ximedica

MANUFACTURING SOLUTIONS

The Ximedica Manufacturing and Post Commercial Solutions business team offers complex, custom, niche manufacturing capabilities with 70,000 square feet of space, including Certified ISO14644-1 Clean Rooms. We have a proven Quality Management System that is ISO13485 certified and are a Class III device manufacturer. Ximedica offers a unique ecosystem of a single organization, from concept to design to commercial manufacturing, providing our customers the best in class service they deserve from a long-term partnership.

Creating value for our clients

Ximedica's manufacturing team of talented and diverse engineers/specialists work closely with research, human factors, design, quality assurance and engineering teams to ensure innovative and robust manufacturing and supply solutions. We provide a flexible value based supply chain solution that both startups & large mature medical device/pharma companies can leverage.

Manufacturing Solutions

We offer a variety of manufacturing solutions

- Design for manufacturability
- Complex manual and semi-automated expertise
- Packaging
- Management of sterilization
- Certified ISO14644-1 Class 7 & 8 Clean Rooms
- Global supply chain management

Supply Chain Development

Ximedica offers full supply chain management services with experience in domestic & global sourcing and vendor qualification by integrating with our client's supply chain, planning for scalable supply options with an internally approved supplier list & Asian support options.

Process Validation & Manufacturing

Our advanced manufacturing teams are practiced in bringing devices to clinical launch and commercialization. We have the facilities, equipment and expertise on-site to produce traceable, compliant products from early design, clinical, design verification builds, and pilot to full commercial manufacturing.

Outsourced Sustaining Engineering "A Competitive Advantage"

Dedicated domestic cross-functional core team to manage Change Control Activities by balancing utilization of domestic & international resources for highest level of productivity & economies of scale.

Potential to decrease annual costs by greater than 20% with increased throughput.

Faster and focused implementation of design or process changes enabling internal teams to focus on the highest of priorities.

MDR Compliance

Ximedica has identified keys to success across three phases to ensure MDR and IVDR compliance: map across functional stakeholders, collate data from disparate sources and formats, understand product functionality and assimilation of relevant data to make decisions, and involve cross-functional stakeholders to provide relevant input.

Data Collection

- Product Prioritization
- Product reclassification
- Collect Tech File
- Collect Existing Documentation

Gap Assessment

- Tech File Gap Assessment
- Gap Closure Plan
- QARA Review & Approval

Remediation

- Remediation
- QARA Review & Approval
- Tech documents per EU MDR
- Submission to Notified Bodies

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Contact us to learn more

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Ximedica is a full-service ISO 13485-certified product development firm. For 30 years Ximedica has provided a unique growth platform enabling organizations to successfully deploy medical technology products into the market.

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