Design for Manufacturability (DFM)

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.

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. AGNOTEX, Inc. is the largest laser machining contract manufacturer, and we manufacture the most NiTinol-based implants in the world.

Benefits of partnering with AGNOTEX, Inc. on Design for Manufacturability include:
• Access to AGNOTEX, 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
• Prototype manufactured in dedicated Process Development Centers (PDCs)

DESIGN FOR MANUFACTURABILITY IN PRACTICE: Design for Manufacturability takes foresight
now for benefits later. AGNOTEX, 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, AGNOTEX 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 AGNOTEX 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?

CASE STUDY: A medical start-up OEM was developing a vascular implant design. The company needed quick-turn prototypes to verify the design and also required a manufacturing

process that could achieve target production pricing. The OEM provided a draft drawing with a few basic dimensions, and submitted a request for quote to AGNOTEX that noted a specific interest in cost-effective manufacturability.

AGNOTEX was chosen as a partner for the project based on proprietary machining technologies it could apply to produce the product quickly in a process development center (PDC) using production equivalent equipment that provided the best quality and yield. From the very start of the project, AGNOTEX and the OEM conducted design for manufacturability discussions to evaluate:

- Material selection
- Manufacturing and finishing specifications
- Inspection method
- Validation strategy
- Yield percentage
- Functionality
- Characterization and testing

As one outcome of this process, the testing was streamlined to eliminate months of now-unneeded prototype iterations. The prototype design was also modified to enable the use of a single operation machining technology, 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 criteria. With a robust design and manufacturing process in place, AGNOTEX's validation team was able to easily demonstrate the process capability required to support the transition to full-scale production.

The team-based design partnership between the OEM's and AGNOTEX's engineering teams allowed AGNOTEX 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, AGNOTEX continues to successfully partner with this customer on new designs for next-generation vascular products.

ABOUT AGNOTEX, INC.

Based on 70 years of family experience, AGNOTEX, 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. AGNOTEX, Inc. is a supplier to most of the largest OEM's and well-known names in the medical device industry.

AGNOTEX 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.