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Manufacturing Process Development for Implantable Medical Devices

From Process Development to Commercial Production

Developing an implantable medical device is only one stage of product development. Equally important is developing a manufacturing process capable of producing that device consistently, repeatably, and at commercial scale.

For implantable medical devices, manufacturing process development extends well beyond production planning. It includes Design for Manufacture (DFM), process optimization, assembly development, tooling design, operator qualification, process validation, and manufacturing transfer. Together, these activities establish a manufacturing system capable of delivering consistent quality throughout the product lifecycle.

Manufacturing engineering should therefore be viewed as a continuation of product development rather than an activity that begins after design is complete.

At Corza Medical, these engineering activities are integrated throughout development to help customers transition innovative concepts into commercially manufacturable products.

Manufacturing Engineering as Part of Product Development

Designing an implant is only one aspect of creating a successful medical device. The manufacturing process must also be engineered to ensure that every product can be assembled using repeatable methods, validated processes, and controlled manufacturing conditions.

Manufacturing process development typically includes:

- Design for Manufacture (DFM)
- Prototype assembly development

- Manufacturing process development
- Assembly sequence optimization
- Custom tooling and fixture development
- Operator training and qualification
- Process validation planning
- Manufacturing transfer
- Commercial scale-up

Each activity contributes to reducing manufacturing variability while improving process robustness and long-term production capability.

Rather than reproducing an existing manufacturing method, engineering teams evaluate every stage of assembly to identify opportunities to improve product quality, process repeatability, and manufacturing efficiency.

Manufacturing Transfer as a Process Development Activity

Manufacturing transfer is often viewed simply as relocating production from one facility to another.

From an engineering perspective, it represents an opportunity to improve the manufacturing process before commercial production begins.

Transferring production provides an opportunity to evaluate:

- Assembly sequence
- Stitch architecture
- Component positioning
- Fixture design

- Operator interaction
- Process flow
- Inspection methods
- Manufacturing documentation

This evaluation frequently identifies opportunities to improve process capability without changing the functional design of the implant.

Typical process improvements include:

- Refinement of stitch architecture
- Development of dedicated assembly fixtures
- Improved operator ergonomics
- Standardized assembly procedures
- Reduced process variability
- Improved manufacturing repeatability
- Increased production efficiency

The objective is not simply to duplicate an existing process, but to establish a manufacturing system capable of supporting long-term commercial production.

Precision Assembly Engineering

Implant manufacturing often combines manual assembly with engineered production controls.

Certain assembly operations continue to require manual execution because they involve complex textile manipulation, implant integration, and precise stitch placement that cannot be fully automated.

These operations may include:

- Precision hand sewing
- Complex stitch patterns
- Knot tying
- Splicing
- Implant component integration
- Final assembly

Repeatability is achieved through standardized work instructions, operator qualification, validated manufacturing procedures, and documented process controls rather than relying solely on operator experience.

This combination of engineering controls and skilled assembly supports consistent manufacturing performance across production lots.

Engineering Stitch Architecture

Stitch architecture influences more than implant fixation.

It also affects manufacturing repeatability, assembly efficiency, implant profile, load distribution, and long-term mechanical performance.

Programmable embroidery systems allow stitch geometry to become an engineering variable rather than simply an assembly method.

Engineering considerations include:

- Stitch spacing
- Loop geometry

- Tension distribution
- Surface profile
- Attachment integrity
- Mechanical performance
- Manufacturing repeatability

Running stitch patterns distribute load differently than locked or non-locked loop constructions. Stitch geometry can therefore be optimized to balance fixation strength, flexibility, manufacturability, and process consistency for the intended application.

By engineering stitch architecture alongside the manufacturing process, assembly performance and product consistency can be improved simultaneously.

Case Study

Manufacturing Transfer of an Implantable Cardiovascular Device

A cardiovascular device manufacturer required the transfer of production for a complex implantable vascular graft while preparing the product for commercial manufacturing.

Although the existing assembly process produced acceptable devices, evaluation identified opportunities to improve manufacturing repeatability, reduce operator-dependent variability, and establish a more robust production process.

Rather than replicating the existing manufacturing method, the engineering team performed a systematic assessment of the assembly process.

The review included:

- Assembly sequence analysis
- Stitch architecture evaluation
- Component positioning
- Fixture assessment
- Operator workflow
- Manufacturing documentation
- Prototype build evaluation

Based on these findings, the manufacturing process was revised through:

- Development of dedicated assembly fixtures
- Optimization of stitch architecture
- Standardization of assembly procedures
- Multiple prototype iterations
- Operator qualification and training
- Process validation planning
- Commercial manufacturing readiness activities

The revised manufacturing process improved repeatability while preserving the functional performance of the implant and supporting successful transition into commercial production.

The same engineering methodology has since been applied across additional cardiovascular and soft tissue repair programs requiring complex textile assembly and validated manufacturing processes.

Engineering Considerations for Commercial Manufacturing

Successful commercial manufacturing depends on controlling process variables as carefully as product design variables.

Important considerations include:

- Controlled cleanroom manufacturing
- Qualified operators
- Standardized work instructions
- Validated manufacturing processes
- Material traceability
- Process traceability
- In-process inspection
- Continuous process monitoring
- Ongoing process improvement

Collectively, these controls establish a manufacturing process capable of producing consistent implantable medical devices throughout commercial production.

Engineering Summary

Manufacturing process development should be considered an integral part of medical device engineering rather than a downstream production activity.

Systematic evaluation of assembly methods, stitch architecture, tooling, operator interaction, and validation strategy improves manufacturing repeatability while reducing variability before commercial production begins.

Questions for Your Manufacturing Partner

When evaluating a manufacturing partner for implantable medical devices, consider asking:

- How is Design for Manufacture incorporated into process development?
- How are manufacturing processes evaluated and optimized during transfer?
- Can custom tooling and fixtures be developed to improve repeatability?
- How are assembly processes validated?
- How are operators trained and qualified?
- How is manufacturing readiness established before commercial launch?
- What mechanisms exist for continuous process improvement after transfer?

These considerations often determine whether a manufacturing process is simply transferred; or successfully engineered for long-term commercial production.

About Corza Medical

Corza Medical partners with medical device companies to develop manufacturing processes that are as carefully engineered as the products themselves. From Design for Manufacture and prototype development through manufacturing transfer, validation, and commercial scale-up, our teams apply manufacturing engineering, precision assembly, and validated production practices to support repeatable, commercially scalable implant production.



Contact Corza Medical today

