New Product Development and Critical Parameter Management

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In the competitive and highly regulated world of medical device development, a structured approach is needed to ensure that each product meets stringent regulatory standards while addressing user needs effectively. This comprehensive guide walks you through the entire process, from the initial concept to maintaining excellence in manufacturing through continuous improvement.

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Understanding the Phase Gate Process in Medical Device Development

The phase gate process is a standard methodology in medical device development, guiding a project from concept to commercialization. At Meddux, our phase gate process allows us to manage the complexities and inherent risks of developing advanced medical technologies through a series of well-defined stages.

The journey begins with the Concept Development Phase, a discovery stage focusing on usability analysis and technology prototyping. This phase lays the groundwork for the entire project. User and brand research are essential at this stage. Identifying genuine user needs and understanding the workflow in clinical procedures are critical steps. This involves conducting interviews, surveys, and observational studies to gather insights. Concurrently, brand research analyzes the market landscape to define the product's brand identity. By understanding competitors, market trends, and potential positioning strategies, we ensure the product will successfully represent the brand and be coherent with other products in the portfolio.

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Documenting key user needs and workflow ensures the product integrates seamlessly into existing practices, minimizing disruption and maximizing efficiency. With a clear understanding of user needs and workflow, we establish the key technical requirements for the product. These requirements include specifications for functionality, performance, safety, and regulatory compliance, ensuring the final product meets all standards.

To drive innovation, we engage in iterative cycles of prototyping—design, build, and test—to explore design options and assess feasibility. This iterative approach allows us to quickly identify and address potential issues, refine the design, and ensure the final product is functional and manufacturable. One of the primary goals during this phase is to mitigate technical risks. By identifying potential challenges early and developing strategies to address them, we avoid costly delays and ensure the project stays on track. Thorough testing, robust design reviews, and detailed risk assessments help us achieve this.

The Concept Development Phase sets the foundation for the entire project. By focusing on user and brand research, identifying technical requirements, and engaging in iterative prototyping, we create a product that meets regulatory standards, addresses user needs, and performs reliably in real-world conditions. This structured approach ensures that we systematically address potential issues, manage risks, and pave the way for successful product development and commercialization.

Mastering the Design and Development Phase for Medical Devices

The Design and Development Phase is the cornerstone of medical device product development. It transforms a concept into a tangible, reliable, and market-ready product. This phase involves rigorous planning, design controls, and engineering testing.

The Design and Development Phase focuses on detailed execution, developing robust manufacturing processes, and implementing rigorous design controls.

The phase begins with a thorough review of the concept to ensure all user needs and technical requirements are well-established and documented. This involves developing detailed design specifications and creating comprehensive project plans that outline each step of the design process. A critical activity during this phase is developing the component manufacturing processes. This involves selecting appropriate materials, designing components, and establishing manufacturing methods. Each component is designed to meet specific performance criteria and regulatory standards. Close collaboration with suppliers ensures they can produce components that meet our specifications.

We work with our suppliers to develop the necessary tools, fixtures, and equipment required for manufacturing the device components. This includes specialized equipment for testing and quality control. Proper tooling ensures that components are manufactured consistently and meet all quality standards. Internal procedures are established to guide the manufacturing process, detailing every step from assembling components to final testing and inspection.

Design controls provide a structured framework for documenting design decisions, tracking changes, and ensuring all design aspects meet regulatory standards.

Our rigorous design control process allows us to identify and address potential issues early in development, reducing the risk of costly delays or product failures. Compiling the Design History File (DHF) is a crucial output of design controls. The DHF is the comprehensive document set that includes all records related to the product's design and development. It provides a detailed account of the design process, including design inputs and outputs, risk assessments, verification and validation results, and design reviews. The DHF serves as the backbone of the product's regulatory submission, demonstrating that the device has been developed in compliance with all relevant standards and regulations.

Pre-Verification and Validation testing will give us a dry run of the formal V&V builds and testing that will occur in the following phase and will give us confidence that the design meets all specified requirements and performs reliably under real-world conditions. We build dry-run controlled test units to evaluate the manufacturing process and device performance and identify any potential issues. Prototypes are tested in simulated V&V test scenarios to confirm that the final product is manufacturable and meets all functional and performance criteria. Engineering confidence testing validates design assumptions and ensures the product meets all specified requirements. It involves a series of tests evaluating the product's performance, safety, and reliability, simulating real-world conditions to ensure the product can withstand everyday use.

The Design and Development Phase focuses on detailed execution, developing robust manufacturing processes, and implementing rigorous design controls, we transform a concept into a tangible, reliable, and market-ready product that meets the highest quality and performance standards.

Ensuring Quality in Medical Device Design Verification and Validation Production

Following design and development, the next step towards market-ready production is completing formal testing through Design Verification and Validation (V&V). This phase ensures that the medical device meets all regulatory requirements, performs reliably and safely in real-world conditions, and is ready for human-use manufacturing.

Design Verification is the demonstration by objective evidence—by inspecting, measuring, and testing—that the design outputs (specifications) have been met and satisfy the design inputs (requirements). Design Verification testing is conducted using approved protocols that identify specifications, acceptance criteria, sample size requirements, statistical methods, and test methods.

It may include bench performance testing, simulated use testing, system verification testing, and environmental testing. Safety and performance testing are integral to the verification process. These tests evaluate production-equivalent devices to ensure the device performance meets the established requirements and operates safely and effectively.

Environmental testing involves subjecting the device to the full range of anticipated shipping and storage conditions, such as high and low temperatures, humidity, and vibration, to ensure it can withstand various environments. These tests verify the device's performance for its actual commercial use case.

Design Validation testing, on the other hand, demonstrates that the product meets user needs and requirements for its intended use. This involves testing the device in real-world conditions to confirm it performs as intended. Validation tests are designed to simulate actual usage scenarios, comprehensively evaluating the device’s performance, reliability, and safety. Usability testing is a crucial part of validation. It involves observing real users as they interact with the device to demonstrate that potential use errors have been sufficiently mitigated to prevent serious harm. This is particularly important for devices that require users to adopt a new procedural workflow.

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Pre-clinical data is often required to validate the performance and safety of novel medical devices in a simulated clinical setting. This involves evaluating the device under approved protocols on a suitable pre-clinical model by medical professionals to gather data on its efficacy and safety. Clinical data collected typically becomes the cornerstone of the regulatory approval process and the gateway into the New Product Introduction (NPI) phase.

The Verification and Validation phase is critical in ensuring a medical device is safe, effective, and ready for the market. At Meddux, we thoughtfully and collaboratively execute these activities by focusing on rigorous testing and statistical analysis to ensure the devices under our care meet the required quality and performance standards. We conduct the controlled manufacturing of devices for pre-clinical and human clinical studies that enable expert physicians to demonstrate the safety and efficacy of the product, which is then used for the regulatory approval process.

Preparing for Commercialization: New Product Introduction and Design Transfer

Following Design Verification and Validation, the remaining activities focus on readiness for human-use manufacturing, including equipment qualification, process validation, and test method validation.

Equipment used in the manufacturing process undergoes Installation Qualification (IQ) and Operational Qualification (OQ) to ensure it meets its specified requirements, is properly installed, and operates as intended. During Installation Qualification (IQ), we verify that the equipment is installed as per the manufacturer's specifications, ensuring it meets safety requirements and is ready for operation in its intended location. Following IQ, Operational Qualification (OQ) tests the equipment across its intended operating range to ensure it functions correctly under various conditions. For example, if the equipment is a thermal sealer, we would test it at different temperatures, pressures, and sealing times to confirm that it can operate at the limits of each parameter.

Assembly processes that perform a critical-to-function assembly step are considered for process validation. Some assembly processes can be verified; for example, an arbor press that inserts a pin into a hole to a specified depth can be measured to confirm acceptability. However, other processes cannot be verified without destructive testing. The quality of an ultrasonic weld joint cannot be evaluated without pulling apart the welded parts. Process validation is performed on processes that cannot be verified through monitoring or measurement.

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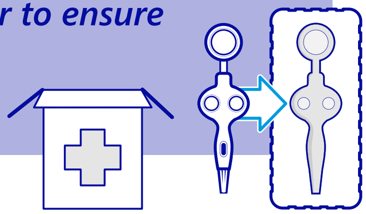
A range-finding study known as Process Characterization (PC) is often conducted first to identify critical process inputs and outputs. A Design of Experiment (DOE) may be required to fully understand how the process inputs affect different outputs of interest. Process-specific Operational Qualification (OQ) is considered for critical processes with a process window. This window is typically driven by the operational range of the equipment and the operator's discretion to run the process within the established process window. The OQ demonstrates that the process can achieve an output that meets specifications at the limits of the process window.

Process-specific Performance Qualification (PQ) is used to demonstrate that the process can achieve an output that meets specifications at nominal process settings under planned manufacturing conditions. It typically involves multiple operators performing the process in different setup batches. It can be used for processes with an operational process window and those without defined operational limits.

Test Method Validation (TMV) is performed to demonstrate that a custom test method or inspection method is suitable for its intended purpose and can produce valid results. A classic example of a test method that should be considered for validation is a manufacturing End-of-Line (EOL) test used to check each assembled unit for proper function. A properly executed TMV will demonstrate that the test method can capably identify good units as good and bad units as bad, regardless of the operator or inspector.

During the New Product Introduction (NPI) phase, the manufacturing process is scaled appropriately and validated for production capability. At Meddux, we develop customized plans based on the product risk level, the launch strategy, and target product volumes. We excel at navigating the challenges that are common to new product launches, and our processes can scale to accommodate the starts and stops that typify early manufacturing while ensuring that each device is manufactured consistently and to the exact quality standards.

The final stages of the New Product Introduction phase focus on component qualification, process performance qualification, and design transfer to ensure the product is ready for commercial manufacturing.

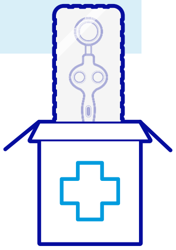


Component Qualification is an assessment of the components or subassemblies that are inputs to the manufacturing process. This assessment is vital for ensuring the reliability and quality of the final product. Using a risk-based approach, we identify critical components and/or critical suppliers for component qualification. By thoroughly evaluating and validating the suppliers' processes, we can analyze the capability of critical-to-function specifications and make data-driven decisions about ongoing quality controls in manufacturing. This helps maintain ongoing product quality, ensuring the device performs consistently and reliably in real-world conditions.

Component qualification typically includes IQ/OQ/PQ of the equipment and process used to manufacture the component, including establishing production process windows. It involves the manufacture of components at the limits of the process window as well as at nominal settings, inspection and statistical analysis of critical-to-function specifications to understand process capability, formal reports documenting the established process used to produce the components, and evaluating the processes for further improvement, if appropriate.

Process Performance Qualification (PPQ), sometimes referred to as “overall process validation,” demonstrates that the overall manufacturing process can produce devices that meet specifications during routine manufacturing, including normal variation in equipment, environmental conditions, materials, and personnel. PPQ typically involves multiple lots of finished device manufacturing under typical environmental conditions representative of routine manufacturing. It includes an independent evaluation of in-process and final inspection quality checks and statistical analysis of critical-to-function specifications of the finished device to understand process capability. A formal report documents the results achieved.

Component Qualification is an vital assessment for ensuring the reliability and quality of the final product.



Design transfer is the culmination of efforts completed throughout the NPI process, ensuring the product design has been adequately documented and confirmed as adequate for the requirements. It also ensures the production manufacturing process can capably produce devices that meet those requirements. Meddux ensures a systematic approach to design transfer using a checklist to ensure all aspects of readiness for commercial manufacturing are complete and documented. Successful design transfer is a collaborative effort between product development, quality, and operations that sets up the product and the team for success in manufacturing.

During the New Product Introduction (NPI) phase, the manufacturing process is scaled appropriately and validated for production capability. Key aspects of this process include qualifying key components and performing PPQ on the overall manufacturing process. These elements, combined with equipment qualification, process validation, and test method validation, ensure the product is ready for design transfer into manufacturing. At Meddux, our team is experienced with the initial market release of first-generation products and employs a risk-based approach to ensure ongoing quality and efficient use of resources as the product launches and volumes scale.

Maintaining Excellence in Medical Device Manufacturing: Critical Parameter Management, Sustaining Engineering, and Continuous Improvement

Maintaining product quality and performance over time is fundamental in the competitive and highly regulated medical device industry. Sustaining engineering and continuous improvement are integral processes that ensure ongoing product reliability and adherence to regulatory standards. Meddux deploys a unique approach to translating high-level device functional requirements down to the constituent operations throughout the manufacturing process. This is known as Critical Parameter Management (CPM), and we implement this systematic approach to ensure ongoing product quality in manufacturing through appropriate controls and monitoring.

We utilize a systems-engineering approach that starts with identifying Critical Functional Requirements (CFRs) that directly impact device safety and performance. We then identify and link Critical-to-Function (CTF) attributes from a top-down perspective. The overall objective is to implement robust manufacturing process controls that ensure consistency across the system, subsystem, component, and manufacturing process. These are linked in a documentation format that traces high-level requirements to ongoing quality controls in manufacturing. CPM is an essential part of our quality control approach, ensuring that critical parameters are meticulously managed throughout the product lifecycle.

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Once the product has moved beyond design transfer and is in commercial manufacturing, ongoing quality is in the hands of the sustaining engineering team. This involves activities such as monitoring key performance indicators (KPIs) for the manufacturing process, including yield, throughput, and on-time delivery. It includes accountability to the Control Plans that are in place to monitor and analyze manufacturing quality control inspection points identified by the CPM process. Tools such as control charts, Pareto analysis, and process mapping help visualize data and highlight areas needing attention. Inevitably, it includes troubleshooting work-stoppages related to components, equipment, and process variation, and responding to post-market surveillance, including field complaints and performance issues. The goal of sustaining engineering is to ensure that products continue to perform reliably and meet customer needs throughout their lifecycle.

Continuous improvement is a pillar of the Quality Policy at Meddux, where we maintain a constancy of purpose to improve. Continuous improvement thinking is encouraged across the organization. Some opportunities for improvement are driven by market feedback, while others are identified internally as part of the manufacturing process. Meddux systems ensure that all proposed changes are carefully reviewed and approved to ensure they do not negatively impact product quality or regulatory compliance. This involves impact assessment and verification and/or validation of any proposed changes. We are also committed to Lean Manufacturing principles, focusing on eliminating waste and improving efficiency. This involves streamlining processes and optimizing workflows to enhance productivity and quality. Successful continuous improvement requires the involvement and engagement of the whole team, fostering a culture where employees are encouraged to identify areas for improvement and contribute creative solutions.

Critical Parameter Management (CPM), sustaining engineering, and continuous improvement are essential practices for maintaining medical device quality, reliability, and compliance. Meddux implements these methodologies rigorously to ensure that the products we manufacture exactly meet their requirements. Our approach helps us continuously enhance our processes and ensures that our products deliver exceptional performance throughout their lifecycle.

Conclusion

By following a structured phase-gate process, mastering design and development, ensuring thorough verification and validation, and maintaining manufacturing excellence through critical parameter management, Meddux demonstrates its expertise in medical device development. This comprehensive approach ensures that each product meets regulatory standards, addresses user needs, and performs reliably when treating patients.

About the Author

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Nate has over 20 years of medical device product development experience, with diverse roles in technology innovation, R&D engineering, manufacturing engineering, program management, technical leadership, and organizational leadership. He has an extensive background in complex technologies, including minimally invasive laparoscopy, endoscopy, interventional cardiology and radiology, surgical stapling, vessel sealing, and ablation therapies. He is a named inventor on more than 30 U.S. patents. He holds a B.A. in Engineering Sciences from Dartmouth College and an M.S. in Mechanical Engineering from Stanford University, Design Division, and Biomechanics Division. Throughout his career, Nate has helped dozens of companies conceptualize, develop, and commercialize novel medical products and technologies for improved patient outcomes.