



5 Reasons to Choose a

Specialized Medical Contract Manufacturer

Projected to be valued at \$430 billion by 2020¹, the medical industry is driven by the precept that the only constant is change. Advancements in data science technologies have taken patient care and the equipment needed to administer it to extraordinary places.

The Internet of Things (IoT), artificial intelligence, machine learning, and other data-driven solutions have given medical hardware developers a number of powerful tools to digitize and automate product development and manufacturing processes. Yet, a lack of production expertise, resources, and in-house capabilities — not to mention the sheer speed at which medical technologies evolve — can be an obstacle to realizing success.



**\$430
billion**

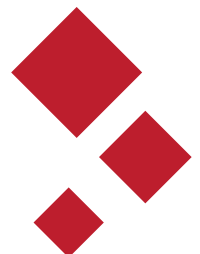
To overcome these challenges, outsourcing to contract manufacturers (CM) focused on healthcare has become the norm. CMs with proven core competencies in medical equipment address industry-specific regulations, compliance, and standards — non-negotiables in today’s competitive marketplace — but the right partnership offers medical OEMs much more:

- 1. LOWER COST/REDUCED CAPITAL EXPENDITURE:** No in-house machinery means no substantial initial capital layout or ongoing upgrades/maintenance spends, which keeps expenses manageable and provides more budgetary flexibility in other business areas.
- 2. ADVANCED TECHNOLOGIES AND EXPERTISE:** Specialized medical CMs holding ISO 13485 certification are uniquely qualified to blend the latest technologies with a breadth and depth of knowledge in support of medical OEM initiatives.

ISO 13485: Why It Matters

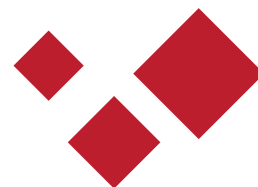
ISO 13485 is the global standard that defines requirements for a quality management system specific to the medical industry. Contract manufacturers that carry ISO 13485 certification:

- Accurately manage documentation, traceability, and manufacturing standards throughout medical equipment project life cycles
- Keep safety, quality, and efficiency top of mind, with emphasis on continuous process/product improvements
- Have highly detailed and proven procedures in place to reduce project cost, waste, rejects/defects, and time to market



- 3. END-TO-END PROJECT MANAGEMENT:** Collaborative problem-solving and supply chain management are supported by streamlined day-to-day operations, including one-on-one communication and accountability.
- 4. SYNERGISTIC SERVICES:** Access to and application of complementary services at the contract manufacturing level provides increased project flexibility without compromising quality, cost, or time:
- **Design for Manufacturability (DfM) Expertise** that aligns with existing OEM testing efforts for long-term product improvements, without consuming internal resources
 - **Application-Level Testing** conducted by specialized CMs brings together years of aggregated experience in testing processes and fixtures to ensure consistent quality in medical equipment assembly while maintaining efficiencies
 - **Product Lifecycle Management** is a critical aspect of product consistency and unplanned changes can be eliminated or managed by an experienced medically-focused contract manufacturer
- 5. SHORTER LEAD TIMES/FASTER TIME TO MARKET:** Accurate and predictable production increases medical OEM confidence across the board, but particularly in obtaining and maintaining a competitive advantage in a dynamic industry.

Partnering With a Specialized Medical Contract Manufacturer



With the demand for medical contract manufacturing, it's not surprising that the number of specialized CMs has increased to nearly 70 over the past two decades.¹ This gives medical OEMs choices, but not every CM is the right fit for your needs.

Ask these questions when comparing and selecting a qualified outsourcing partner:

- Does the CM have the capabilities to handle your product's quality system requirements?
- Does the CM have medical hardware expertise?
- Does the CM have the capacity to handle your project in terms of lifecycle time and manufacturing volumes?
- Does the CM have experts that complement your in-house team?
- Does the CM offer a service-centric culture that's focused on your product success?

Medical OEMs turn to GMI Solutions as their specialized medical contract manufacturer because, quite simply, we deliver a pivotal partnership: We go the extra mile to exceed expectations — not just meet them — and apply our expertise, experience, and forward-thinking service to benefit the OEM, in the short- and long-term.

Contact GMI Solutions today to find out why we're trusted with manufacturing what matters.

SOURCES

¹ Business Wire, Medical Device Contract Manufacturing Market, 2030 - ResearchAndMarkets.com, July 17, 2019



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