DESIGN FOR MANUFACTURABILITY:
Design Optimization Collaboration Provides Lowest Total Cost for Medical Implants

Product design contributes significantly to the overall cost of the finished medical device. As a result, medical device OEM’s that have the foresight to consider manufacturing and design issues upfront shorten their product development time, minimize development cost and ensure a smooth transition into production for quick time-to-market.

**Design for Manufacturability** is the process of proactively designing products:
1. To use the most innovative and cost effective manufacturing methods,
2. To align the design specifications with the functional requirements and optimize the manufacturing functions, including: fabrication, finishing, testing, assembly and packaging, and
3. To use automation and validated processes to ensure the highest level of quality, regulatory compliance and speed-to-market.

Going hand-in-hand with Design for Manufacturability is Concurrent Engineering. **Concurrent Engineering** is the practice of developing products and their manufacturing processes in simultaneous, parallel paths. If new processes are required for manufacturing, then the product and the process must be developed concurrently.

Design for Manufacturability and Concurrent Engineering are proven design methodologies that work for any size company. The process often can cut in half costs and time-to-market while adding significant improvements to quality and delivery. We have found these services to be most impactful when applied to projects that involve tight tolerances and exotic materials, including NiTiNol. Norman Noble, Inc. is the largest laser machining contract manufacturer, and we manufacture the most NiTiNol-based implants in the world.

Benefits of partnering with Norman Noble, Inc. on Design for Manufacturability include:
- Access to Norman Noble, Inc.’s innovative machining and finishing technologies for implants and devices
- Product design support, which establishes the feature set, how well the features work, and, accordingly, the marketability of the product
- Prototypes manufactured in dedicated Process Development Centers (PDCs)

**Design for Manufacturability in Practice**
Design for Manufacturability takes foresight now for benefits later. Norman Noble, Inc.’s Design for Manufacturability services have realized substantial benefits for clients of all sizes. Design for Manufacturability studies are selected based solely on market potential.

In broad terms, Norman Noble assesses a Design for Manufacturability project’s viability by determining:
1) Can we take the current concept to something that can be manufactured and compliant?

2) Can it be reviewed and revised to enable Norman Noble to use the newest and most efficient technology to reduce cost and maximize quality?

3) Can it be validated so the process can be repeated for a high yield?

Consider the following example.

A medical start-up company needed a supplier to provide initial prototypes and pricing for large-scale production of a medical implant. The start-up provided a draft drawing with a few basic dimensions, and requested a quote from Norman Noble with a specific interest in cost-effective manufacturability.

Norman Noble was uniquely qualified for the project and was chosen because of its proprietary technologies, which can be applied to enable commercialization of some products with reduced cost and improved quality. In some cases, these products could not be produced at all using conventional technologies.

From the very start of the project, NNI did two things: designed for manufacturability and partnered with the client. This process evaluated:
- Material
- Manufacturing method
- Inspection method
- Validation
- Yield
- Functionality
- Characterization and testing

As one outcome of this process, NNI streamlined testing and eliminated unneeded prototype iterations. Norman Noble also modified the prototype design to enable the use of state-of-the-art manufacturing technologies, which drastically improved the manufacturing process flow. Additionally, by developing some of the functional specifications, the team minimized the amount of traditional inspection required and implemented automation for dimensional and visual checks. With a robust design and manufacturing process in place, Norman Noble’s validation team was able to easily demonstrate process capability for full-scale production.

The team-based design partnership between the OEM’s and Norman Noble’s engineering teams allowed Norman Noble to produce high quality products in high volume in accordance with all project milestone due dates. Together, we achieved a significant cost reduction in manufacturing the final device. As a result of the project and a successful product launch, the customer has grown from a start-up, to a very large medical OEM. Today, Norman Noble continues to successfully partner with this customer on new designs for next generation products.

About Norman Noble, Inc.

Established 69 years ago, Norman Noble, Inc. remains a family-owned and -operated company offering the most advanced processes for ultra-precision micromachining. The company is known for its exceptional ability to achieve sub-miniature precision beyond the reach of most manufacturers.
Norman Noble, Inc. is a supplier to most of the largest OEM’s and well-known names in the medical device industry.

Norman Noble manufactures medical implants and devices to customer specifications in compliance with FDA regulations and ISO 9001 and ISO 13485. We offer validated manufacturing processes for Vascular implants and Orthopedic Implants. State-of-the-art processes include laser machining and welding, Swiss turning and milling, conventional and wire EDM, high-speed 7-axis contour milling, Nitinol shape setting and clean room assembly and packaging. Prototype services are available in separate and fully dedicated process development centers. FDA Registration #1531050. For more information, please visit www.nnoble.com.