

# MEDICAL DEVICE OUTSOURCING

Fully-Integrated Contract Manufacturing  
for Complex Medical Devices and Components

## INNOVATIVE & SCALABLE EXPERT SOLUTIONS

### SPECTRUM ADVANTAGE

Medical device outsourcing is a vital component of the life science industry. Typical to the industry are cyclical fluctuations in demand. Contract outsourcing offers the solution to managing these highs and lows that consume internal resources and jeopardize new product development.

Spectrum offers dedicated internal resources at each stage of its fully integrated custom product manufacturing process. From concept to device manufacturing, all the way through to an order and direct-to-user product fulfillment. Our complete, turn-key operation includes engineering and design to microfluidics chemical formulation, custom packaging, and specialized kitting. Combined with our global footprint, we help lower your fixed overhead costs and provide access to foreign markets.

Spectrum's all-star team of medical, design, engineering and manufacturing experts leverage the ideal combination of Six Sigma, Lean Manufacturing, Theory of Constraints, and FEMAs to deliver the products and services crucial in supporting a global healthcare system.

Advancing your medical device product program means choosing the right outsourcing partner. This decision should include one with the proven ability and skill to handle the complexities of mass-scale medical manufacturing. There is no substitute for medical industry experience or certifications.

**We focus our expertise on every details so you don't have to.**

- 1 Medical Product Design, Development, CAD and Concept Prototyping
- 2 R&D Scientists and Engineers Including Quality, Design Controls and Process Validation
- 3 Injection Molding & Expert Tooling with Rapid Prototyping Capabilities
- 4 Microfluidics Chemical Formulation Development
- 5 Custom Packaging, Unique Barcode Serialization, and Specialized Kitting
- 6 Direct-to-User Global Fulfillment with SaaS biosample chain-of-custody & customizable track-and-trace notifications

- ✓ Dedicated account managers with technical and commercial capability
- ✓ FDA Registered Medical Device Organization, ISO 13485 Certified
- ✓ Current Good Manufacturing Practices (CGMP) Compliance



# COMPLEX IVD AND MEDTECH DEVICES



## SPECTRUM EDGE

At Spectrum, our contract manufacturing and outsourcing capabilities focus exclusively on the highly specialized life science MedTech industry. Your market success hinges not only on the innovative medical device design, development, and manufacturing of your outsourcing partner, but additionally requires a vast range of academic influence, expert experience, and critical patient understanding. It's from this exact scientific-based medical ecosystem that we craft your specialized product success roadmap.

FDA registered and ISO 13485 certified, Spectrum is regularly audited by federal and industry officials to ensure compliance with stringent federal regulations such as 21 CFR Part 820. We manufacture medical products for various regulatory jurisdictions, including the US (FDA), Europe (CE), Health Canada, and APAC region. These include low-risk to higher-risk IVDs and medical devices using the FDA's cGMP standards.

### LEVERAGE EXPERIENCE

Gain critical regulatory understanding with our pure medical expertise



### DRIVE PREDICTABILITY

Achieve absolute quality, cost effectiveness, and increased efficiency through Six Sigma, Lean Manufacturing, Theory of Constraints, and FEMA principles



### SPEED TO MARKET

Competitive lead times, supported by fully integrated capabilities, offer a faster and more efficient time to market strategy that showcases our built-in capacity designed to flex with your business



### NEXT-GEN DIAGNOSTICS

Onsite formulation labs drive highly effective, forward looking, and innovative molecular diagnostic testing



### REAL-TIME OVERSEE VISIBILITY

Web-based portals provide instant custom order and inventory visibility as well as resource management with SOX compliant control and accuracy. In addition, API interface offers same day and 99+% on-time ship with quality control at both pick and pack.



### ROBUST QUALITY & DEDICATED CLEAN ROOMS

Essential in providing stability, reliability, & control with batched quality product releases & lot-based testing



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