VASMED

White paper on

An Agile Framework for End-to-End Development of Active Medical Devices

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Contents

1. Purpose

This whitepaper details Vasmed's comprehensive, structured, and compliant framework for end-to-end product development of advanced medical devices. The primary focus is on Class III active medical devices for diagnosis and therapy, including implantable and life-supporting systems.

The core objective is to present an efficient, risk-based methodology that encompasses:

- **Mechanical Design & logic design**
- **Electronics (PCBA) Development**
- **Multi-Controller Firmware Software development:** Incorporating advanced algorithms (e.g., PID controls, filters, mathematical modelling) with inherent redundancy.
- **Application Software Development:** full stack development of database back end, middle ware in C++ and front end in Qt/QML, within a Qt framework or proprietary framework.
- **Regulatory and documentation compliance,** to all relevant essential and critical standards as per IEC, ISO and MDR requirements.

This framework emphasizes an agile project management approach executed by Vasmed's technical team, characterized by:

- Iterative Prototyping
- Continuous Verification with Tangible Proof Points at each stage
- Periodic and Comprehensive Risk Evaluation: Including Design Failure Mode and Effects Analysis (DFMEA), clinical risk assessment, and software risk analysis.
- Rigorous Testing and Structured Validation
- Manufacturing Setup and Certification readiness

The delineated process aims to achieve certification readiness for these complex medical devices within an approximate 18-month timeframe. This is accomplished by proactively addressing and mitigating technical and clinical risks while ensuring rigorous adherence to international safety and software lifecycle standards, specifically IEC 60601-x and IEC 62304.

2. Introduction

The development of active medical devices for diagnosis and therapy, presents substantial technical and regulatory challenges. These devices often integrate

complex mechanical assemblies, electronics, multi-layered firmware, and intuitive application software, all while demanding the highest levels of safety, reliability, and efficacy. This document details a robust service offering designed to navigate these complexities, providing a systematic pathway from concept to certified product, underpinned by a proactive and comprehensive risk management philosophy.

2.1. Background: Existing Technical Approaches & Limitations

Traditional medical device development can suffer from siloed engineering disciplines, leading to integration challenges and overlooked risks late in the lifecycle. Waterfall methodologies, while structured, may lack the flexibility to adapt to evolving requirements or unforeseen technical hurdles and risks discovered during development, potentially extending timelines and increasing costs. Furthermore, ensuring consistent compliance with stringent standards like IEC 60601-x and IEC 62304 throughout the development lifecycle requires a deeply integrated quality management system where risk management is not merely a checkbox activity but a driving principle. Limitations in early-stage risk identification, prototyping, and verification can also lead to costly redesigns. This white paper proposes an integrated, agile, and fundamentally risk-based approach to mitigate these common pitfalls.

2.2. The Imperative of Skilled Execution and a Risk-Based Approach

Beyond processes and methodologies, the successful realization of complex medical devices hinges critically on the expertise, collaborative capability, and risk-aware mindset of the development team. Each phase, from intricate mechanical design to safety-critical firmware and compliant software, demands specialized knowledge and seasoned engineering judgment, consistently applied through the lens of risk management as defined in ISO 14971.

Our approach emphasizes the deployment of cross-functional teams, where individuals possess deep expertise in their respective domains—mechanical engineering, electronics design, firmware programming, application software development, quality assurance, and regulatory affairs—all trained and experienced in risk management principles. This collective cross functional proficiency ensures that technical and clinical risks are identified early, evaluated thoroughly, and mitigated effectively, enabling the development of innovative yet safe solutions that consistently meet project targets within the demanding regulatory landscape.

3. Core Architecture

Our product development services are built upon an integrated framework that ensures seamless collaboration between various engineering disciplines and continuous alignment with regulatory requirements, with risk management as its central pillar. This holistic approach covers the full spectrum of device creation, from initial ideation through to manufacturing readiness, driven by a team skilled in translating complex requirements into tangible, high-quality, and safe medical devices. We leverage on a platform-based strategy with pre-existing core components (certified PCBAs, software libraries) for accelerated, risk-reduced, and cost-effective medical device creation. This allows focus on your product's novel features and proprietary algorithms to be added without IP conflict and confidentiality.

Annexure A – shows the overall model of Product development approach.

3.1. Mechanical Design and Engineering

Our mechanical design and engineering phase begins with conceptualization and industrial design, translating user needs and clinical requirements into ergonomic and manufacturable physical forms. A risk-based approach is integral from initiation.

Key activities include:

- **Material Selection:** Rigorous evaluation based on biocompatibility (ISO 10993) (as per the class of the device), sterilizability (If applicable), structural integrity, potential failure modes, and cost-effectiveness.
- **Advanced CAD Modeling:** Utilization of tools like SolidWorks or Creo for detailed 3D representations.
- **Design Failure Mode and Effects Analysis (DFMEA):** Proactive identification of potential mechanical failure modes, their root causes, and their impact on device safety and performance.
- **Finite Element Analysis (FEA):** Simulation and optimization of mechanical performance under diverse stress, thermal, and fluidic conditions, directly addressing risks identified during DFMEA and validating design robustness.
- **Mechanism Development (for active devices):** Focused design of intricate mechanisms, emphasizing reliability and characterization of potential failure points.
- **Application of Design Principles:**

- **Design for Manufacturability (DFM) and Design for Assembly (DFA):** Optimization for efficient, scalable production, mitigating manufacturing-related risks.
- **Design for Servicing (DFS):** Minimization of risks and complexities associated with device maintenance and repair, enhancing long-term safety and reliability.

- **Rapid Prototyping:** Iterative physical evaluation for early identification and resolution of design flaws, and verification of implemented risk control measures.

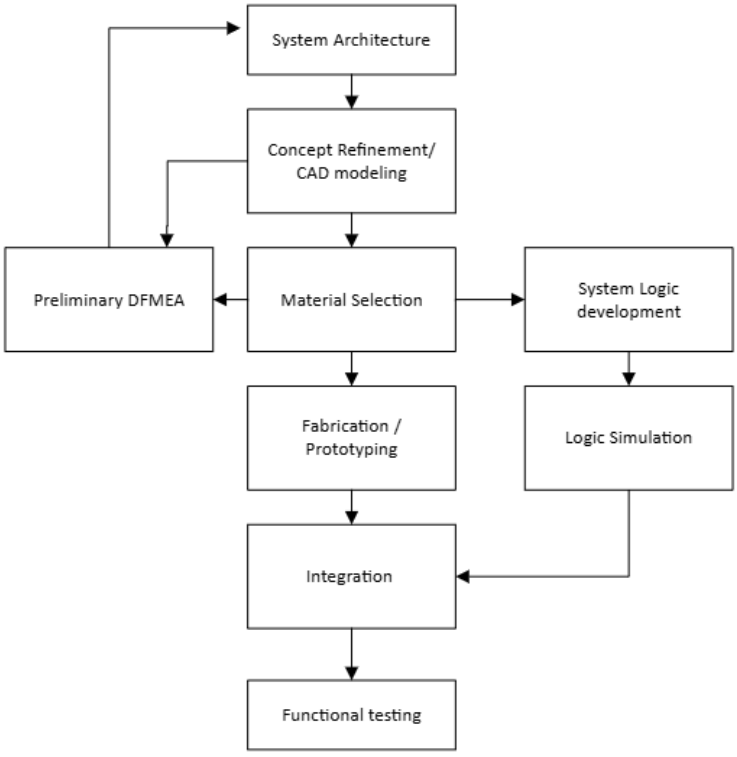


Figure 1: Mechanical Design framework

3.2. PCBA Design, Fabrication, and Realization

Vasmed's approach to Electronics and Printed Circuit Board Assembly (PCBA) development is centered on a robust, platform-based strategy. This methodology leverages a core, IEC certified, controller-integrated PCBA architecture, featuring known and reliable controllers (e.g., from Texas Instruments and STMicroelectronics). This foundational platform is consistently utilized across diverse medical device requirements.

Core Platform and Customization:

The cornerstone of our PCBA development is a standardized, pre-certified main controller board. This platform provides the essential processing capabilities and common interfaces. To meet the unique demands of each product, specialized **Data Acquisition PCBA daughter boards** are seamlessly integrated. This modular design allows for tailored functionality, such as specific sensor interfaces or unique signal processing capabilities, without redesigning the core control system.

This platform-based strategy significantly facilitates the development of risk-mitigated designs and enables a more deterministic approach to electrical safety testing compared to developing entirely new PCBAs for each product.

Key Advantages and Development Stages:

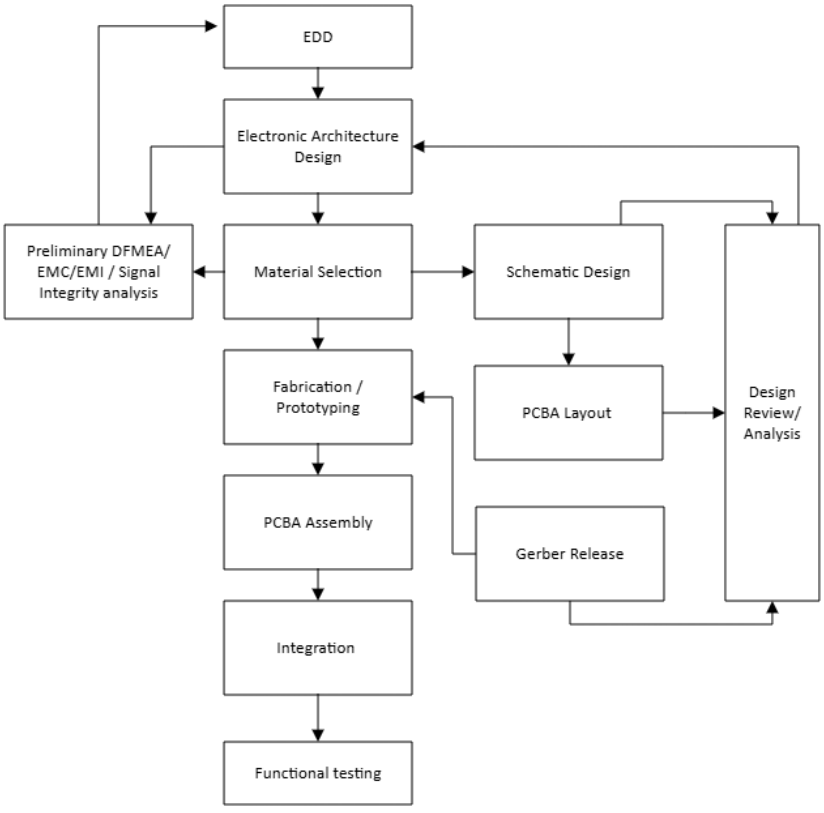
- **Reusable Certified Components:** A significant advantage of this model is the ability to reuse **certified battery PCBA modules** and their associated **validated software code**. Power management and battery systems are notoriously challenging areas in medical device development, often subject to stringent regulatory scrutiny. By leveraging pre-certified and field-proven battery solutions and their firmware, we significantly reduce development timelines, mitigate risks, and streamline the certification process for new devices.
- **Platform Adaptation and Architecture Definition:** Development for a new product begins with adapting the core IEC certified PCBA platform. This includes selecting and configuring the appropriate 32-bit Microcontroller Units (MCUs) or Central Processing Units (CPUs) from our established families (e.g., Texas Instruments, STMicroelectronics) based on the specific device's processing power, peripheral integration needs, power consumption targets, and inherent safety feature requirements. Detailed architectural documents are created for integrating the necessary data acquisition and other peripheral interface daughter boards.
- **Schematic Capture and PCB Layout:** This phase focuses on the design of the data acquisition daughter boards and any necessary interface circuitry. Emphasis is placed on ensuring signal integrity, power integrity, Electromagnetic Compatibility (EMC) and Interference (EMI) compliance (per IEC 60601-1-2), and effective thermal management. Multi-layer board designs (with careful separation of power, ground, and signal planes), potentially incorporating High-Density Interconnects (HDI), are engineered to prevent common failure modes such as short-circuits and crosstalk.
- **Component Sourcing and Qualification:** For both the core platform and custom daughter boards, prioritization is given to medical-grade components with established reliability, comprehensive specifications, and robust supplier

lifecycle management. This mitigates risks associated with component obsolescence or substandard performance.

- **Power Management Integration:** While often leveraging certified battery PCBAs, the overall power management design for the integrated system (core board + daughter boards) is carefully considered. This includes efficient power distribution and ensuring strict adherence to electrical safety standards for the complete assembly. Failure Mode and Effects Analysis (FMEA) is applied to these integrated power subsystems.
- **Fabrication and Assembly:** PCBAs (both core and daughter boards) are manufactured through qualified vendors. The process includes rigorous In-Circuit Testing (ICT) and Functional Testing (FCT) to validate quality, confirm reliability, and verify the efficacy of implemented risk control measures for the entire electronic assembly.

This platform-centric approach to PCBA development, emphasizing the reuse of certified core controller and battery modules alongside customizable data acquisition boards, allows Vasmed to accelerate product development, enhance reliability, and more efficiently navigate the complexities of medical device design and certification. Figure 2: Mechanical Design framework

Figure 2: Mechanical Design framework



3.3. Platform-Centric Firmware Development

Vasmed's firmware development for active medical devices is engineered for reliability, safety, and real-time performance, strictly adhering to IEC 62304. Our approach leverages a platform-based PCBA architecture, predominantly utilizing standardized controllers (e.g., from Texas Instruments and STMicroelectronics families). This strategy significantly enhances firmware reusability, accelerates development cycles, and simplifies the integration of product-specific functionalities, such as those required by peripheral daughter boards.

Core Principles & Advantages:

- **Accelerated Development through Reusability:**
  - A significant portion of the firmware, including low-level drivers, Hardware Abstraction Layers (HALs), and core communication protocol stacks (e.g., SPI, I2C, UART), forms a pre-validated, reusable library. This is a direct benefit of our standardized PCBA platform.
  - Development efforts are thus concentrated on application-specific modules that implement unique device functionalities, control peripheral daughter boards, and execute advanced algorithms. This targeted approach drastically reduces overall development and verification time, leading to faster code releases.
- **Modular and Layered Architecture:**
  - Firmware is designed with a layered and modular architecture. This promotes separation of concerns, facilitates component-specific risk analysis, and allows for efficient integration of both reusable core components and new application-specific modules, including those for daughter board peripherals.
- **Critical Algorithm Implementation:**
  - Advanced algorithms, such as Proportional-Integral-Derivative (PID) control loops, digital filters (e.g., FIR, IIR) for sensor data optimization, and mathematical models of physiological processes, are meticulously implemented and integrated. Each algorithm undergoes rigorous design, coding, tuning, verification, and risk assessment to ensure stability, accuracy, and safety.
- **Software Quality Assurance (SQA) and Standards:**
  - Strict adherence to standardized coding structures and guidelines enhances code readability, maintainability, and reduces error potential.
  - SQA tools, including static and dynamic analyzers, are employed throughout the development lifecycle to proactively identify defects and ensure compliance.

- **Deterministic Performance and Safety:**
    - The firmware architecture ensures predictable timing and execution of critical tasks.
    - Where applicable, multi-controller designs, hardware/software redundancy (watchdog timers, heartbeat mechanisms), and fail-safe principles (error detection, fault containment, graceful degradation) are implemented to enhance fault tolerance and mitigate operational risks.
- **Comprehensive Risk Management (IEC 62304):**
    - A software risk management process, fully compliant with IEC 62304, is integral to the entire lifecycle. Potential software hazards are identified early, with mitigation strategies embedded into the architecture and design, and all activities meticulously documented.
- **Security and Communication Integrity:**
    - Secure bootloaders and robust, error-checked communication protocols are implemented to protect against unauthorized access and ensure reliable data exchange.
- **Streamlined Verification, Validation, and Release:**
    - **Unit Testing:** Reusable core modules have established test suites. New application-specific modules undergo exhaustive unit testing.
    - **Integration Testing:** Focuses on the seamless interaction between core libraries and new modules, particularly those interfacing with daughter boards.
    - **System Testing:** Validates the complete firmware on target hardware, ensuring all requirements are met under operational conditions.
    - Successful completion of these rigorous testing phases, supported by comprehensive IEC 62304 compliant documentation, is mandatory for firmware release.

  This platform-centric methodology allows Vasmed to efficiently develop sophisticated, safe, and reliable firmware, reducing time-to-market while upholding the highest quality and regulatory standards.

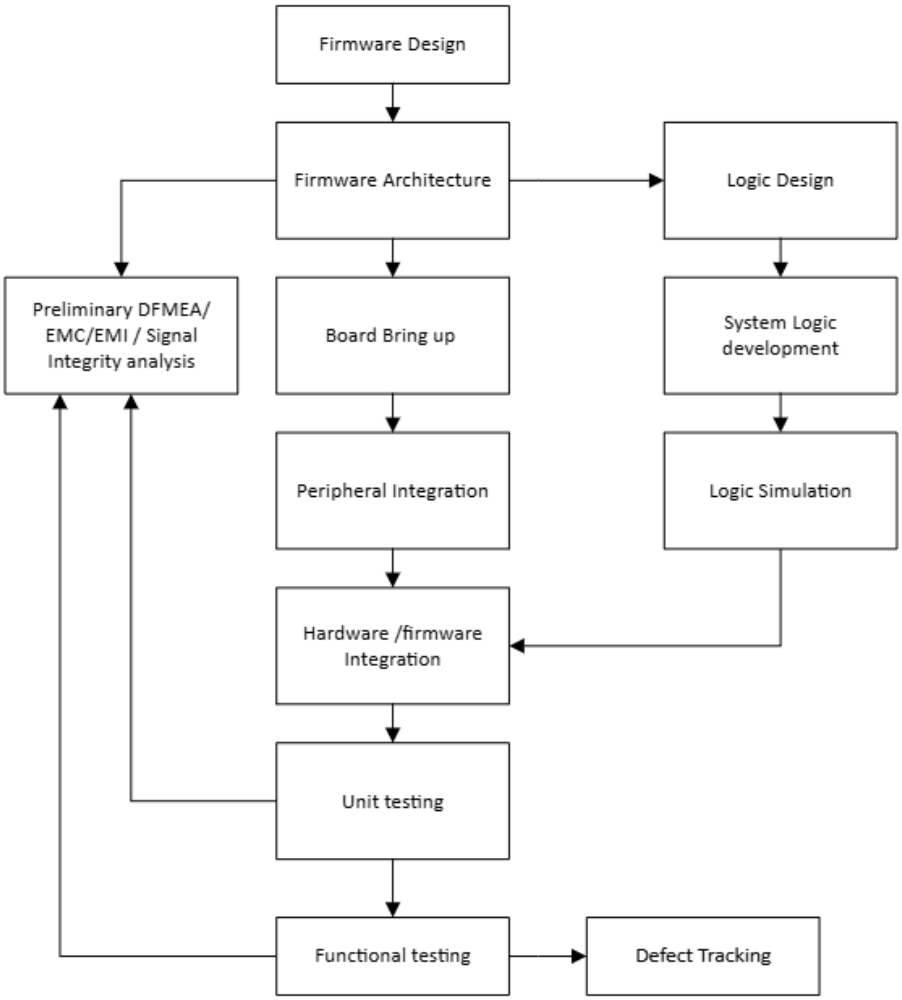


Figure 3: Mechanical Design framework

3.4. Application Software Development

Application software development adheres to a full-stack methodology, ensuring a robust, maintainable, and compliant solution, developed within a framework that aligns with IEC 62304. This approach leverages the Qt framework, recognized for its capabilities in creating compliant medical device software.

Full-Stack Architecture:

- **Front-End Development:** The user interface (UI) and user experience (UX) are developed using Qt/QML. This allows for the creation of sophisticated, responsive, and intuitive graphical interfaces suitable for complex medical device interactions. QML's declarative syntax facilitates rapid UI development and iteration, while Qt's comprehensive libraries provide the necessary building blocks for rich application features.
- **Middleware Development:** Core application logic, data processing, device communication interfaces, and business rules are implemented in C++. This layer

serves as the crucial link between the front-end and the back-end database, as well as interacting with the device firmware. The use of C++ ensures high performance, efficient memory management, and the ability to implement complex algorithms and state machines critical for medical applications.

- **Back-End Database Management:** Data persistence, storage, and retrieval are managed using either a secure proprietary database solution tailored to specific device requirements or a robust open-source option like PostgreSQL. The choice of database considers factors such as data integrity, scalability, security, and regulatory compliance for patient and device data.

Software Quality Assurance (SQA) and Compliance:

- **IEC 62304 Compliance:** The entire software development lifecycle, from requirements specification through design, implementation, testing, and release, is governed by the principles and requirements of IEC 62304 ("Medical device software – Software life cycle processes"). This includes rigorous documentation, risk management activities specific to software, and configuration management. The Qt framework itself provides features and tools that support building IEC 62304 compliant applications.
- **Standardized Code Structures and SQA Tools:** Development follows strictly defined coding standards and utilizes standardized code structures to enhance clarity, consistency, and maintainability. Static code analysis and other SQA tools are integrated into the development pipeline to automatically detect potential defects, security vulnerabilities, and deviations from coding guidelines, ensuring a high level of code quality.

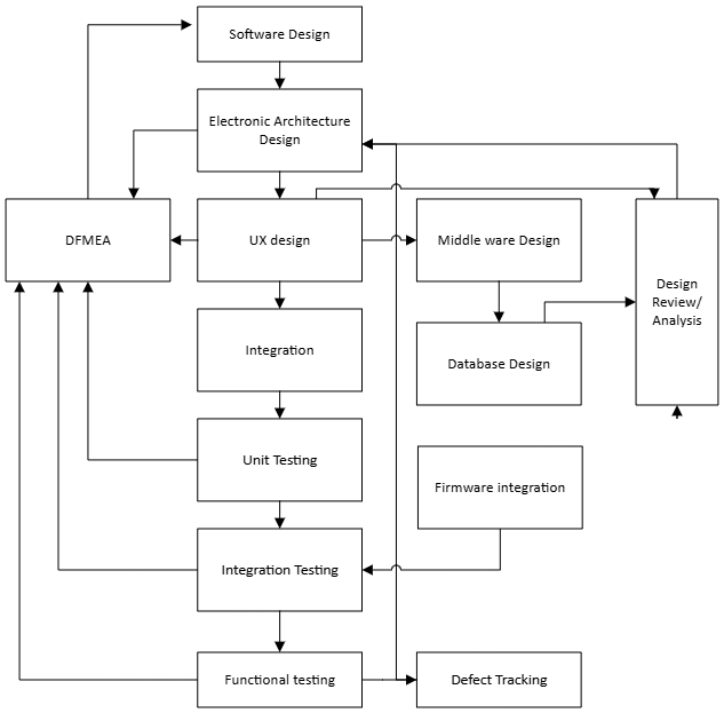
Verification, Validation, and Release:

- **Unit Testing:** Individual software components and modules (across front-end, middleware, and back-end) undergo thorough unit testing to verify their functional correctness and adherence to specifications in isolation.
- **Integration Testing:** Components are systematically integrated and tested to ensure seamless interaction, data integrity across interfaces, and correct behavior of combined functionalities.
- **System Testing:** The complete application software is tested as a whole, often in conjunction with the target medical device or a high-fidelity simulation environment. This phase validates that all system requirements are met, including performance, usability, security, and safety aspects under various operational scenarios.
- **Configuration Management:** Version control and change management are rigorously maintained throughout the development lifecycle using GitLab-based

tools. This ensures traceability of all software items, facilitates collaborative development, manages build and release pipelines, and provides a stable, auditable baseline for all verification, validation, and release activities, aligning with IEC 62304 requirements for software configuration management.

- **Release Process:** A formal release process, compliant with IEC 62304, ensures that all verification and validation activities are completed and documented, all risks have been appropriately addressed, configuration baselines are established, and the software is deemed safe and effective for its intended use before deployment.

Figure 4: Mechanical Design framework



4. Regulatory Compliance and Quality Management:

All development activities are underpinned by a robust Quality Management System (QMS) compliant with ISO 13485. Central to this QMS is the comprehensive application of risk management according to ISO 14971. Furthermore, an Enterprise Resource Planning (ERP) system is utilized to ensure adherence to various QMS processes, facilitate defect tracking, and support project management activities..

4.1. Adherence to IEC 60601-x Series and Integrated Risk Management

Our design process proactively adhere to the IEC 60601-x series of standards is a fundamental aspect of the development process. The implementation of IEC

60601-1, which addresses general safety and essential performance, is guided by the principles outlined in ISO 14971. This integrated methodology ensures that requirements for electrical safety, mechanical integrity, radiation protection, and thermal management are systematically incorporated throughout the design and development lifecycle. Learnings from clinical evaluations of similar devices on the market are also considered to proactively address known use-related aspects.

Furthermore, specific requirements from collateral standards such as EMC (IEC 60601-1-2), Usability (IEC 60601-1-6 & IEC 62366), Alarms (IEC 60601-1-8), and Home Healthcare environments (IEC 60601-1-11) are implemented to ensure the device meets all necessary safety and performance benchmarks. Compliance with relevant particular standards (IEC 60601-2-x) is also achieved through this comprehensive approach to safety and performance engineering.

4.2. Software Lifecycle Management under IEC 62304

For Vasmed's medical device software, IEC 62304 guides the lifecycle requirements. Our process begins with software safety classification, informing a detailed development plan that integrates software risk management. We analyze software requirements to identify safety-related aspects derived from system-level hazard analysis. The software architectural design incorporates control strategies, such as segregating critical components and building in fault tolerance. During detailed design and implementation, Vasmed applies coding standards and conducts reviews to minimize defects. Software unit verification, integration, and system testing are performed to confirm the effectiveness of implemented controls and detect anomalies. Software risk management activities, including techniques like FMEA for software components, are conducted and documented throughout the lifecycle to systematically manage software contributions to device safety.

5. Project Management and Execution Methodology

Our project management and execution methodology combines the flexibility of Agile practices with the structured oversight and rigorous risk management required for medical device development.

5.1. Agile Project Management Framework and Team Capability

An Agile project management framework is adopted, promoting flexibility and continuous stakeholder feedback. Development work is broken into time-boxed sprints. Regular review meetings ensure transparency. The product backlog is dynamically managed. The success of this agile model relies on our engineering teams' capability to rapidly iterate, solve complex problems, and deliver

functional increments, all while maintaining a steadfast focus on risk identification and mitigation within each sprint.

5.2. Milestone-Driven Development

While Agile provides operational flexibility, key milestones ensure structured progress and formal review points where risk management activities are critically assessed in the Vasmed PRP process,

Refer Annexure B for our Product Realisation process

5.3. Comprehensive Testing Strategy for Risk Reduction

Our multi-faceted testing strategy is fundamentally designed for risk reduction. Unit testing verifies that individual components function as intended, mitigating the risk of component-level failures. Integration testing focuses on interfaces, addressing risks associated with incorrect interactions between components or software modules. System testing validates the overall device against requirements, with specific test cases designed to challenge implemented risk controls under normal and fault conditions. Regression testing ensures that changes do not introduce new risks or reintroduce previously mitigated ones. Each test phase generates documented results that feed back into the risk management process.

5.4. Structured Verification and Validation (V&V) with Evidentiary Proof of Safety & performance.

A structured V&V approach is critical for demonstrating device safety and effectiveness. The Verification Plan explicitly links verification activities to identified risks and their control measures. Traceability matrices ensure that all risk controls are verified. Design Verification activities confirm that design outputs meet design inputs, with a specific focus on safety-related specifications and risk mitigations. Documented evidence from these activities serves as proof of effective risk control.

The Validation Plan outlines how the device will be validated to meet user needs and intended uses safely. Design Validation, often involving clinical evaluations for active medical devices, provides the ultimate proof that the device is safe and effective when used as intended, and that all residual risks are acceptable. The results of these evaluations are crucial inputs to the final risk-benefit analysis.

6. Master deliverable list (MDL)

Aligned with Vasmed's Product Realization Process (PRP), the Vasmed Master Deliverable List (MDL) constitutes a comprehensive and structured compilation of all documentation and outputs generated throughout the product development lifecycle. This list serves as a critical tool for project management, quality assurance, and regulatory compliance.

Purpose and Structure:

The MDL meticulously itemizes all documents, records, and tangible outputs required to demonstrate that the medical device has been developed in accordance with predefined requirements and applicable standards. It is strategically structured to correspond with the distinct phases and milestones of Vasmed's PRP. This ensures that for each stage of product realization—from initial concept and feasibility through design, development, verification, validation, and transfer to manufacturing—all necessary deliverables are identified, tracked, and completed.

Traceability and Regulatory Submission:

A key function of the MDL is to establish and maintain clear traceability between design inputs (e.g., user needs, technical specifications, regulatory requirements) and design outputs (e.g., design specifications, verification reports, validation data). This comprehensive documentation trail is essential for demonstrating design control and is a cornerstone of submissions for various regulatory applications worldwide (e.g., FDA, CE marking). The MDL organizes these documents in a logical manner, facilitating efficient compilation of regulatory dossiers.

A	B	C	D	E	F
No.	cument N	emplate no	Requir ed	Document Name	Owner
Project Start					
Feasibility Phase					
1	EXX0001	VM0504T01	Yes	Customer requirements specifications	
2	EXX0002	VM0502T01	Yes	Project Plan	
3	EXX0003	VM0501T01	NO	Business Case	
4	EXX0004	VM0503T01	Yes	Proof of concept document	
Proof of Concept					
Design Input Phase					
5	EXX0001	VM0504T01	Yes	Customer Requirement Specifications	
6	EXX0005	VM0504T02	Yes	Application Specification	
7	EXX0006	VM0503T02	Yes	Technical Requirements Specification	
8	EXX0008	VM0503T07	Yes	Industrial Design Document	
9	EXX0009	VM0503T09	Yes	Product Risk Management File	
10	EXX0010	VM0507T01	Yes	Regulatory Plan	
11	EXX0011	VM0503T18	Yes	Software Requirements Specification	
12	EXX0012	VM0505T01	Yes	Configuration Management Plan	
13	EXX0013	VM0504T04	Yes	Usability Specification	
Design Start					
Design Phase					
14	EXX0007	VM0503T03	Yes	Product Design Specification	
15	EXX0015	VM0503T05	Yes	Mechanical Design Document	
16	EXX0016	VM0503T06	Yes	Electrical Design Document	
17	EXX0017	VM0503T04	Yes	Software Design Document	
18	EXX0008	VM0503T07	Yes	Industrial Design Document	
19	EXX0014	VM0503T08	Yes	User Interface Document	
20	EXX0018	VM0503T11	Yes	Requirements Traceability Table	
21	EXX0019	VM0503T12	Yes	DFMEA	
22	EXX0030	VM0503T16	Yes	Software Development Plan	
23	EXX0020	VM0503T14	Yes	Software Build Procedure	
24	EXX0021	VM0503T15	Yes	Software Release Note	
25	EXX0031	VM0503T17	Yes	Software Problem Report	
26	EXX0022	VM0508T01	Yes	Verification Plan	
27	EXX0023	NA	Yes	User Manual	
28	EXX0024	VM0510T01	Yes	Device Validation Plan	
29	EXX0025	VM0506T01	Yes	Reliability Plan	
30	EXX0026	VM0503T15	Yes	Labeling Plan	
31	EXX0027	VM0510T01	Yes	Manufacturing Plan	
32	EXX0028	VM0511T01	Yes	Serviceability Plan	
33	EXX0029	VM0503T12	Yes	Bill of Material	
34	Part no.	NA	NO	Service Manual	
35	EXX1000	NA	Yes	DWG reference for BOM	
36	Doc. No	NA		Part specification	
37	EXX06XX	NA	Yes	PCBA Layout, Schematics, Gerber files	
38	EXX0025-X	VM0506T02	Yes	Reliability test plan and report (Electrical Reliability Analysis)	
39	EXX0027-X	VM0506T02	Yes	Manufacturing Checklist Completion	
40	EXX00XX	VM0502T04	Yes	Detailed Design Review Minutes	
Design Freeze (Verification & Validation Transfer)					
Design output - Qualification Phase - Verification					
44	EXX0026-0	NA	Yes	Label Approval Report	
45	EXX0022-0	NA	Yes	Verification Report	
46	NA	Third Party	Yes	IEC 1-2 Test Report	
47	NA	Third Party	Yes	Packaging Test Report	
48	NA	Third Party	Yes	IEC 1-1, 2-34 Safety Test reports	
49	NA	Third Party	Yes	Biocompatibility test report	
50	EXX0009	VM0503T09	Yes	Product Risk Management File	
Design output - Qualification Phase - Validation					
51	EXX0027-0	QMS	Yes	Process Validation Records	
52	EXX0027-0	QMS	Yes	Pilot build history	
53	EXX0024-0	QMS	Yes	Design Validation report	
54	EXX0024-X	QMS	Yes	Clinical Evaluation Report	
55	EXX0009	QMS	Yes	Product Risk Management File	
Limited Commercial Release					
56	EXX0051	QMS	Yes	Defect Tracker	
57	Doc. No	QMS	Yes	Technical Master File	
58	Doc. No	QMS	Yes	Declaration of Conformity	
59	Doc. No	QMS	Yes	Design Transfer File	
60	Doc. No	QMS	Yes	Final Design Review Meeting (LCRM)	
Production Release (Limited Commercial Release)					

7. Manufacturing Transition and Certification Support

The transition to manufacturing is guided by robust Design for Manufacturability (DFM) principles, applied early in the design phase to ensure efficient and repeatable production processes. Vasmed utilizes a comprehensive Enterprise Resource Planning (ERP) system, which is integral to our ISO 13485 compliant Quality Management System. This ERP system provides meticulous manufacturing control, including detailed work order management, process routing, and quality data collection. It also ensures complete material traceability, tracking components from procurement through to the final device assembly, a critical aspect of medical device manufacturing. Quality control checkpoints and production line tests are systematically implemented to verify adherence to specifications and ensure product consistency. The Technical File/Design Dossier compiled for regulatory submission includes all relevant manufacturing and quality control documentation

Vasmed facilities include ISO 13485 Class 10,000 cleanroom and ESD areas for handling active medical devices.

8. Timeline Considerations for Active Medical Devices Development

Vasmed targets certification readiness for active medical devices used in diagnosis or therapy within an approximate 18-month timeframe. This accelerated timeline is significantly supported by our **platform-based development strategy**, which leverages pre-existing, proven architectural components and software code, particularly for the PCBA and associated firmware. This reuse, combined with a proactive risk management approach integrated throughout all phases, minimizes late-stage surprises and redesigns, directly contributing to faster product realization.

The successful achievement of this 18-month goal is also contingent upon several critical factors: the clarity of initial requirements, efficient decision-making processes, the project team's experience in risk-based design, and the effective parallelization of workstreams.

Leveraging the Platform for Speed and Efficiency:

Our platform approach, centered around a certified core controller-integrated PCBA and reusable battery PCBA modules, offers substantial time savings:

- **Reduced Hardware Design Cycles:** By using a standardized core PCBA, the need to design and certify the main processing and power management units from scratch for each new product is eliminated. Development focuses on integrating specialized data acquisition or peripheral daughter boards.

- **Accelerated Firmware and Software Development:** A significant portion of the firmware and foundational software code, already validated on the core controllers and battery systems, is reused. This dramatically reduces coding, debugging, and unit testing efforts. Software development can more quickly focus on application-specific logic and UI/UX elements.
- **Streamlined Verification and Validation (V&V):** Since core components and software modules are pre-validated, V&V activities can be more targeted, concentrating on the new or modified elements and their integration with the established platform. This reduces the overall V&V burden and associated timelines.
- **Deterministic Regulatory Pathways:** Utilizing IEC certified components and a well-documented platform architecture can lead to more predictable interactions with regulatory bodies, potentially shortening review times.

Integrated Phased Timeline with Risk Management:

The phased timeline incorporates risk management activities explicitly at each stage:

- **Phase 1: Concept & Feasibility (M1) (Months 1-3):**
    - Initial risk management planning, hazard identification.
    - Preliminary clinical risk review.
    - Assessment of platform suitability and definition of customization requirements (e.g., daughter boards, specific software modules).
- **Phase 2: Iterative Prototype Development & Verification (M2) (Months 3-12):**
    - Ongoing Design Failure Mode and Effects Analysis (DFMEA) for new components/interfaces.
    - Software risk analysis for new and reused code integration.
    - Verification of risk controls in each prototype, leveraging established test protocols for platform components.
- **Phase 3: Design Freeze & Pre-production Verification (M3) (Months 10-14):**
    - Finalization of the risk management file.
    - Verification of all critical risk controls for the integrated system.
    - Design for Manufacturability (DFM) and Design for Servicing (DFS) risk reviews completed.

- **Phase 4: Validation, Manufacturing Setup & Regulatory Preparation (M4) (Months 13-18):**
    - Validation of risk controls in the final product.
    - Compilation of the risk management file and other regulatory submission documents, streamlined by the well-documented platform components.

  Timelines for clinical trials and regulatory reviews remain external factors.

9. Conclusion & Technical Summary

The development of advanced medical devices, particularly active systems for diagnosis and therapy, demands a development framework where safety and risk management are not afterthoughts but are integral from inception to market release. The described service framework provides such a comprehensive solution. It combines detailed mechanical and PCBA design with robust firmware and sophisticated application software development, all governed by a proactive, iterative, and comprehensive risk-based methodology compliant with ISO 14971. Adherence to IEC 60601-x and IEC 62304 is embedded within this risk-centric agile project management approach. This methodology, executed by skilled teams, features iterative prototyping where continuous verification and periodic risk evaluations (including DFMEA, DFM/DFS considerations, clinical risk assessment, and software risk analysis) are evidenced by tangible proof points. With dedicated support for manufacturing transition and certification, this framework is designed to navigate the complexities of medical device development, facilitating an 18-month development cycle for such active medical devices by systematically identifying, evaluating, and mitigating risks to deliver safe, effective, and compliant products.

10. Definitions and Abbreviations

* **PCBA:** Printed Circuit Board Assembly
* **MCU:** Microcontroller Unit
* **CPU:** Central Processing Unit
* **TI:** Texas Instruments
* **STM:** STMicroelectronics
* **Qt:** A cross-platform application development framework
* **QML:** Qt Modeling Language (for user interface design)
* **GUI:** Graphical User Interface

* **IEC:** International Electrotechnical Commission

* **IEC 60601-x:** A series of technical standards for the safety and essential performance of medical electrical equipment.

* **IEC 62304:** A standard specifying lifecycle requirements for the development of medical software and software within medical devices.

* **ISO 14971:** Medical devices – Application of risk management to medical devices.

* **V&V:** Verification and Validation

* **SOP:** Standard Operating Procedure

* **FMEA:** Failure Mode and Effects Analysis

* **DFMEA:** Design Failure Mode and Effects Analysis

* **DFM:** Design for Manufacturability

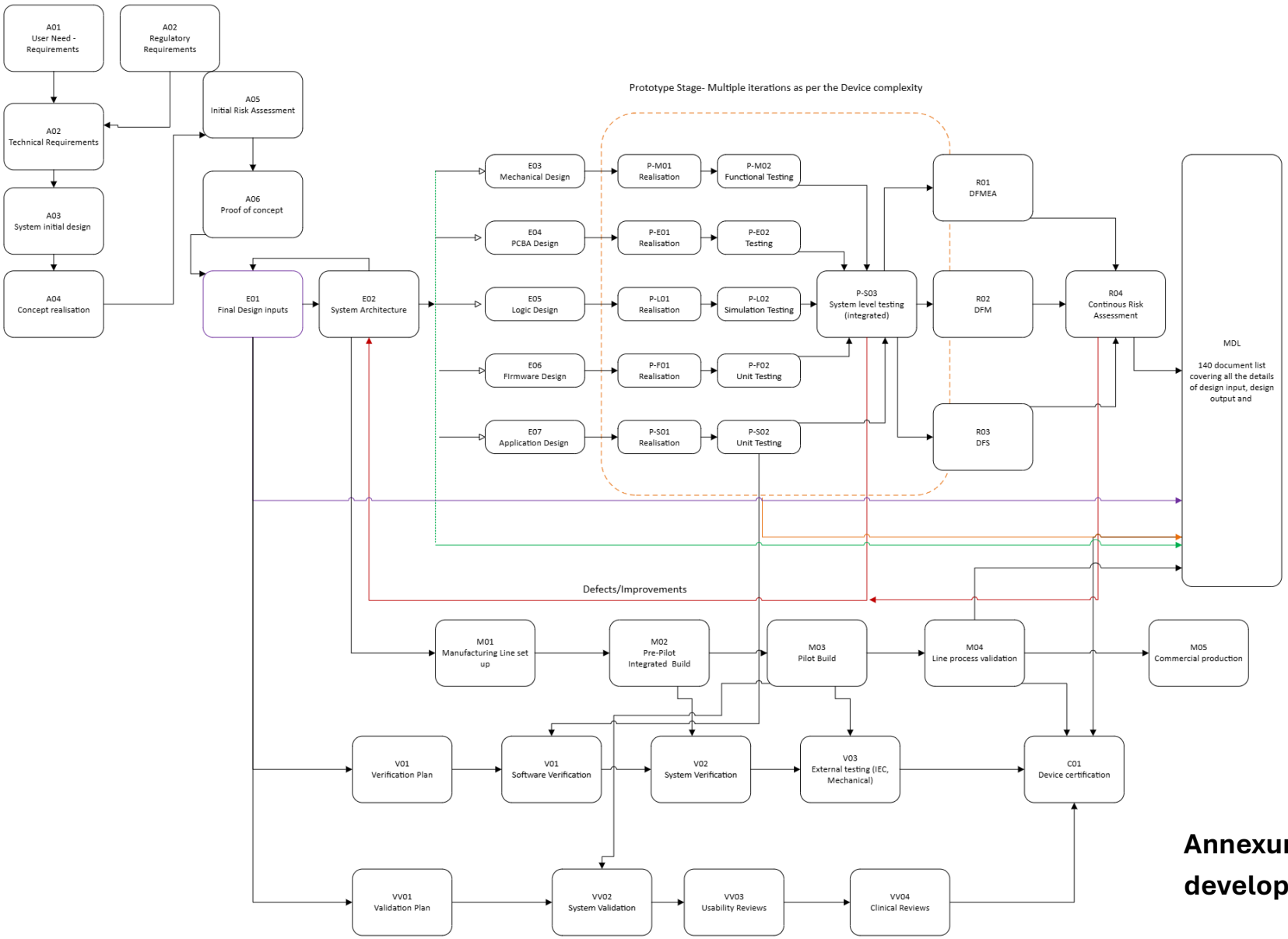
* **DFS:** Design for Servicing

* **PID:** Proportional-Integral-Derivative (controller)

* **Active Medical Device:** Any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or grav

11. References

1. VM01 – Vasmed Business Process overview
2. VM02 – Vasmed Quality Manual
3. VM04 – Vasmed Product realisation procedure
4. VM22 – Vasmed Software development procedure



Annexure A: Our product development model

Annexure B: Our product Realization Process Template