A New Approach to Contract Medical Device Manufacturing Relationships

Contract manufacturing for medical devices is one of the fastest growing segments of the medical device industry. Why? Because in the race to bring new devices to market, device makers from the largest OEMs to small startups have found that it is more efficient to leverage the experience and facilities of outside organizations for device development rather than recruit, hire, and train people and purchase equipment and facilities.

Contract manufacturing organizations (CMOs) continue to refine their operations to better serve the evolving needs of device OEMs. Many firms have focused on developing a core expertise such as extrusion, molding, or machining to serve a multitude of device components and types. The new approach CMOs are adopting a "general contractor" approach, serving as the Tier 1 supplier and partnering with elite firms specializing in specific phases of device development for specific types of devices, driving new efficiencies to further accelerate time to market and improve product quality.

The Growth of Contract Manufacturing

The market for contract medical device manufacturing reached nearly $50 billion in 2014, up from $33 billion in 2011, and is expected to approach $120 billion by 2023, according to a recent report by market research firm Visiongain. Why is outsourcing growing so fast? It works!

Outsourcing manufacturing to third parties has been estimated by Visiongain to reduce the cost of device development 10-30 %. The report notes that, "Medical device companies are rapidly adopting the use of contract manufacturers as a strategic plan to stay ahead in an intensely competitive market space." CMOs are in turn continuing to look for ways to grow their businesses by delivering even better savings and faster development cycles.

Finding the Right Partner

Finding the right medical device contract manufacturing partner can be a challenge. By most estimates there are more than 6500 medical device companies in the United States alone. A review of supplier directories of industry website QMED finds more than 500 contract manufacturers. These range from small machine shops that specialize in making precision components to the largest OEMs in the world. Many of the smaller firms are highly specialized and optimized for

specific functions such as tooling, machining, prototyping, testing and trial design and management.

In a 2014 survey of medical device OEMs conducted by Capstone Partners, "quality" was cited as the top priority in evaluating manufacturing outsourcing vendors, followed by "product cost," "delivery," and "technical support." Quality is more than just the ability to produce a device to specification, it is a system of compliance that must be documented and demonstrated in every phase of development, and is an increasingly important issue for regulators. Pulling together the right team that can be trusted to meet these priorities and deliver the highest quality device at the lowest cost, on schedule with on going support can be an enormous challenge.

The Rise of "Concept to Commercialization"

Early contract manufacturing focused on production, with design, development, prototyping, verification and clinical trials often performed by device makers in-house. Over time, CMOs expanded to offer all of these services, leading many to claim that they could offer an entire package of services from "concept to commercialization" to better manage the process. This approach was borrowed from the pharmaceutical industry, and is attractive because it gives device makers a single point of contact for project management and risk ownership for new devices.

However, the medical device market is very different from the pharmaceutical market. The approval process for new drugs is relatively standardized. The device market is highly specialized, and regulations vary from device to device, and from device category to device category. In addition, each phase of medical device development has its own unique requirements, regulations and risks. Design, verification, clinical trials, manufacturing, packaging and labeling, and device monitoring are all complex practices in their own rights, and require exceptional expertise. This makes it unlikely that a single CMO can house experience and expertise, and show a track record of success in every aspect of device development for every type of medical device. Should a CMO stumble at any phase of the process, the consequences can be severe.

A New Approach to Concept to Commercialization
A 2010 report by McKinsey and Company, "Design to Value in Medical Devices," noted that, "As price pressures increase, medical device makers need to re-think product development processes." The article advocates for a rigorous focus on the value of the device to customers throughout the device development process, with stakeholders in each phase of the product cycle continually looking for opportunities to add value and cut costs and time frames.

A new breed of CMO is emerging, using a different approach to contract manufacturing that can deliver this kind of value. Instead of attempting to offer everything a device maker needs within a single organization, they offer a core competency as a sort of general contractor for medical device development. A general contractor engages experts in every aspect of the project, managing their work and holding the risk and responsibility for the project's success. This approach can result in a higher quality product due to expert involvement at each phase, and improved efficiency because each sub contractor has deep experience in its sector.

Bringing together a team of specialized experts in each phase of device development gives OEMs the advantage of experienced teams that can wring new efficiencies at each step. For example, a company that has deep experience, and the right equipment may also be able to make design recommendations that improve production time and part quality, while lowering costs. The lead firm, managing the overall process, should have the relationships and experience to access the right resources to deliver this kind of value.

Pioneering the General Contractor Approach
Phase 2 Medical Manufacturing, Inc., a medical device contract manufacturer with locations in Rochester, NH and Tijuana, MX is a pioneer in this new approach. The company began as a manufacturer of highly complex single use, disposable medical devices and built a strong reputation and record of success. As Phase 2 contemplated how to best move into making new devices for new markets, they quickly realized that it was not feasible to offer a "one size fits all" approach. The resources needed were too great, and they wanted to be sure to offer customers the highest level of quality and efficiency.

Phase 2 Medical began to source and qualify a wide range of subcontractors and partners, sifting through the thousands of companies in the industry to find the very best, building strong relationships with companies that have the right people, processes,

equipment and facilities in multiple areas of medical device manufacturing. In addition to installing a robust quality system, the company has continued building internal core competencies in project management, lean manufacturing, and design for manufacturing (DFM). Most importantly, significant capability in sterile barrier packaging, labeling, and sterilization management allow Phase 2 to offer medical device OEM's a truly turnkey manufacturing solution.

The New Model

This new general contractor model for CMOs allows manufacturers to achieve the promise of the "concept to commercialization" value by mobilizing the best people, processes and technology for a project, while still maintaining a single point of contact and accountability.

This model provides complete transparency and visibility to the entire distributed manufacturing team, with each subcontractor identified, qualified, budgeted and scheduled to get the highest value from the best resources. Original manufacturers know who is working on their product, when, how much it will cost, how long it will take, and when it will be finished. The general contractor manages the process and communicates with the customer. The medical device company can focus on the project at the highest level of schedule and budget, leaving the day-to-day management to a CMO.

Medical device makers are under intense pressure to bring new devices to market faster, and to lower production costs. Medical device CMOs are continually evolving in response, working to find new ways to make production more efficient. CMOs that can deliver new efficiencies while being accountable to budget and timeline will likely be most successful. The general contractor model for contract manufacturing is a new step in the evolution of the CMO, increasing productivity and quality while driving down the cost and time of commercializing new medical devices.