MIS
Midwest Interventional Systems

Design Control **Process**

About the **Process**

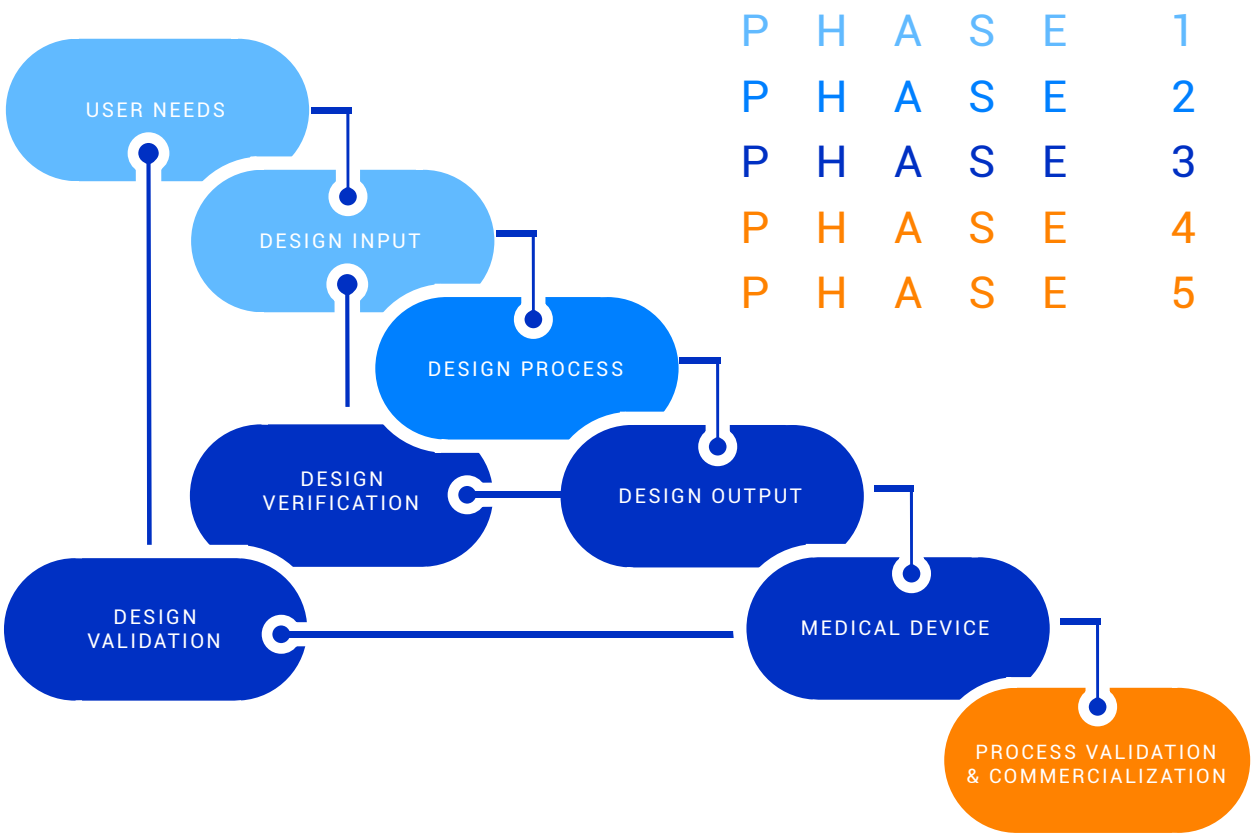
In accordance with FDA Design Control Guidance and ISO 13485, MIS has formalized a phase-based approach for our customers to successfully design, develop, and manufacture a robust and reliable medical device. Whether you are starting with a brand-new concept that requires feasibility prototypes or have a fully developed product and need a reliable manufacturing partner, MIS is positioned to accommodate our customers' needs wherever they may be in the product development process.

Our Development Process consists of **five phases** with detailed design controls and deliverables in each phase. Each of the deliverables in eachphase can either be completed by MIS with customer approval or executed by the customer, allowing for a very flexible and responsive partnership on each project. Execution of this phase-based approach ensures a complete design history file that meets applicable regulations, while ensuring flexibility to meet specific customer requirements and timelines.

5 Phases

C1 C2 C3 C4 C5

Phase & Design **Reviews**



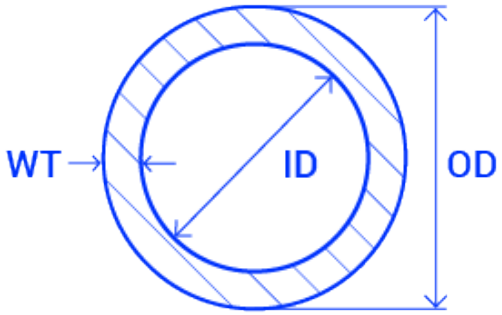
Our robust system covers the entire design process all the way through commercialization. MIS is equipped to take your product from concept to market, without sacrificing cost or time.

C1 C2 C3 C4 C5

Concept

The first phase of the design control process is Concept Development and Optimization. The purpose of this phase is to develop and evaluate initial designs, design inputs, project requirements, project budget and timeline, and any additional customer requirements. MIS will partner with the customer to develop a set of design inputs and initial functional requirements. If the customer already has these, MIS will aid in a review of the design inputs – user needs and intended uses – to develop the Product Specification or Customer Input Documents.

The completion of this phase is summarized as **Concept Freeze**.



Design Control Deliverables for **Concept Development**:

- Preliminary Design Inputs – Input/ Output Matrix
- Project Plan
- Design concept CAD Models
- Design and order initial material, tooling, fixtures
- Prototype concept units
- Draft Product FMEA
- Critical functions test report
- Preliminary regulatory strategy
- Preliminary clinical strategy
- Concept Freeze review and scope out Design Freeze work

C1 C2 C3 C4 C5

Feasibility

Following the Concept Phase is the Feasibility Phase (Phase 2). The purpose of this phase is to continue to develop the product design, the associated manufacturability processes, and the required test methods. These actions and deliverables drive to establish target design requirements and ensure the design will meet the product specification requirements. MIS approaches this design and development process leveraging Design for Manufacturability (DFM) and vendor selection/management to ensure the long-term customer needs and volumes will be met.

Completion of this phase is summarized as **Design Freeze** following Pre-DV testing and Phase Reviews.

Design Control Deliverables for **Feasibility**:

- Prototype build documentation
- Design for Manufacturability and Assembly / Tolerance Review
- Design FMEA update
- Order Design Freeze material, tooling and fixturing (as required)
- Prototype builds
- Design Freeze review and scope our DV activities
- Test method development
- Perform pre-DV testing and detailed report
- Clinical risk analysis
- Risk assessment of manufacturing processes
- Confidence & Reliability level agreement
- Preliminary BOM and cost estimate
- Regulatory and Clinical Considerations

C1 C2 **C3** C4 C5

Design Verification

After completion of Phase 2, the project will move into the Design Verification (DV) Phase (Phase 3A). The purpose of this phase is to conduct design verification and validation testing to demonstrate that the design outputs meet the design inputs. Design outputs that are essential for the proper functioning and safety of the device are identified through review of the project risk documentation. Our engineering team can draft and perform all the protocols, builds, and testing management for Verification Testing, leveraging **in-house validated test methods** to reduce costs for our customer. It is common for the customer to complete the Design Validation testing based on their preferred KOL relationships while MIS supports the builds needed for this testing and reporting. Upon comple-tion of DV activities, MIS will deliver a complete technical file and DHF that will support the customer's regulatory submission. As an additional option, there is a second component to Phase 3 which is Phase 3B. This phase serves as a good plateau point depending on specific customer and project needs. If First-In-Human (FIH) trials are required, all of the previous work can be leveraged to support these studies. This phase is intended to deliver the minimum viable product for all phases of clinical trials. In this phase MIS will support the appropriate lot release testing for product verification and ongoing human use builds to support trials for as long as needed.

Design Control Deliverables for **Design Verification**:

- Complete Design Inputs – Product Specification
- Detailed assembly, component drawings, and specifications
- Final Design FMEA with documented RPN Levels
- Draft Process FMEA
- Complete approved vendor documentation
- Test method validation (as required)
- Build design verification units and execute design testing
- Biocompatibility testing
- Accelerated aging testing
- Packaging, sterilization, and transit testing validation
- Design validation plan, protocol
- Finalize regulatory strategy
- Finalize clinical strategy
- Support regulatory submission

C1 C2 C3 C4 C5

Transfer & Commercialization

The final phases of the Development Process are Process Validation and Commercialization. The purpose of Process Validation is to establish a manufacturing process that consistently meets all product requirements without the need for ongoing verification testing. MIS partners with our customers to develop and execute an **Operational Qualification** and **Process Qualification** plan to minimize or eliminate ongoing product verification testing based on each customer's needs. In parallel to Process Validation, MIS will initiate the Commercialization process through an **initial pilot line ramp**. Additional activities within this phase include onboarding and ramping of line resources, training, implementation of process specifications and process controls/monitoring, and closure of design review action items. Upon successful completion of Commercialization, the product enters the Post-Market Surveillance process and MIS continues support of the production line with planned ramp strategies, aggressive OEE targets, and a robust VIP program to achieve short and long-term cost targets.

Design Control Deliverables for **Transfer & Commercialization**:

- Complete Process FMEA
- Complete Manufacturing Ramp Plan
- Acquire/ implement production tooling, assembly, and inspection fixtures
- Process validation plan and protocols
- Approved I/O matrix
- Qualification test methods report
- Process Qualification/ Validation IQ, OQ, PQ
- Device Master Record
- Training to scale up manufacturing line

About **MIS**

Midwest Interventional Systems is a private contract design, development, and manufacturing company based in Maple Grove, Minnesota. We specialize in catheters, delivery systems, and other minimally invasive medical devices. Midwest Interventional Systems provides custom turnkey solutions by partnering with our customers, who range from start-ups to multinational corporations within the minimally invasive device space. Our mission is to provide the medical device world with a level of service that is unmatched, with the ultimate goal of enabling medical device companies and inventors tobring their **life-changing**, innovative products to market with a **scalable and sustainable** platform.

We make it easier for you to **save lives**.

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