

Design for Manufacturability (DFM)

Design Collaboration Provides Lowest Total Cost for Cost of Goods (COG'S) in 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 rapid 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.

SIMULTANEOUS ENGINEERING is the practice of developing products and their manufacturing processes in concurrent, parallel paths. If new processes are required for manufacturing, then the product and the process must be developed concurrently.

Design for Manufacturability and Simultaneous 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 Ti6AL4V. Croom Precision Medical hosts multiple additive manufacturing systems for Ti6AL4V and SS 316L production.

Benefits of partnering with Croom Precision Medical on Design for Manufacturability include:

- Access to Croom Precision Medical 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
- Design and manufacture of fixturing and gauging for production lines
- Prototype manufactured in a dedicated Process Development Center (PDC)

DESIGN FOR MANUFACTURABILITY IN PRACTICE: Design for Manufacturability takes foresight now for benefits later. Croom Precision Medical and its 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, Croom Precision Medical 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 Croom Precision Medical 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 custom additively manufactured implant design. The company needed quick-turn prototypes to verify the design and also required a manufacturing process that could achieve target COG's. The OEM provided a draft drawing with a few basic dimensions, and submitted a request for quote to Croom Precision Medical that noted a specific interest in cost-effective manufacturability.

Croom Precision Medical was chosen as a partner for the project based on proprietary finishing 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, Croom Precision Medical and the OEM conducted design for manufacturability discussions to evaluate:

- Material selection
- Manufacturing and finishing specifications
- Inspection method
- Validation strategy
- Yield percentage
- Functionality
- ASTM 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, Croom Precision Medicals 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 Croom Precision Medicals engineering teams allowed Croom Precision Medical 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, Croom Precision Medical continues to successfully partner with this customer on new designs for next-generation class 2 and 3 implants. .

ABOUT CROOM PRECISION MEDICAL

Established over 35 years ago, Croom Precision Medical remains a family-owned and operated company in partnering with global healthcare and aerospace companies as an outsourced manufacturing service of high precision components and medical devices.. The company is known for its exceptional ability to respond to supply chain demands in small to medium sized implant manufacturing. Croom Precision Medical is a supplier to most of the largest OEM's and well-known names in the medical device industry.

Croom Precision Medical manufactures medical implants and devices to customer specifications in compliance with FDA regulations and ISO 13485:2016. We offer validated manufacturing processes for Orthopedic Implants. State-of-the-art processes include metallic additive manufacturing, laser machining, Swiss turning and milling, conventional and wire EDM, high-speed 5-axis contour milling, advanced grinding, robotic finishing and clean room assembly and packaging. Prototype services are available in separate and fully dedicated process development centers.

For more information, please call **+353 61 397 744** or visit <https://www.croomprecision.com/>