Roundtable Q & A: Contract Manufacturing

Matt Giza, Brian Green, Eric Resnick, Tricia Rodewald, & Jake Rost

Question 1: For a medical device company, what's the most important consideration to ensure they are selecting the best contract manufacturing partner?

Matt Giza
General Manager, Cogmedix

Given the regulated nature of the medical device industry, I would say the most important consideration is compliance. The medical device company is responsible for ensuring the partner they select is compliant with the FDA Quality System Regulation (QSR). A full quality system evaluation needs to be performed and yearly audits are required.

Following compliance, I might argue the next most important consideration is experience. Building finished devices entails quite a bit more responsibility than building components or subassemblies, from several perspectives, including the QSR, test, inspection, documentation, and packaging. Medical device companies can view how many products a contract manufacturer has listed with the FDA as one indicator relating to their experience. Another indicator into the effectiveness of the CM's quality system is to ask the CM how they performed on recent ISO 13485 audits or re-certifications and FDA inspections.

Following compliance and experience, trust, global supply chain, and flexibility are key. At Cogmedix, we always suggest that new customers consider calling any of our current customers for direct feedback. If a CM isn't willing to provide customer references, or has a hard time coming up with them, the medical device company may want to proceed with more caution.

Trust: To protect your intellectual property and competitive advantage, it is essential to work with an experienced and trustworthy outsourcing partner.

Diversified domestic and global supply chain network: Contract manufacturers with expansive supply-chain networks are able to secure world-class prices and

contingencies for varying quantities of parts. By providing well developed supply management capabilities and a secure infrastructure, outsourcers can optimize cost across their entire customer base and rapidly adjust to meet constantly fluctuating demands.

Brian Green
Engineering Manager (Texas facility), Suntron Corp.

Ensure your contract manufacturer is ISO13485 certified and registered with the FDA. The best partner will have comprehensive capabilities needed for production of medical devices including:

- Traceability: For purchasing, receiving, inspection, manufacturing, packaging, and shipping
- Robust Controls: Including storage, handling, process manufacturing
- Defect Tracking: Process data collection supporting continuous improvement
- Complaint Processing: Corrective action system to receive and document complaints and address the root cause
- Returns Processing: Processing warranty returns and non-warranty upgrades
- Record Keeping: Maintenance of Device Master Records, Device History Records, and Quality System Regulations
- Direct Order Fulfillment: Conforming to FDA requirements

Eric Resnick
VP of Engineering, West Pharmaceutical Delivery Systems

Culture. All good contract manufacturers will possess a strong management team,

technical capabilities, a quality management system, clean facilities, new equipment, and lists of references. But what lies beneath the surface is the most important, as it gets to the basic question “Do they get it?” “It” meaning, what it takes to be a medical device manufacturer. Can employees articulate what the quality policy means to them? Is there focus on prevention of defects, safety incidents, variation, waste, etc? Is there a common language throughout the organization based on GMP? Is the workplace visual and does it tell a story?

Tricia Rodewald
Director of Marketing & Strategic Alliances, Pro-Dex Inc.

From our perspective, a contract manufacturer that fosters a collaborative work culture is the most important consideration for a medical device company.

In today’s fast-changing, hyper-competitive marketplace, the primary survival tool of a medical device company is adaptability. And adaptability is rooted in collaboration.

No matter how talented individual people are within a company, if they are unable to work collaboratively and acclimate to an ever-changing environment, they are leaving their company and their partners vulnerable and unable to function at full capacity.

Technically skilled associates working collaboratively is what makes developing and manufacturing high-quality products in accelerated time-frames possible.

Jake Rost
VP/GM of Medical, Sparton Corp.

One of the most important considerations is the CM's experience with the medical device company's industry and related technology, especially if it involves a Class III device.

Question 2: How do you address the issue of concerns over quality control with potential customers?

MG: Quality control is paramount in building medical devices. High quality products are realized through effective execution of a robust quality system, adherence to the regulation, and data analysis. Product specifications need to be reduced to well documented work instructions that remove the "hero in the loop" and tribal knowledge. The work instructions should be validated through a consistent, well documented process validation and NPI methodology. Once this is complete, strict adherence to the work instructions, documenting and taking action on all non conformances, and tracking performance metrics will identify issues real time, capture them prior to the product shipping, and allow input back into the process for continuous improvement. Active, documented training of all resources is required and should be open for auditing.

BG: Suntron uses industry leading DFM and DFT tools to proactively identify opportunities for manufacturing defects before they occur. Additionally, Suntron has a thorough quality data collection system that identifies defects down to the component level. This data is referenced in daily management walk-throughs at a

granular level, and analyzed weekly by the quality and manufacturing engineering teams. A corrective action system is used to find and address root cause for trending issues. Quality reports are made available to our customers for their review, which encourages our customers to work in partnership to continuously improve product quality.

ER: Focus on philosophy and methods. Look at quality through the prism of risk; what are the severity, likelihood, and detectability of a defect making it to an end user? Primary efforts should be on eliminating occurrence of defects and this requires robust problem solving and root cause investigation skills. Don't over rely on detection or increased inspection. Increased inspection is a corrective action if a known defect has been produced, but it is not a preventative action. That requires eliminating likelihood. Also, SPC is far more effective than product control; detect potential defects at the earliest process step.

TR: In tandem with collaboration, communication is key. Contract manufacturers must effectively communicate inside their organization between all departments—RA/QA, engineering, business development, operations through to marketing, customer service, accounting, and purchasing—as well as with their medical device partners.

There are usually less quality control issues when communication is open and flowing.

Furthermore, a contract manufacturer significantly dissipates concerns about quality when they can actually demonstrate to their medical device customer that their processes cultivate effective communication and collaboration—from the initial phases of design all the way through distribution.

JR: Our certifications to ISO standards, audits by the FDA, and routine evaluations by our customers assures our potential customers that we have the quality control systems in place to be compliant with the FDA and meet their quality requirements. We also have benchmarked many of the leading quality control systems from industries outside of medical to further augment our quality control methods.

Question 3: What benefits does a contract manufacturing partner offer specifically to medical device companies versus doing all tasks in-house?

MG: We believe the primary benefit is time-to-market. Whether the medical device company is a start up or a Fortune 500 company, an agile CM can help get products to market more quickly, assuming they have experience in NPI. Start-up companies are generally short staffed due to the desire to control cash flow and should focus on innovation and marketing that will fuel their differentiation and growth in the market. Large companies are often challenged with launching new products because it interferes with other internal high volume manufacturing or the process internally is simply too cumbersome to effectively launch a product into production in a timely manner. In the case of a start-up company, there are significant capital preservation advantages given the simple fact that the investment that would go into developing a team and facility that is enabled to receive, inspect, inventory, kit,

assemble, QA, test, package, and store products will all be avoided, or certainly significantly reduced.

In addition, as often is the case in a start up or a new product launch, the “standing army” is avoided and the medical device company generally only pays for the time resources used on their products. In the case of a larger medical device company, it is highly likely the CM has a lower overhead and cost structure so savings are realized quickly, not to mention the value of getting a product to market weeks or months sooner. That’s tough to measure, but a significant part of the equation.

Once the product is mature, working with a CM helps reduce costs by leveraging a global supply chain shared by many customers, improving ability to react to demand by leveraging resources across many programs, and continuing to take advantage of the earlier entry into the market. Of course, with a trusted CM, it also ensures that the medical device company’s products are being manufactured in a compliant manner, which is absolutely critical.

BG: Contract manufacturers that specialize in medical devices will have an infrastructure comprised of capital and trained personnel ready to implement a detailed and established set of manufacturing procedures. The infrastructure will be robust with technical capabilities that allow the OEM to focus on its core competency along with ensuring compliance to design specifications. A manufacturing partner leverages material spend throughout the supply chain to assist with driving down overall product cost. Additionally, the partner will be accustomed to meeting regulatory requirements and can help guide the medical device company through areas where they would normally need to hire individual experts.

ER: It is unlikely that one company can be considered expert in the field of developing, marketing, selling, and producing all of its medical devices. To do so would be a financial burden in terms of employment needs and capital investment. By using CM partners, the medical device company can leverage experts in specific fields or industries. These fields are often very competitive, leading to reductions in COGS when compared to internal captive manufacturing. Also, by using outside services, you are able to gather diverse opinions and techniques that will benefit the quality of your products.

TR: Medical device companies can quickly lose market share if their product isn’t ready. This is why accelerating time-to-market is a significant benefit of partnering with a manufacturer who is able to compress the development cycle.

The smaller size of most contract manufacturers makes collaboration between cross-functional teams more effective, reducing costly errors and redesigns; prototypes can be made in-house, allowing for adjustments to be made in minutes rather than days; test methods are shorter and more scientific, minimizing iterations.

All these factors compress time-frames without compromising quality, safety, reliability, and budget, relieving many headaches for medical device companies.

JR: Having a reliable contract manufacturing partner allows medical device companies to focus on innovation and expand market share while trusting their CM with delivering product in a more efficient variable cost model. Additional benefits include having a manufacturing partner focus on post market release activities like cost improvements, reliability, and service.

Question 4: Any thoughts/comments on contract manufacturing you'd like to share?

MG: Contract manufacturing has evolved significantly since the '70s. We firmly believe that companies of all sizes need to consider and implement some form of outsourcing strategy with contract manufacturers. There are advantages to companies of all sizes with respect to time-to-market, cost savings, reaction time to demand fluctuations, and more.

BG: When medical device companies align with an experienced contract manufacturing partner, the results lead to direct capability with demonstrated results. The proficient medical device contract manufacturing partner provides sound manufacturing expertise, supply chain leverage, workforce flexible, quality data collection tools, and FDA compliant processes, allowing the medical device company to speed their product to market.

ER: Partner selection is critical to a successful relationship between CM and client. The best partnerships are based not on price, but on total cost benefit analysis. If the most expensive potential CM partner can reduce the probability of an expensive recall, isn't that valuable? Also, the CM who routinely exceeds expectations and delivers satisfaction will allow the client to reduce its necessary level of management and oversight, allowing the client to focus on value added products. A medical device company should always take a balanced approach consisting of technical, quality, and commercial experts when it comes to CM selection and performance.

TR: When the vantage points of engineering, design, regulatory compliance, procurement, business development, and manufacturing are taken in to account—from product conception all the way through delivery—every department is contributing fully to the timely launch of a successful product.

This not only helps expose issues faster, it also ensures the best cost, quality, reliability, regulatory compliance, and speed-to-market for their customers.

In order for a contract manufacturer to offer maximum value to their medical device partners, their work culture must foster multidisciplinary teams working together cohesively and iteratively, not in silos.

JR: Having a defined scope of work in advance of evaluating contract manufacturing partners will save the medical device company a lot of time and money in the evaluation process. It also ensures some consistency when evaluating proposals from the CMs.

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