INCOSE

ASIA-OCEANIA SYSTEMS ENGINEERING CONFERENCE

# Sustainable MedTech

## Systems and Lifecycle Management Approaches for Remanufacturing

INCOSE AOSEC · 2025

**AUTHORS**

Sharad Rayguru, and Aniket Mitkari

**PUBLICATION DATE**

July, 2026

**SUBMISSION #**

59

INCOSE PUBLICATIONS

# Sustainable MedTech: Systems and Lifecycle Management Approaches for Remanufacturing

**Sharad Rayguru**
**Philips Healthcare Pvt. Ltd.**
**Amar Madhuban Tech Park,**
**5th Floor, Unit 501&502,**
**S.No. 43/44, Baner,**
**Pune - 411045.**
**Sharad.Rayguru@incose.net**

**Aniket Mitkari**
**Philips Healthcare Pvt. Ltd.**
**Amar Madhuban Tech Park,**
**5th Floor, Unit 501&502,**
**S.No. 43/44, Baner,**
**Pune - 411045.**
**ani.mitkari4@gmail.com**



## Abstract

The medical technology (MedTech) industry is experiencing a significant transformation toward sustainability, driven by environmental concerns, evolving regulatory demands, economic considerations, and a heightened focus on innovation and patient care. This paper presents a systems-oriented approach to sustainable MedTech by integrating systems engineering principles with lifecycle management strategies in remanufacturing processes.

It demonstrates how early-stage systems thinking contributes to waste reduction, lifecycle extension, and optimized resource utilization particularly for widely used materials such as cast iron, aluminium alloys, and cast steel. The study emphasizes the critical roles of reuse, refurbishment, and recycling in minimizing environmental impact while upholding regulatory compliance and performance standards.

Furthermore, it explores the challenges and opportunities associated with implementing remanufacturing strategies, supported by structured frameworks and practical case studies. These examples illustrate how MedTech organizations can advance ecological sustainability, economic efficiency, and social responsibility. Ultimately, the paper provides strategic insights into aligning sustainable development goals with technological innovation and enhanced healthcare delivery.

**Keywords** – Sustainability, Medical devices, MedTech, Remanufacturing, Recycle, Reused, Regulatory, FMEA (Failure Mode and Effects Analysis), LCA (Life Cycle Assessment), SLCA (Systems Life Cycle Assessment), Life Extensions, Degradation

# Introduction And Background

The medical technology (MedTech) sector is undergoing a significant transformation, driven by the urgent need to adopt sustainable practices. In this context, sustainable MedTech aims to reduce environmental impact across the entire product lifecycle from initial design and manufacturing to use, reuse, remanufacturing, recycling, and eventual disposal. This approach not only ensures compliance with evolving regulatory standards but also fosters innovation, enhances cost-efficiency, and contributes to improved healthcare outcomes.

As MedTech devices continue to grow in complexity, sustainability can no longer be addressed in isolation. It requires the early integration of lifecycle considerations and the application of systems thinking to inform decisions related to material selection, design for durability, and end-of-life recovery. These

factors are particularly critical when working with commonly used materials such as aluminium alloys, cast iron, and cast steel, whose reuse potential depends on their long-term degradation behavior and performance characteristics.

Figure. 1 is illustrating the demands for sustainability in MedTech industries.

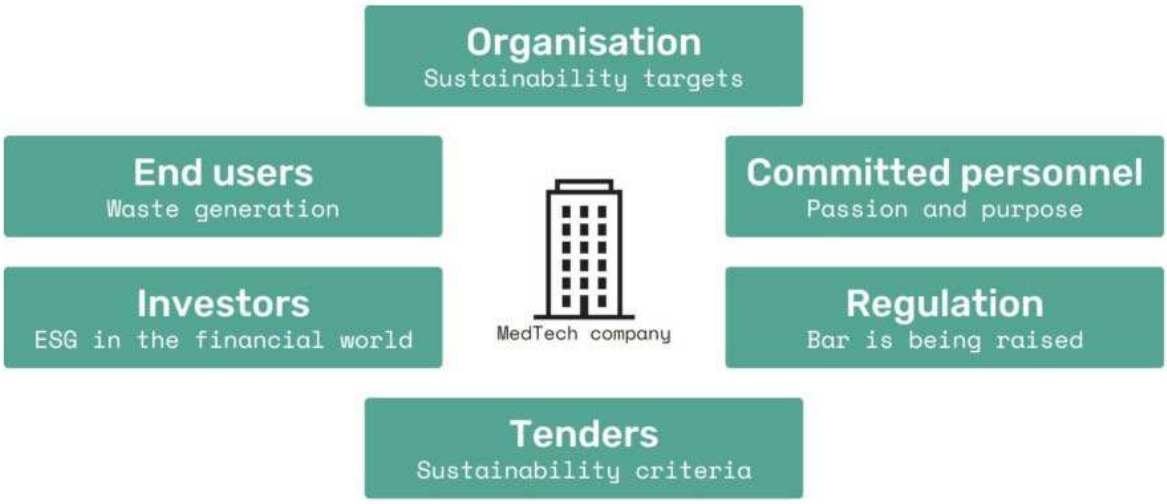


**Figure 1. Sustainability Demand of Medtech Industry**

Figure 1 presents a visual overview of the key forces driving sustainability in the MedTech industry. It highlights how regulatory pressure, environmental concerns, and economic incentives are converging to influence product development strategies. The figure underscores the need for integrating eco-conscious practices from the design phase through to end-of-life management. It also reflects the industry's shift toward circular economy principles, emphasizing reuse and remanufacturing. This visual sets the foundation for the paper’s argument that sustainability must be embedded across all stages of MedTech innovation

Systems-based management approaches, including eco-design principles and environmental impact assessments, offer structured methodologies for analyzing and improving ecological performance while supporting remanufacturing strategies. These tools enable MedTech organizations to reduce waste, enhance reliability, and meet evolving regulatory and clinical expectations.

While recycling is often viewed as the primary environmental strategy, the broader scope of responsible resource management includes reducing carbon emissions, minimizing energy and water usage, and curbing material waste across the entire value chain.

Ultimately, responsible healthcare involves delivering high-quality care while preserving environmental and economic resources for future generations. This paper examines systems-based frameworks that enable MedTech companies to align remanufacturing efforts with broader resource-conscious objectives and innovative-driven development.

# Design Concepts

Identifying the right methodologies and enabling technologies is essential for achieving sustainability objectives. Implementing solutions such as process optimization and structured assembly sequencing can significantly reduce both manufacturing time and overall production costs.

At the early stages of the design process, it is essential to assess the manufacturing capabilities of the organization. This enables the development of alternative technologies for producing components and

supports informed decision-making regarding the reusability of existing parts or the feasibility of their continued use.

## Cost-optimization

Establishing manufacturing centers within India presents a direct strategy for mitigating the rising costs associated with importing specialized equipment from abroad. Utilizing domestically manufactured equipment offers several advantages:

- Access to government incentives that lower operational expenses
- Easier maintenance through locally available technical expertise.
- Quicker software updates and troubleshooting facilitated by regional support teams.
-

## Manufacturing

The integration of structured management approaches in the MedTech sector facilitates a multidisciplinary strategy for new product development. By combining advanced manufacturing processes with comprehensive product oversight, organizations can accelerate production timelines while minimizing resource consumption. This approach also ensures the following:

- Streamlining all stages of production
- Securing rapid authorization and alignment from key stakeholders
- Implementing automation across manufacturing units
- Maintaining comprehensive data, records, and 3D models to reduce future iteration costs and development time

To further enhance streamlined manufacturing processes and lifecycle efficiency, it is crucial to understand the material properties and technical factors that influence the feasibility of remanufacturing and the long-term performance of devices.

# Technical Approach

A variety of metals with low degradation rates are commonly used in the construction of medical devices, including cast iron, ductile iron, cast steel, casting bronze, and aluminium alloys. Understanding the degradation behavior of each metal is essential for evaluating its longevity and suitability for reuse or remanufacturing. Figure 2 presents a comparative overview of material degradation.

This paper focuses on aluminium alloy due to its widespread application in medical device manufacturing and its unique combination of performance, recyclability, and degradation characteristics. Among the various metals used in MedTech, aluminium alloy stands out for its lightweight nature, biocompatibility, and corrosion resistance properties that make it particularly well-suited for a wide range of diagnostic and therapeutic equipment.

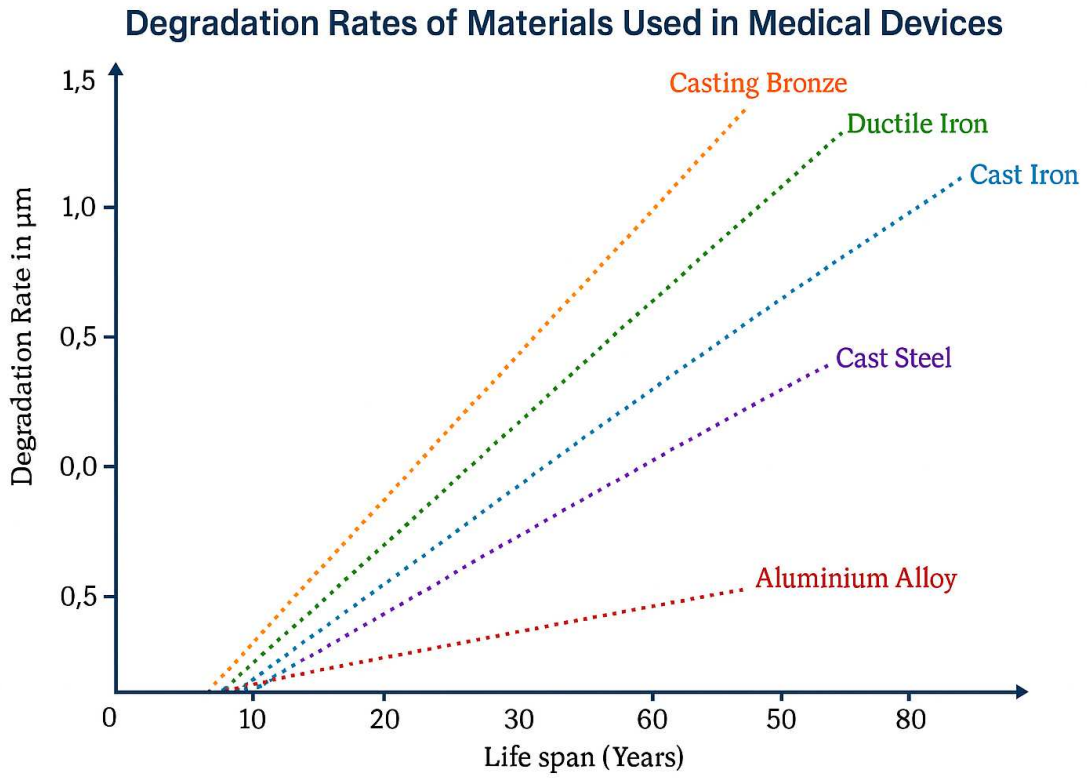


**Figure 2. Material Degradation Rate**

Above figure 2 illustrates how different metals used in medical devices degrade over time when exposed to operational and environmental stress. This comparison provides valuable insight into each material's structural reliability and long-term performance. By analyzing these patterns, the figure supports informed decisions about material selection for remanufacturing. Aluminium alloy, with its low degradation rate and high recyclability, emerges as a preferred option for sustainable design. This evidence reinforces the paper's core argument that choosing the right materials is essential for extending product lifecycles and achieving environmentally responsible MedTech innovation.

Many medical devices are designed for reuse or repair throughout their operational lifespan. To ensure consistency and compliance with applicable statutory and regulatory requirements, it is essential to include detailed information in the product labelling. Clear labelling supports the maintenance of device quality, safety, and effectiveness across multiple use cycles and during routine servicing or refurbishment.

The steady growth of remanufacturing in the U.S. across key sectors such as aerospace, heavy-duty equipment, and IT devices. It highlights the increasing market value and adoption of remanufacturing practices, reflecting a shift toward sustainable production. The data supports the paper's subject that remanufacturing is both economically viable and environmentally beneficial. This trend underscores the importance of integrating circular economy principles into MedTech systems. The figure also validates the strategic relevance of remanufacturing in long-term industry planning (See figure 3).

**TOP FIVE INDUSTRIES IN THE U.S. REMANUFACTURING (Estimated 2023- 25)**

| Industry | Production | Employment |
|---|---|---|
| Aerospace | $17.5 billion | 42,300 |
| Heavy Duty/ Off-Road | $10.1 billion | 27,200 |
| Vehicle Parts | $8.3 billion | 36,400 |
| Machinery | $7.2 billion | 31,000 |
| IT Devices & Electronics | $4.6 billion | 21,700 |

**Figure 3. U.S. Remanufacturing Growth (2023–2025): Highlights sector-wise expansion**

Remanufacturing is defined as "the rebuilding of a product to the specifications of the original manufactured product using a combination of reused, repaired, and new parts." Figure 3 illustrates the growth of remanufacturing in the United States, where the industry reached a market value of $47 billion by 2023 reflecting a 15% increase from the previous decade. Building on this momentum, the industry continued to expand between 2023 and 2025, with significant contributions from sectors such as aerospace, heavy-duty/off-road equipment, and vehicle components.

According to recent estimates, the aerospace sector alone increased its remanufacturing output from $13 billion in 2011 to $17.5 billion by 2025. Other sectors, including heavy-duty/off-road equipment and IT devices, also experienced substantial growth. Overall, the U.S. remanufacturing industry has demonstrated consistent year-over-year expansion during this period, driven by growing demand for sustainable production methods, cost-effective repair solutions, and the broader adoption of circular economy principles across industrial supply chains.

To support informed decision-making regarding when remanufacturing is appropriate, the following flowchart provides a detailed framework for evaluation.

The decision-making framework shown in Figure 4 helps determine whether changes made to a medical device qualify as remanufacturing. By evaluating modifications in components, materials, and performance specifications, it provides clarity on regulatory classification. This structured approach ensures that organizations maintain compliance while optimizing product lifecycle strategies. Figure 4 plays a key role in supporting the integrating systematic tools into sustainable MedTech development.

This flowchart guides whether a device modification qualifies as remanufacturing. It evaluates:

- Changes in components or materials.
- Impact on safety and performance.

The revised version distinguishes between the outcomes "Likely Remanufacturing" and "Likely Not Remanufacturing", providing clear guidance for regulatory compliance and lifecycle management decisions.

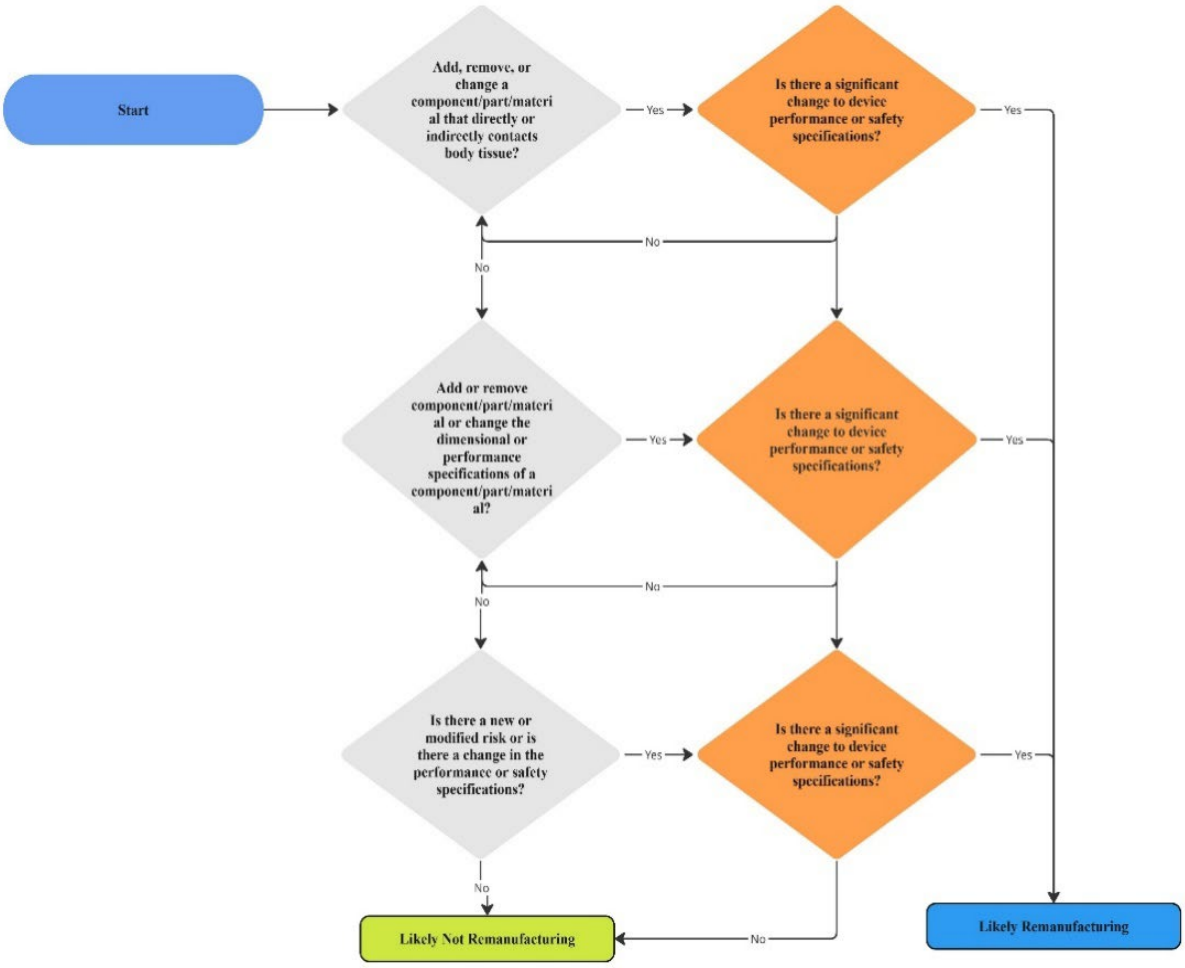


**Figure 4. Decision Flowchart for Remanufacturing Eligibility**

After examining technical considerations, particularly material degradation and remanufacturing feasibility, it is essential to translate these insights into actionable criteria that establish the key requirements for sustainable and regulatory-compliant remanufacturing.

## Key requirements

It is a common perception that remanufactured parts inherently perform below newly manufactured components; this assumption does not hold in regulated and quality-controlled remanufacturing environments. Certified remanufacturing processes are governed by stringent inspection, disassembly, cleaning, replacement, and testing procedures often in compliance with original equipment manufacturer (OEM) standards or relevant industry regulations.

Numerous studies and industrial practices have demonstrated that remanufactured parts can match or even exceed the quality and reliability of new parts, especially when wear-prone components are replaced with upgraded materials or enhanced through modern processes (e.g., laser cladding, precision machining, and surface treatments)

Sustainable remanufacturing involves several key requirements to ensure the process is environmentally friendly, economically viable, and socially responsible.

1. **Economics**:
1. **Cost Efficiency**: Implementing cost-effective processes to make remanufacturing financially viable.
2. **Market Demand**: Ensuring there is sufficient demand for remanufactured products to sustain the business.

2. **Environmental**:
1. **Resource Efficiency**: Minimizing the use of new raw materials by maximizing the reuse of existing components.
2. **Waste Reduction**: Reducing waste through efficient disassembly, cleaning, and reassembly processes.
3. **Energy Efficiency**: Using energy-efficient technologies and processes to reduce the carbon footprint.
3. **Social**:
1. **Job Creation**: Providing employment opportunities and supporting local economies.
2. **Health and Safety**: Ensuring safe working conditions and practices for employees.
4. **Regulatory Compliance**:
1. **Standards and Certifications**: Adhering to relevant standards and obtaining necessary certifications to ensure quality and safety.
2. **Environmental Regulations**: Complying with environmental laws and regulations to minimize the ecological impact.
5. **Quality Management**:
1. **Inspection and Testing**: Implementing rigorous inspection and testing procedures to ensure remanufactured products meet or exceed original specifications.
2. **Continuous Improvement**: Continuously refining processes and practices to improve resource efficiency and operational effectiveness.

The following table provides a comparative overview of remanufacturing, refurbishing, reuse, and recycling. It highlights the key distinctions between these strategies in the context of medical device development and long-term resource management.

| Term | Definition | Key Characteristics | Medical Device Example |
|---|---|---|---|
| **Remanufacturing** | The process of restoring a used product to a like-new condition that meets original specifications, using a mix of reused, repaired, and new parts. | 1.Involves disassembly, inspection, replacement of worn parts, testing, and reassembly.<br>2.Must meet original performance and safety standards.<br>3.Often subject to regulatory oversight (e.g., FDA in the US). | An X-ray machine remanufactured with a new control unit and refurbished imaging components |
| **Reuse** | Using a product or component again for the same or a different purpose without significant modification. | 1.Minimal or no processing involved.<br>2.May include cleaning or basic maintenance.<br>3.Often limited by wear and hygiene concerns. | Reusing hospital beds or surgical instruments after cleaning and disinfection |

| | | | |
|---|---|---|---|
| **Recycling** | The process of breaking down used products or materials into raw materials to make new products. | 1. Involves physical or chemical processing<br>2.Results in loss of original form or function<br>3.Common for metals, plastics, and electronics | Melting down aluminium casings from retired equipment to manufacture new parts |
| **Refurbishing** | Restoring a used product to a functional or aesthetically improved condition, but not necessarily to original specs. | 1.Less rigorous than remanufacturing<br>2.May include repairs, software updates, cosmetic fixes<br>3.Typically for resale or reuse with extended life | Replacing screen and housing of a patient monitor, updating software |

**Table 1. Comparative Overview of Remanufacturing, Refurbishing, Reuse, and Recycling**

By embracing remanufacturing, reuse, and recycling, we can significantly extend a product's useful life. However, it's essential to first understand how to manage each stage of a product's journey from creation to disposal for truly sustainable development.

Life Cycle Management provides direction towards building a sustainable system with continuous improvement. It exclusively focuses on approaches like Business approach, budget aspect & technical approach.

In general, it allows us to identify the problem very early in the stage, at that stage financial impact will be very little.

Medical products have crucial factors as they are directly connected with human life risk, so it must be developing the medical products with appropriate functioning for this critical reason. Associated with life cycle management, being able to develop a sustainable medical product to create a positive impact in medical industries.

While the comparative overview outlines the fundamental distinctions between circular strategies, the Life Cycle Assessment (LCA) provides a quantitative evaluation of their environmental impacts, offering deeper insight into the advantages of remanufacturing within the MedTech sector.

The LCA (Life Cycle Assessment) process was conducted in accordance with ISO 14040 and ISO 14044 standards to evaluate the environmental impacts of remanufacturing versus producing new medical devices. The assessment covered four key stages: Goal and Scope Definition, Inventory Analysis, Impact Assessment, and Interpretation.

**There is a framework (Figure. 5) for making life cycle screenings which include 4 steps:**

1. **Goal and scope definition:** The goal contains information about the objective of performing the LCA. Target audiences & the product on which it will be perform. Scope includes product related information such Boundary, Functional unit, data parameters, Impact assessment method etc.
2. **Life cycle inventory analysis (LCI):** Its emphases the result of the product under the LCA study by aggregating all fractional contributions of the inputs and outputs from each unit process within the product system for the product. It generates quantitative environmental load information of a product in its entire life cycle.

3. **Life cycle impact assessment (LCIA):** Due to environmental load it will create environment impact, which then assessed by a process which is call as "Characterization".
4. **Life cycle interpretation:** In this stage recognize the environmental issues & assessed the result.

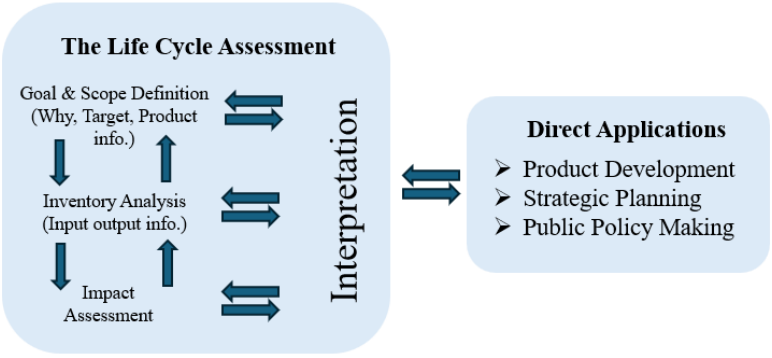


**Figure 5. Phases of Life Cycle Assessment (LCA)**

Adaptive life cycle management with the help of technology underpins a sincere attempt at upgrading the medical technology industry forever. Using predictive design can potentially accelerate the production and introduction of newer technology to the healthcare industry and create noticeable results for clinical healthcare. We are also looking at substantial benefits on the part of concerned stakeholders in the medical technology industry. Here are some of the most noticeable impacts of life cycle management (See figure 6):

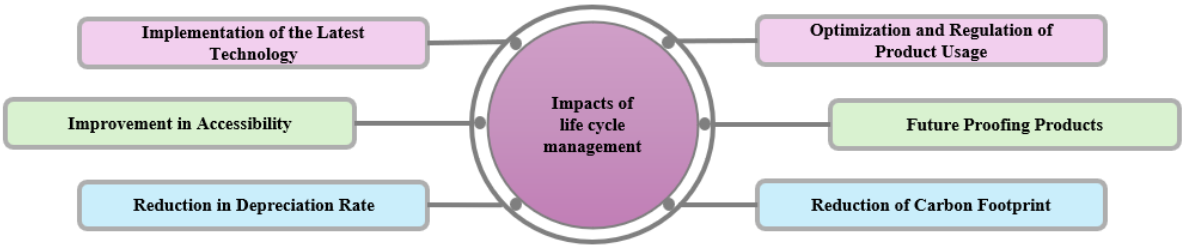


**Figure 6. Potential impacts of adapting life cycle management**

Having gained knowledge about remanufacturing, reuse, and recycling, to ensure successful implementation, the next step involves in integrating a systems engineering approach via the Sustainable VEE model.

# Implementation

## Traditional VEE model

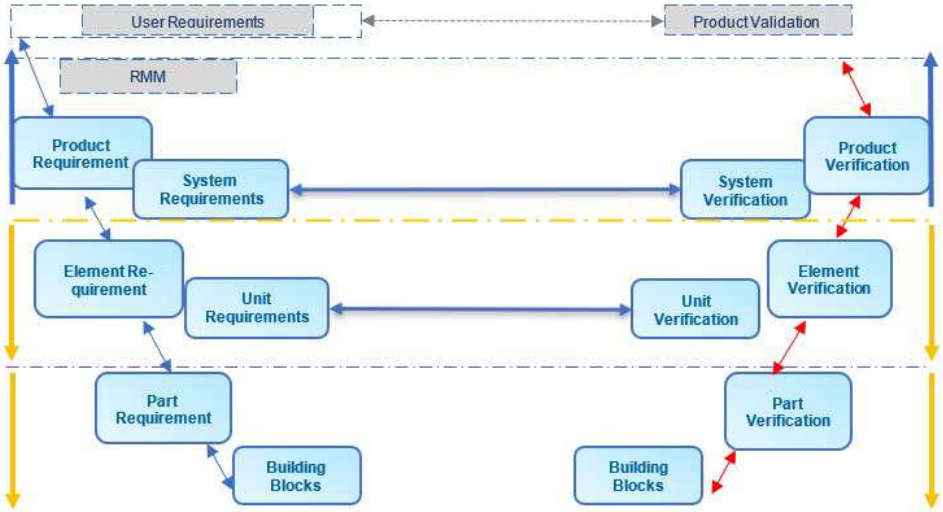


**Figure 7. Traditional V-Model for System Development**

The Figure 7.V-model is a representation of a system's development lifecycle. It is used to produce rigorous development lifecycle models and project management models.

The V-model summarizes the main steps to be taken in conjunction with the corresponding deliverables within the system life cycle framework, it describes the activities to be performed and the results that must be produced during product development.

The left side of the "V" represents the decomposition of requirements and the creation of system specifications. The right side of the "V" represents an integration of parts and their verifications validation. However, requirements need to be validated first against the higher-level requirements or user needs.

Validation can be expressed with the query "Are you building the right thing?" and verification with "Are you building it right?"

To ensure successful implementation, the next step involves integrating a systems engineering approach via the Sustainable VEE model.

## Sustainable VEE model

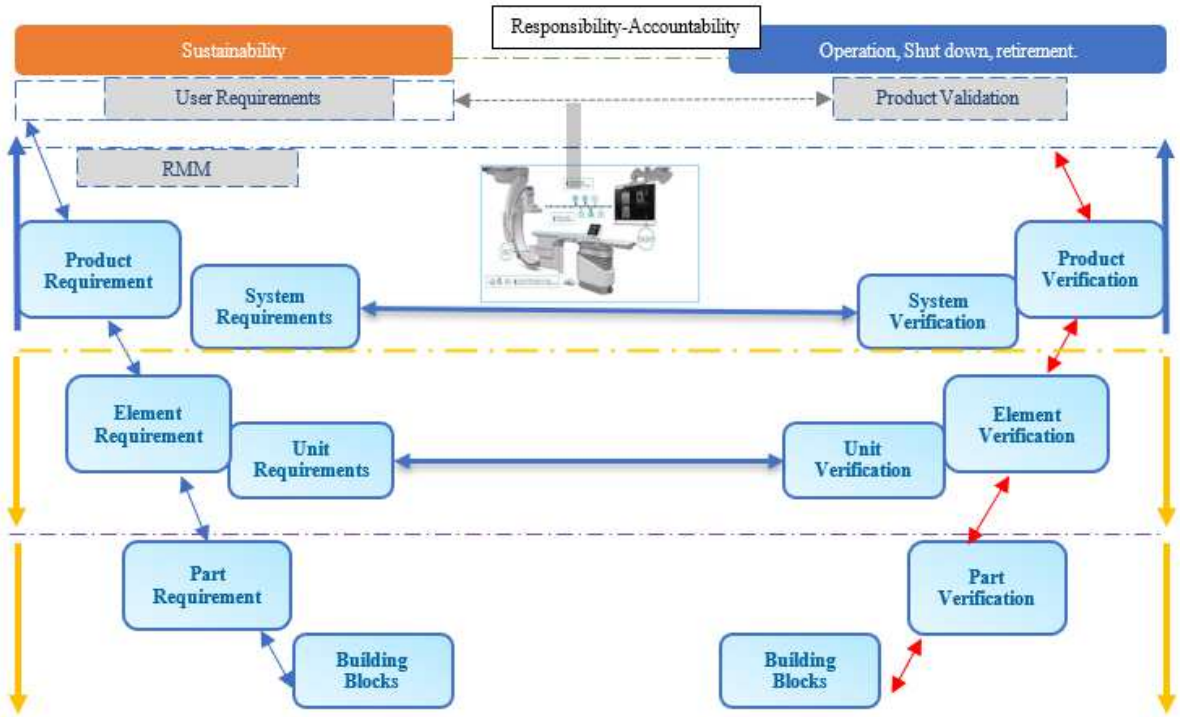


**Figure 8. Sustainable VEE model for Systems Engineering**

Figure 8 introduces the Sustainable VEE model, a structured evolution of the traditional V-model, specifically adapted to embed sustainability into each phase of systems engineering. Rather than presenting generic lifecycle stages, this model distinctly defines the phases of Definition, Development, and Deployment, each integrated with sustainability checkpoints and decision-making tools.

Systems engineering, within this framework, becomes a strategic enabler of innovation, quality, and long-term environmental responsibility. The Sustainable VEE model avoids overlapping definitions by clearly delineating the purpose and scope of each phase. It incorporates tools such as Life Cycle Assessment (LCA), Failure Mode and Effects Analysis (FMEA), and degradation modeling to guide early-stage decisions and ensure alignment with sustainability goals.

Unlike traditional waterfall models, which often lack adaptability, the Sustainable VEE model supports iterative validation and continuous improvement. It emphasizes proactive systems management ensuring that systems are not only built to specification but are also optimized for reuse, remanufacturing, and regulatory compliance. This approach addresses the challenges of evolving standards and resource constraints by embedding sustainability into the technical direction and management of system development.

The Sustainable VEE Model was applied to an aging ultrasound probe with aluminum alloy housing. Initially designed with a 10-year lifecycle, the probe was assessed for remanufacturing at year 9. The technical assessment (using FMEA) revealed fatigue in connector pins and minor pitting on the probe causing due to saline exposure. By integrating lifecycle data with the Sustainable VEE model, design revisions and remanufacturing steps were validated through iterative simulation and testing, resulting in an extension of lifecycle to 20 years, while maintaining FDA compliance.

## Systems life cycle assessment

**SLCA (Systems Life Cycle Assessment) Example: Portable Ultrasound Device:**

SLCA (Systems Life Cycle Assessment) is a method that evaluates the environmental and social impacts of a system over its entire life cycle, from raw material extraction to end-of-life treatment. SLCA can help you identify the hotspots, trade-offs, and opportunities for improvement in your system design and management. For example, you can use SLCA to compare different materials, technologies, or scenarios for your system, and select the ones that have the lowest environmental footprint and the highest social benefit.

A manufacturer evaluates the environmental and social impacts of a portable ultrasound device using SLCA across its entire lifecycle:

**Raw Material Extraction:** Aluminium alloy and plastics are assessed for energy consumption and mining impacts. Aluminium is preferred due to its high recyclability and lower long-term degradation.

**Manufacturing:** The company uses energy-efficient CNC machining and modular assembly to reduce emissions and waste.

**Use Phase:** The device is designed for low power consumption and minimal maintenance, improving operational sustainability in rural clinics.

**End-of-Life:** SLCA identifies hotspots in disposal and encourages remanufacturing of key components like transducers and control units, reducing landfill waste and conserving resources.

## Adopt and implement circular design principles

Circular design principles are guidelines that help you design systems that are more sustainable and circular. Some of the circular design principles are design for durability, design for modularity, design for adaptability, design for disassembly, design for reuse, design for repair, design for refurbishment, and design for recycling.

Circular business models are strategies that help you capture the value of your system beyond its initial use. Some of the circular business models are product as a service, product leasing, product sharing, product take-back, product remanufacturing, and product recycling. By implementing these models, you can create new revenue streams, reduce costs, and enhance customer loyalty and satisfaction.

**Circular Design Principles Applied**

To enhance sustainability, the device incorporates:

- **Design for Durability**: Rugged casing and corrosion-resistant materials extend lifespan.
- **Design for Modularity**: Easily replaceable probe and battery modules simplify repair and upgrade.
- **Design for Disassembly**: Snap-fit components and minimal adhesives allow efficient end-of-life processing.
- **Design for Reuse and Remanufacturing**: Key parts are labeled and standardized for recovery and reconditioning.

- **Product-as-a-Service Model**: Instead of selling, the company leases devices with maintenance included, ensuring controlled lifecycle management and incentivizing reuse.

## Review and improve your system continuously

This means monitoring and evaluating your system performance, identifying gaps and risks, and implementing corrective and preventive actions. You also need to keep up with the latest trends, technologies, and best practices in resource optimization and circularity, and seek opportunities for innovation and learning. By doing so, you can ensure that your system remains relevant, efficient, and effective in the long term.

There are several related issues that concern enterprise management and systems integration, economic systems analysis, cognitive ergonomics, and system assessment and evaluation for trustworthiness and responsible resource management.

Having understood remanufacturing, reuse, recycling, degradation, and lifecycle assessment (LCA) and their importance for long-term resource efficiency, we have conducted a study and examined the materials using various tools. Now, we need to delve into the next section.

# Results

The degradation rate of an alloy refers to the gradual deterioration of its mechanical and structural properties due to environmental and operational factors such as stress, corrosion, temperature, and cyclic loading. For example, in aluminum alloys commonly used in medical devices and lightweight structural components, degradation may occur through mechanisms like fatigue crack initiation, oxidation, or microstructural changes over time. Although aluminum alloys can exhibit a long aging life (typically 50–75 years), the degradation rate increases significantly under repetitive use, sterilization cycles, or exposure to moisture and saline environments. Understanding this rate is critical in remanufacturing, as it helps assess the residual life and reusability of components. Monitoring degradation enables predictive maintenance, ensures patient safety in MedTech applications, and informs decisions on whether to reuse, refurbish, or replace components thus directly supporting lifecycle extension and sustainability goals.

We have studied the 5 diverse types of material with its property considering its current life (Approx.10 Years) & extension of life (Approx. 20 Years).

The Table 2. provides a comparison of varied materials based on their fatigue strength, aging duration, and factor of safety (FoS). Also, a quantitative comparison was conducted for commonly used materials in medical device manufacturing, focusing on key parameters influencing sustainability, performance, and remanufacturing potential. The selected materials include aluminum alloy, cast iron, ductile iron, cast steel, and casting bronze. Table 2 summarizes their properties.

| Material | Density ($g/cm^3$) | Corrosion Resistance | Recyclability | Fatigue Strength (MPa) | Ageing (Years) | Factor Of Safety (FoS) | Typical Degradation Rate | Suitability for Remanufacturing |
|---|---|---|---|---|---|---|---|---|
| **Aluminum Alloy** | 2.7 | High | >95% | 100–200 | 50-75 | 1.5 to 2.5 | Low | High |
| **Cast Iron** | 7.2 | Moderate | ~80% | 90–150 | 100 | 2.5 to 4 | Moderate | Medium |
| **Ductile Iron** | 7.1 | Moderate-High | ~85% | 120–200 | 100 | 2.5 to 4 | Moderate | High |
| **Cast Steel** | 7.8 | Moderate | ~90% | 250–500 | 80 | 2.5 to 4 | Low | High |
| **Casting Bronze** | 8.7 | Very High | ~90% | 150–300 | 100 | 3 to 4 | Very Low | Medium |

**Table 2. Evaluation and Quantitative comparison of Material Suitability for Remanufacturing Based on Degradation Behavior**

**Effect of properties on sustainability decisions:**

Density influences the weight of medical devices, affecting energy consumption during transport and handling. Lower-density materials like aluminium alloy support lightweight design, improving efficiency and usability.

Corrosion Resistance determines a material's durability in clinical environments. High resistance reduces maintenance needs and extends service life, making materials like casting bronze and aluminium alloy more sustainable.

Recyclability directly impacts circularity. Materials with high recyclability, such as aluminium alloy and cast steel, enable efficient resource recovery and reduce environmental burden.

Fatigue Strength affects a device's ability to withstand repeated stress. Materials with higher fatigue strength, like cast steel, are ideal for long-term use but may require more energy-intensive processing.

Ageing reflects the expected lifespan of a material. Longer ageing periods support extended product cycles, reducing the frequency of replacements.

Factor of Safety (FoS) indicates the margin against failure. A higher FoS enhances reliability, which is crucial for patient safety and regulatory compliance.

Degradation Rate helps assess how quickly a material deteriorates. Lower degradation rates favor remanufacturing by preserving structural integrity over time.

Suitability for Remanufacturing combines all these factors to guide material selection. Materials scoring high in recyclability, durability, and low degradation like aluminium alloy are preferred for sustainable MedTech applications.

**Key Observations:**

- Aluminum alloys, due to their low density, excellent corrosion resistance, and high recyclability (>95%), are widely used in diagnostic equipment housings and are highly suitable for remanufacturing.
- Ductile iron offers a good balance of strength and remanufacturing feasibility, although it is heavier than aluminum and may require more robust handling during disassembly.
- Cast steel provides the highest fatigue strength, making it ideal for structural components but is more energy-intensive to process.
- Casting bronze, while excellent in corrosion resistance and stability, is less common in high-volume MedTech manufacturing due to its weight and cost.

Above table provides a clear and data-driven foundation for selecting materials based on both technical performance and metrics, supporting downstream decisions in lifecycle planning and remanufacturing strategies.

Failure Mode and Effects Analysis (FMEA) is a widely adopted methodology for enhancing reliability, safety, and quality in engineering systems. In this study, FMEA was applied to aluminum alloy components to systematically identify potential failure modes, assess associated risks, and evaluate their impact. The results of this analysis are presented in Figure 10.

The following analysis was conducted for the use of aluminium alloy, considering various functionalities under different environmental conditions and prolonged usage.

The identified failure mode related to environmental exposure is the degradation of aluminium, potentially leading to part fracture. Given the component's critical function, the severity of this failure is considered high. To mitigate this risk, we have implemented protective coatings and corrosion testing as preventive controls. Both the likelihood of occurrence and the ability to detect this issue are rated at 2, indicating a very low risk. Consequently, the resulting Risk Priority Number (RPN) is 36, which is within acceptable limits.

For extended use, the identified failure mode is insufficient fatigue strength, which has the same high severity as environmental degradation. To address this risk, we have increased the factor of safety as a preventive measure. However, the likelihood of occurrence remains high, and the detection rating is also elevated at 3. As a result, the Risk Priority Number (RPN) is 162, which is considered high and unacceptable.

| ID | Item/Function | Requirement | Potential Failure Mode | Effect | Cause / Mechanism of Failure | Severity | Prevention Control | Occurrence | Classification | Detection | RPN [S*O*D] |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | General use of Aluminum Alloy | Withstand environmental conditions for 10+ years | Unable to withstand environmental conditions | Part Fractured | Corrosion or material degradation due to environmental exposure | 9 | Protective coating, corrosion testing | 2 | Acceptable | 2 | 36 |
| 2 | Under continuous loading | Support structural integrity for extended use (>10 years) | Fatigue crack growth due to repeated stress | Structural failure, crack propagation | Insufficient fatigue strength or weld integrity under cyclic loads | 9 | Increased Factor of Safety, fatigue testing, weld inspection | 6 | Not acceptable | 3 | 162 |

**Figure 9. Failure Mode and Effects Analysis (FMEA) Table for Aluminum Alloy**

An RPN (Risk Priority Number) of 162 is considered high and unacceptable in most engineering and medical device contexts. Industry standards, such as those used in ISO 14971 for medical device risk management, typically flag RPN values above 100 as requiring corrective action. Values exceeding 150 often indicate a significant risk that could compromise safety or performance, especially in critical applications like MedTech. In this case, the high RPN reflects a combination of severe impact, high likelihood of oc-

currence, and limited detectability necessitating design changes or preventive measures to ensure regulatory compliance and patient safety.

Figure 10. Bathtub Curve indicating early failures, stable performance, and wear-out phase, highlighting the critical window for remanufacturing and reuse.

The bathtub curve is a well-established reliability model, it is particularly useful here to illustrate how degradation patterns of MedTech components such as aluminium alloy housings correlate with failure rates over time, reinforcing the need for timely remanufacturing decisions.

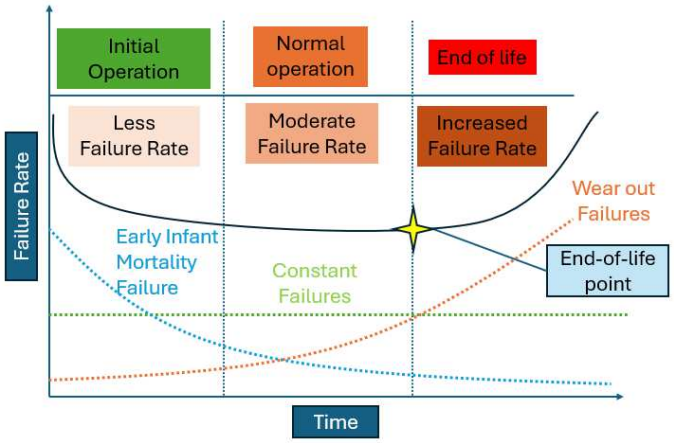


**Figure 10. Bathtub Curve Representing Failure Rates**

# Discussion

The findings highlight the effectiveness of remanufacturing and lifecycle management strategies in enhancing sustainability within MedTech systems. A key trade-off observed is between cost-efficiency and the complexity of implementing these systems across diverse medical devices. The integration of system-level approaches offers new insights into optimizing resource use while maintaining product quality and compliance. Importantly, this paper introduces a structured framework that bridges technical feasibility with environmental responsibility, marking a significant advancement in sustainable healthcare engineering.

Remanufactured medical device especially single-use devices (SUDs) like electrophysiology catheters and ultrasound probes—must meet stringent FDA 510(k) clearance requirements. These include functional performance and sterility testing that often exceed the sampling protocols used for new devices.

In fact, reprocessed devices are tested individually for performance and sterility before release, whereas new devices may be batch-tested and distributed before sterility results are finalized.

This rigorous testing has led to findings that remanufactured devices fail less frequently than new ones, particularly in high-use hospital environments. For example, remanufactured ultrasound catheters have shown comparable or better durability under repeated sterilization cycles compared to new units, due to enhanced inspection and component replacement during reprocessing.

Moreover, refurbished imaging equipment (e.g., MRI and CT scanners) restored to OEM specifications often matches the performance of new systems, with degradation rates remaining within acceptable thresholds over extended use.

These devices are typically used in facilities with budget constraints, where performance reliability is critical.

The FDA emphasizes that remanufactured devices must maintain substantial equivalence to new devices in terms of safety and effectiveness throughout their lifecycle. This includes maintaining degradation rates within industry-accepted limits, ensuring that remanufactured components do not compromise patient safety or clinical outcomes.

# Conclusion

This study underscores the transformative potential of integrating sustainability into systems engineering through the Sustainable VEE model, offering a structured and data-driven approach to managing the entire lifecycle of MedTech devices. By leveraging tools such as Life Cycle Assessment (LCA), Failure Mode and Effects Analysis (FMEA), and degradation modeling, organizations can make informed remanufacturing decisions that extend product lifespans, reduce environmental impact, and ensure regulatory compliance.

The ultrasound probe case study exemplifies how lifecycle extension from 10 to 20 years can be achieved through targeted remanufacturing strategies, validating the model's practical applicability. Moreover, the comparative analysis of materials highlights aluminium alloy as a leading candidate for sustainable remanufacturing due to its favourable properties.

Looking ahead, future research should focus on:

Developing predictive analytics frameworks to anticipate degradation and optimize remanufacturing schedules.

Integrating AI and IoT technologies for real-time lifecycle monitoring and adaptive maintenance.

Establishing global standards and certifications to harmonize remanufacturing practices across regions.

By embracing these directions, the MedTech industry can evolve toward a more resilient, cost-effective, and environmentally responsible future where innovation and sustainability coalesce to improve healthcare outcomes.

# References


[1]Wikipedia, “Remanufacturing,” *Wikipedia*, [online]. Available: https://en.wikipedia.org/wiki/Remanufacturing

[2] U.S. Food and Drug Administration, “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,” *FDA Guidance*, 2023. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

[3] A. Van den Berg and P. Lubbers, “Sustainability in MedTech Development: An Iterative Approach Based on Ecodesign and Life Cycle Screenings,” *OnDrugDelivery*, [Online]. Available: https://www.ondrugdelivery.com/sustainability-in-medtech-development-an-iterative-approach-based-on-ecodesign-and-life-cycle-screenings/

[4] ISO, “Life Cycle Assessment: Best Practices of International Organization for Standardization (ISO 14040 Series),” *APEC*, 2004. [Online]. Available: https://www.apec.org/docs/default-source/Publications/2004/2/Life-Cycle-Assessment-Best-Practices-of-International-Organization-for-Standardization-ISO-14040-Ser/04_cti_scsc_lca_rev.pdf

[5] Deloitte, “Linear and Closed-Loop Models,” *Deloitte United States*, 2010. [Online]. Available: http://www.deloitte.com/assets/DcomUnitedStates/Local%20Assets/Images/Full%20Size%20Images/us_LinearandClosedloopmodels_500x428_101910Fig1.jpg

[6] J. C. Kaiten, S. N. Kara Stonehouse, “Large Scale Collaboration towards Sustainable Development,” *Master’s Program in Strategic Leadership Towards Sustainability*, Blekinge Institute of Technology, 2010.

[7] S. C. Rowe et al., “Sustainable Remanufacturing,” in *Sustainable Design and Manufacturing 2024*, Springer, 2024, pp. 1–15. [Online]. Available: https://link.springer.com/chapter/10.1007/978-3-031-52649-7_1

[8] Remanufacturing Industries Council, “Specifications for the Process of Remanufacturing,” *RIC001.1-2016*, [Online]. Available: https://remancouncil.org/wp-content/uploads/_pda/2020/04/RIC001.1-2016-Specifications-for-the-Process-of-Remanufacturing.pdf

[9] Reverse Logistics Association, “Reverse Logistics Trends in Remanufacturing,” *RLA*, [Online]. Available: https://rla.org/media/article/view?id=713

[10] MDPI, “Special Issue: Sustainable Remanufacturing,” *Sustainability*, MDPI. [Online]. Available: https://www.mdpi.com/journal/sustainability/special_issues/Sustainable_Remanufacturing

[11] MDPI, “Metals: Article on Material Degradation and Circularity,” *Metals*, vol. 14, no. 3, 2024. [Online]. Available: https://www.mdpi.com/2075-4701/14/3/352

[12] M. P. Ercolino, “Failure Criteria for Real-Time Assessment of Structural Degradation,” *Proc. AAM 2020*, University of Greenwich. [Online]. Available: https://gala.gre.ac.uk/id/eprint/30049/

[13] U.S. Food and Drug Administration, “Remanufacturing Medical Devices,” FDA Guidance, 2021. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

[14] iHealthcareAnalyst, Inc., “Refurbished and Remanufactured Medical Devices Market Trends,” 2023. [Online]. Available: https://www.ihealthcareanalyst.com/refurbished-remanufactured-medical-devices-market-trends/

# Biography

**Sharad Rayguru.** Sharad is a Lead Systems Designer at Philips Healthcare India, specializing in systems engineering and model-based systems engineering. He has driven R&D initiatives, enhanced best practices, and conducted impactful research showcasing the value of systems engineering in medical devices R&D. Sharad holds a degree in Mechanical Engineering, a master's in Control Systems, is a member of TLI Cohort 9, and an experienced Systems Engineering practitioner.

**Aniket Mitkari**. Aniket is a System Designer at Philips Healthcare India, working in system requirements documentation. He has over five years of experience as a design engineer. Aniket has both a diploma and a bachelor's degree in mechanical engineering.