare settings. These flowcharts provide a visual representation of the various stages and considerations essential for ensuring product quality, patient safety, and regulatory compliance.

The study is limited to the FDA data. The data on EU based on MDR and Asian medical device recalls are neglected due to limitations on reaching to the dataset. However, as FDA has been used globally the study will give a view on the recall side.

3. Results

Device design and manufacturing review flowchart is developed as you can see in Figure 2 for each medical device to go through it to avoid the recalls. The device design and manufacturing review process encompasses several critical stages aimed at ensuring the quality and safety of medical devices. Firstly, the medical device goes through the Early Design phase, this step involves abstracting the medical device and outlining its basic features and functionalities. It sets the foundation for the following design phases. Subsequently, in the Detail Design phase, detailed specification and technical requirements are defined with continuous enhancement based on user feedback and regulatory considerations. The Design to Protect Patient phase emphasizes the application of safety measures to mitigate potential risks and hazards associated with device use. Following this, the Production Validation stage involves validating manufacturing processes to ensure consistent production according to approved specifications. The Software Design section specifically addresses the design and development of software components within the device, ensuring their functionality and reliability. If there's a software device problem, the flowchart directs back to the Production Validation stage for reevaluation. If there's no software device problem, it proceeds to the next step. The Supply Chain management phase focuses on securing raw materials and components required for manufacturing, In the Verification, if the device does not pass verification, it triggers a recall and directs back to the Early Design stage for further evaluation. If the device passes verification, it moves to the next step which is Validation process which verifies that the device meets design requirements and user needs, ensuring safety, efficacy, and regulatory compliance (Figure 2).

To address the potential problems and recalls associated with various types of medical devices, including implantable devices, drug delivery systems, and diagnostic imaging devices, a systematic approach is essential (Saphra, 2022). By transitioning these concerns to a structured flowchart, such as one focusing on maintenance/calibration, regulatory compliance, risk management, patient safety, and integration with healthcare systems, proactive measures can be implemented to mitigate risks and ensure patient well-being.

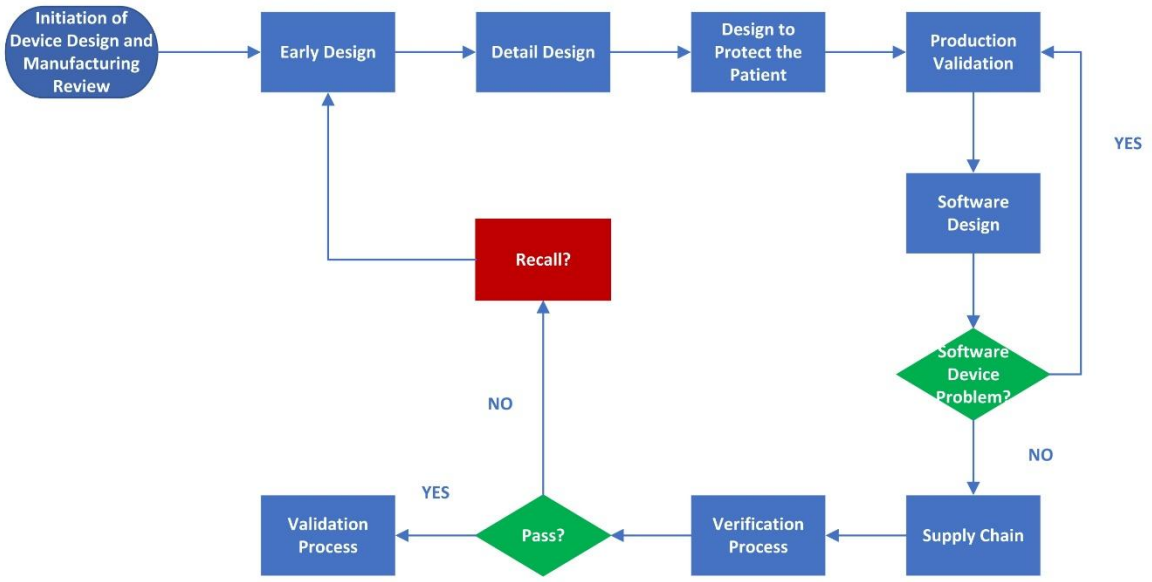

Figure 2. Manufacturing flowchart.

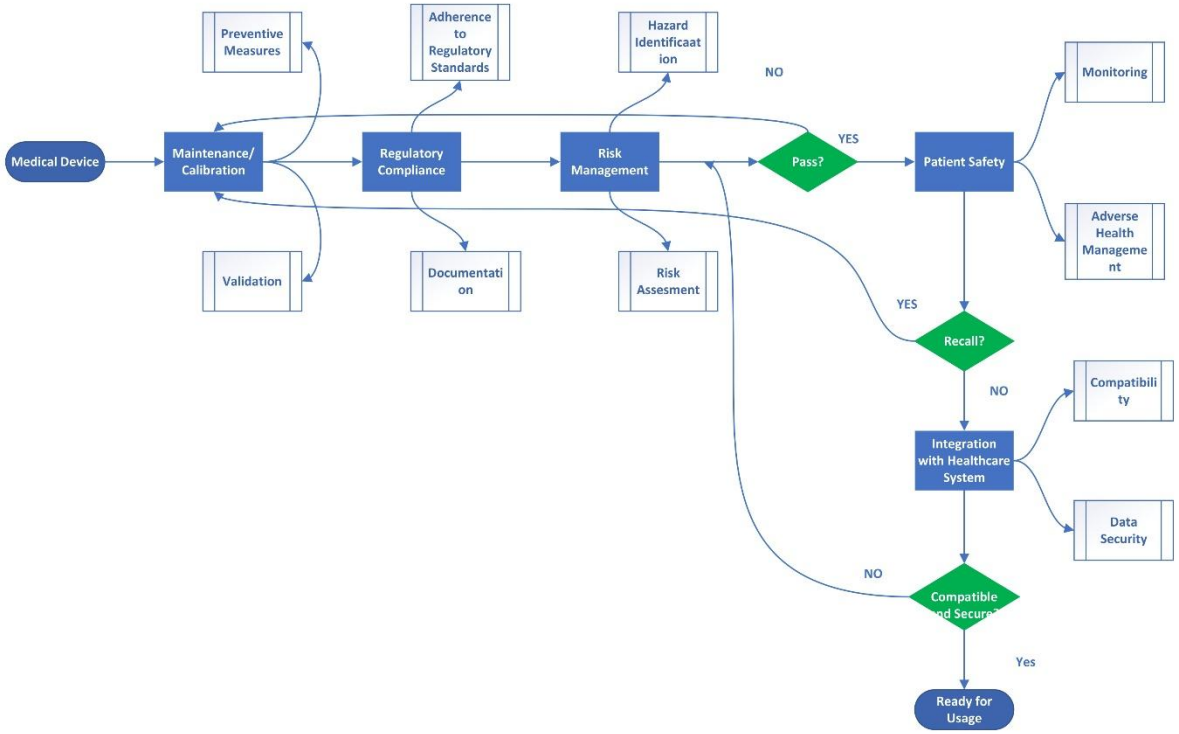

Figure 3. Hospital flowchart.

To begin with, in figure 3 the introduction of the flowchart where the devices will be passed down in the hospital, the medical device will undergo Maintenance/Calibration to ensure accurate calibration and maintenance through training programs and preventive maintenance schedules. Regulatory Compliance addresses documentation, reporting requirements, and adherence to regulatory standards. Risk Management involves identifying and mitigating potential hazards associated with device use to ensure patient safety. If the device doesn't pass the Risk Management section, it will be directed back to Maintenance/Calibration to ensure accurate maintenance and calibration. Patient Safety measures prioritize monitoring device performance and managing adverse events. In the event of a recall, the device should be returned to Maintenance/Calibration. Lastly, Integration with Healthcare Systems ensures compatibility and data security for continuous data exchange. If the device is found incompatible or insecure, it should be returned to Risk Management to re-evaluate and identify possible drawbacks. These processes collectively contribute to effective medical device management within healthcare settings, prioritizing patient safety and regulatory compliance.

The primary data source for the analysis will be the Food and Drug Administration Medical Recall Database, a comprehensive repository of recall information maintained by the U.S. Food and Drug Administration. By accessing this database, detailed records of medical device recall that occurred between the years 2020 and 2023 will be obtained. The approach will involve navigating the Food and Drug Administration database interface to specify search criteria relevant to the study, such as recall reasons, device categories, severity levels, and other key parameters. The study focuses on case studies involving critical medical devices such as implantable defibrillators and pacemakers (used in cardiac care), infusion pumps and drug delivery systems (for accurate medication administration), and diagnostic imaging devices like MRI machines and CT scanners, with particular attention to software defects. By exploring recall data for these devices, the study aims to gain insights into safety issues, regulatory challenges, and quality concerns, ultimately working to improve patient outcomes and minimize risks to public health (Maude, 2012).

Over the period of 2020-2021, pacemakers experienced recalls specifically related to software design issues. Similarly, defibrillators encountered software design recalls in both 2020-2021 and 2023. Infusion pumps also faced software design recalls during this timeframe. MRI machines encountered software design problems in both 2020-2021 and 2023, while CT scanners grappled with software design issues spanning the entire period from 2020-2023. These instances highlight the recurring challenges posed by software-related issues across a range of medical devices, emphasizing the critical need for continuous monitoring, rigorous quality assurance processes, and timely corrective actions to ensure patient safety and device effectiveness (FDA, 2012; FDA, 2019).

Medical device recalls are classified by how serious they are:

1.Class I: Most severe. The device could cause serious health issues or death.
2.Class II: Less severe. The device might cause temporary health problems or has a low chance of causing serious harm.
3.Class III: Least severe. The device is unlikely to cause any health problems.
4.Market Withdrawal: Minor issues; the company removes the product without FDA action.

Most recalls between 2020 and 2023 involved Class II devices (like MRI machines and pacemakers), while Class I devices (like infusion pumps) were also affected. The Food and Drug Administration MAUDE database helps track and analyze these incidents, allowing faster action when issues arise (FDA, 2012).

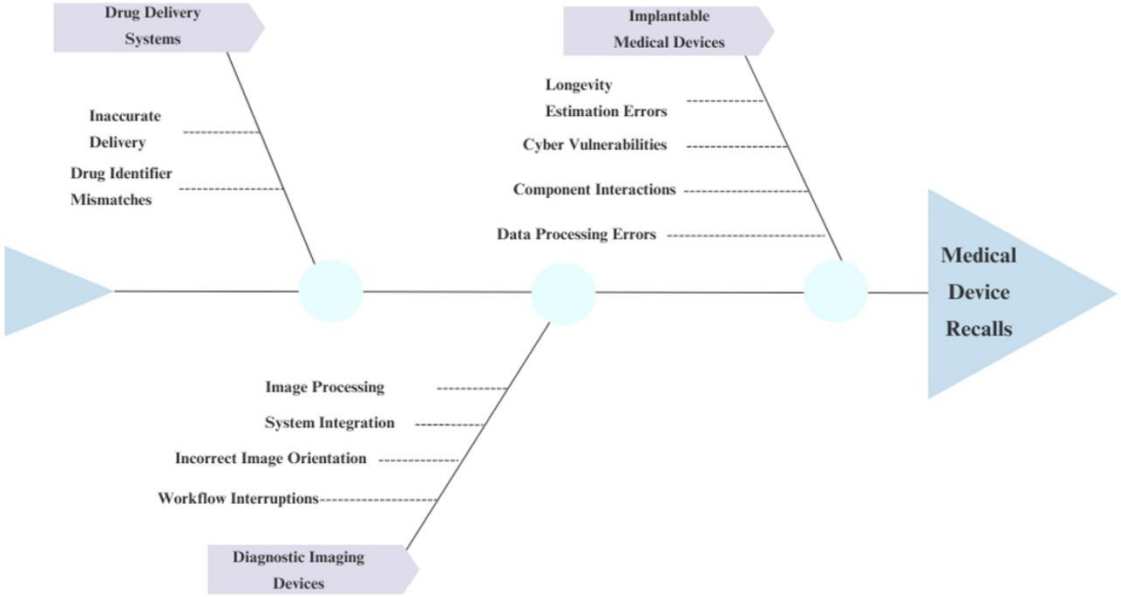

Figure 4. Fishbone diagram of the medical device recalls.

Root cause analysis is essential for identifying and addressing issues in medical device recalls. In this study, a fishbone diagram (Figure 4) is used to investigate the causes of software-related problems in pacemakers, defibrillators, infusion pumps, MRI machines, and CT scanners. This analysis provides insights into the factors contributing to device recalls and proposes strategies for improving safety and reliability (FDA, 2017).

Key findings include:

- Implantable Medical Devices (Pacemakers and Defibrillators):

1. Battery life estimation errors leading to device failure.
2. Cyber vulnerabilities affecting device functionality.
3. Software-hardware conflicts impacting shock delivery.
4. Data processing errors cause incorrect functioning.

- Drug Delivery Systems (Infusion Pumps):

1. Inaccurate medication delivery compromising patient safety.
2. Drug identifier mismatches causing dosing errors.

- Diagnostic Imaging Devices (MRI and CT Scanners):

1. Software flaws lead to inaccurate imaging results.
2. Integration issues with other systems affect performance.
3. Incorrect image orientation causes potential misdiagnosis.
4. Workflow interruptions leading to delays and re-scans.

A collaborative approach involving manufacturers, regulators, healthcare providers, and patients is crucial to prevent future incidents and improve device safety.

4. Discussion

The study of medical device failure management, specifically focusing on software-related issues in devices such as pacemakers, defibrillators, infusion pumps, MRI machines, and CT scanners, highlights the critical need for a vigorous and integrated approach to device life cycle management. The implementation of the Integrated Medical Device Life Cycle Management Framework (IMDL Framework) ensures that every phase, from design to deployment, adheres to strict safety, quality, and regulatory standards. This approach not only reduces the likelihood of device failures and recalls but also significantly improves patient safety and clinical outcomes.

An effective device life cycle management strategy incorporates risk management, regulatory compliance, and continuous monitoring, which enable healthcare providers and manufacturers to detect potential issues proactively. Addressing problems early in the development and deployment phases can greatly reduce adverse events and improve the reliability of medical devices in practice.

The new age medical devices such as AI integrated and wearable devices should be also considered very carefully. These devices will develop new risk factors

which need to be assessed also. Especially, decision support systems, machine learning algorithms, cyber security systems are the newest components of the new era.

Additionally, the collaborative effort between engineers, healthcare professionals, regulatory bodies, and manufacturers is key to enhancing device reliability. The study demonstrates the importance of early detection of risks, thorough testing protocols, and the ongoing need for innovations in software design and integration. This will be essential in ensuring that future generations of medical devices are both safe and efficient in clinical practice.

Furthermore, the study highlights the importance of effective supply chain management, regulatory compliance, and healthcare system integration in the overall process. Collaboration across various stakeholders is vital in the development of a culture of continuous improvement and innovation, allowing manufacturers to address complex challenges more effectively. The findings also underscore the necessity for ongoing risk assessments.

5. Conclusion

The project introduces the Integrated Medical Device Life Cycle Management Framework (IMDL Framework), designed to address challenges related to medical device recalls. This framework covers every stage of a device's development, from early design to deployment in healthcare settings, ensuring safety, efficiency, and regulatory compliance (Figure 5). By integrating the manufacturing process with hospital management, this approach aims to improve patient outcomes and enhance medical device management.

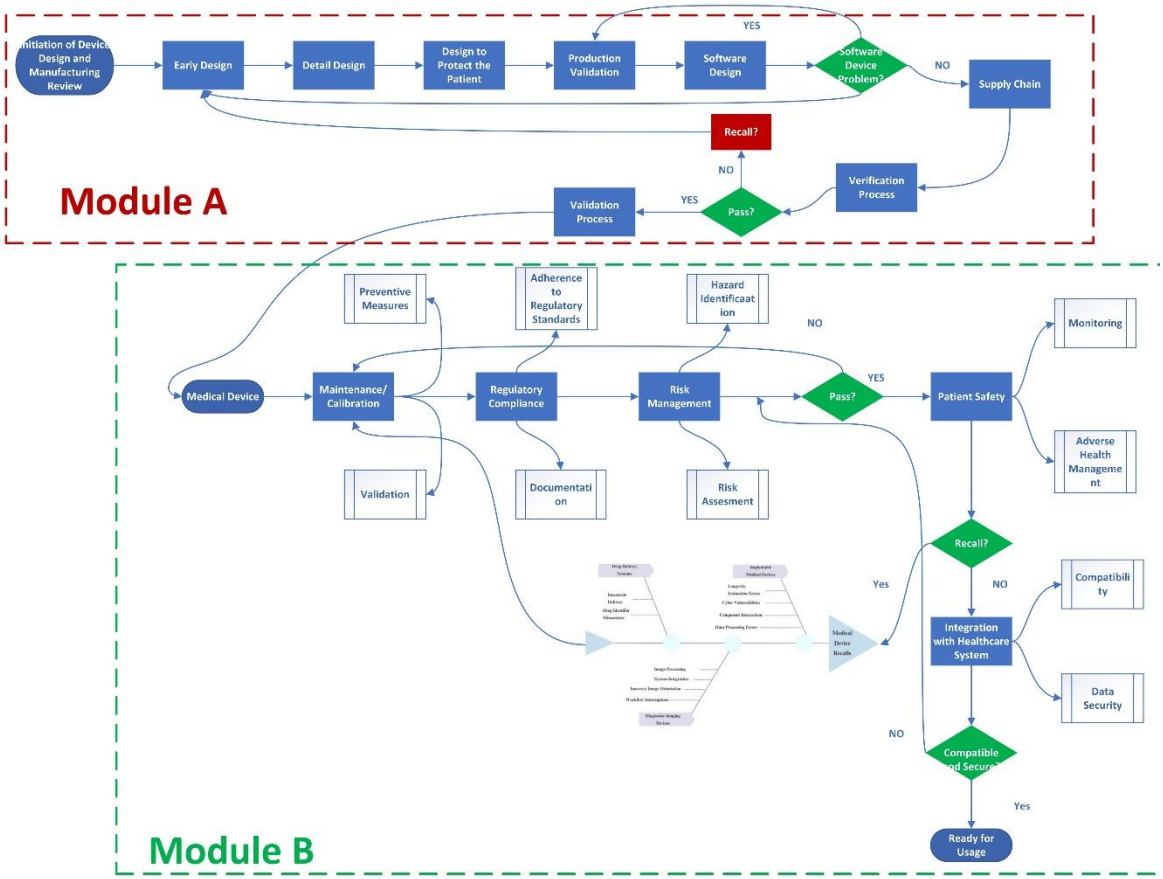

Figure 5. Integrated medical device life cycle management framework (imdl framework).

In Module A, the process begins with the Initiation of Device Design and Manufacturing Review. The Early Design phase outlines device features, followed by Detail Design, which specifies safety and regulatory measures. Production Validation ensures consistent manufacturing, and software issues are addressed. After passing Verification and Validation, the device is ready for production and supply.

In Module B, the device enters healthcare facilities for Maintenance and Calibration, followed by Regulatory Compliance and Risk Management to ensure adherence to safety standards. Patient Safety is prioritized, with recalls triggered if safety issues arise.

Finally, the device undergoes Integration with Healthcare Systems to ensure compatibility and security.

This approach raises continuous improvement through data analysis, interdisciplinary collaboration, and innovation, ultimately leading to safer, more reliable medical technologies. It aims to transform medical device management by promoting quality, safety, and patient care through systematic processes and teamwork.

Suppose a pacemaker is passed through the flowchart. In

that case, the process begins with the early conceptualization phase, where the device's fundamental features are defined based on user needs in collaboration with healthcare professionals and patients. In the detailed design phase, specifications like size, power consumption, and compatibility are outlined, and safety measures such as fail-safe mechanisms are integrated. During the software design phase, reliable components are developed and rigorously tested for quality and regulatory compliance. Supply chain management ensures the procurement of high-quality materials, while regulatory compliance involves thorough documentation and reporting to meet approval standards. Risk management identifies and assesses potential hazards, with a focus on patient safety. Finally, integration with healthcare systems ensures compatibility with electronic health records and other systems. This process ensures the pacemaker meets all qualities, safety, and regulatory requirements throughout his life cycle.

Author Contributions

The percentages of the authors' contributions are presented below. All authors reviewed and approved the final version of the manuscript.

	F.S.	S.C.
C	20	80
D	30	70
S	20	80
DCP	80	20
DAI	70	30
L	60	40
W	90	10
CR	40	60
SR	20	80
PM	30	70

C=Concept, D= design, S= supervision, DCP= data collection and/or processing, DAI= data analysis and/or interpretation, L= literature search, W= writing, CR= critical review, SR= submission and revision, PM= project management.

Conflict of Interest

The authors declared that there is no conflict of interest.

Ethical Consideration

Ethics committee approval was not required for this study because there was no study on animals or humans.

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