Guidelines for Selecting a Medical Device Contract Manufacturer

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Twenty years ago, many pharmaceutical and medical device companies viewed device contract manufacturers (DCM) as vendors or suppliers. The relationships were purely transactional. Pharmaceutical and biopharmaceutical companies were somewhat reluctant to outsource higher risk, more complex device assemblies. Today, they are looking for ways to reduce internal resources and expect more ownership of the supply chain, which means contract manufacturers are now providing additional services including drug handling, cold chain storage, sterilization, analytical testing and final packaging.

Collaborating with the right DCM early on, in the process can have many benefits, including risk mitigation, innovative strategies and a faster speed-to-market.

Selecting an experienced device contract manufacturer is an important decision that may impact a drug product's ultimate success, so a methodical risk-based approach should be taken. Consider these guidelines when evaluating potential device contract manufacturers to choose one that will be the best fit for your company.

- **Perform a comparative analysis:** This analysis can be completed quickly with minimal expense, and will narrow the list considerably. Subsequently, by following a risk analysis of each option, a cross-functional site audit is advisable to evaluate not just capability, but cultural fit. Quite often, medical device or combination product manufacturers are sought based on core technical competency or manufacturing capability, when in fact a company's culture is just as important or more important to the success of the program. When performing comparative analysis and evaluating the DCM's manufacturing capability, consider the following to establish strategic fit:

Company / Experience

- Does the DCM produce a product with similar features and characteristics? Or have they in the past?
- Does the DCM have final packaging, drug handling and labelling capabilities?
- What is their history of performance during a build (tooling, equipment)?
- What is the total cost of ownership associated with working with this DCM?

Engineering capabilities

- Does the DCM's technical staff possess the education, background, training and experience to be successful with this endeavor?
- Does the DCM have the capability to perform manual, semi-automated and/or fully automated assembly?
- What type of final acceptance activities will be required?
- What support will be required for product serialization? Have they implemented for other products?
- What's the DCM's technical solution and the risk associated with that solution?

Delivery / Support

- How successful is the DCM in scale up and commercialization, and can they handle the projected volumes?
- What's their ability to meet deadlines, post commissioning support and provide references?
- Does the DCM have a robust equipment, qualification and validation process in place?

Financial Strength

- What is the financial stability of the proposed partner?

Quality Systems

- Does the facility and infrastructure align with the overall manufacturing environment and have the proper risk mitigation controls?
- Does the DCM calibration preventive maintenance and statistical process control systems in place?
- Do they have ISO certification and what is it in?
- Is there a sense of quality control when you're on the audit?
- Does this device require a core competency or specific innovative technology that the DCM can support?

- **Understand their product development and manufacturing capabilities:** Manufacturing complex drug delivery devices such as autoinjectors, pen systems and respiratory devices requires the right people, advanced processes and equipment. Before selecting a partner, it is critical to understand if the device contract manufacturer has knowledgeable project teams that are capable of providing necessary support. During initial product development phase, the right DCM partner will be able to provide valuable input on device design ensuring the design and manufacturability are robust for commercialization. They should be able to provide appropriate scale-up plans for the device including risks/delays associated with each phase of the product lifecycle. Additionally, they should propose a tooling and assembly strategy that meets your commercial plans. Some core capabilities to identify in a device partner include:
  - Tooling
  - Molding
  - Assembly expertise
  - Automation experience
  - Metrology

- **Look for a proven quality management system:** Before making your decision, assess the robustness, reliability and track record of the DCM's quality management system (QMS). It is essential that they have a demonstrated record of compliance with processes for traceability and documentation on device history records, reports on calibration procedures and test data – all of which will help with FDA and ISO 13485 compliance. Requesting third-party certifications and regulatory inspection history (and if there were any findings) may provide a view into the overall compliance profile. Pharmaceutical companies should look for a DCM whose QMS approach fulfills key elements of its own QMS. At the same time, the DCM's QMS should not merely be an extension or rely upon the sponsor's QMS.
  - **Does the DCM follow FDA guidelines** 21 CFR Part 11, Part 820 & Part 210 &211? what ISO standards are they certified to and ISO standards do they follow for testing?

- **Understand how the DCM manages risk:** An evaluation of the DCM's risk management program should be a part of the review process in both the due diligence and audit. If possible, review how Failure Mode and Effects Analysis (FMEA's) are generated and managed. Are other tools utilized and are they applied appropriately and consistently? Application of an overall risk management process throughout the QMS may provide further assurance that the contract manufacturer will recognize and institute actions to prevent future issues of critical or major concern.

  When reviewing the strength of a risk management program, evaluate how the DCM is applying risk management into its QMS, including: internal audits, nonconforming products, complaints, corrective and preventive action (CAPA) and change management. Look for evidence of the practices described above as another early indicator of quality culture fit and future success.

- **Visit the site:** Pharmaceutical and medical device companies need DCMs that embrace their values and are motivated to continuously improve and add value. Once you have narrowed the field down to a few potential candidates, it is in your best interest to conduct a site visit. It all starts with the agenda and what you want to accomplish. Do you need device design, industrialization and commercialization? Or is this a device transfer project? This will help frame the visit and ensure you meet with the right team.

  Once at the site, look to see if the DCM can demonstrate what was presented/proposed such as operational excellence, lean manufacturing and a robust quality system. What technologies are they using to ensure quality is met? Is there a continuous improvement mindset and a culture that is compatible? These factors should be included in the overall risk profile and potential impact to the total cost of entering into a partnership. Site due diligence and compliance audits can mitigate the risk of selecting a contract manufacturer that might result in the high costs associated with poor quality (including unanticipated increased oversight).

- **Consider the supply chain:** Material costs of medical device manufacturing can be a significant portion of the finished product. It is therefore imperative that the pharmaceutical company evaluate the methodologies and techniques utilized by the supplier to manage their vendor base. How are MRP systems and vendor quality control programs integrated? Understand the buying power that they may be able to offer in order to procure the required materials at lower prices without sacrificing quality or delivery timeframes.

- **Evaluate using a multifunction team:** Initial due diligence reviews of potential DCMs should be conducted by a team inclusive of technical, business, operations and quality representatives. The due diligence visits should cover core aspects of the DCM, such as:

  - Quality Management System
  - Risk management approach
  - Manufacturing capabilities
  - Design control system
  - Root cause analysis
  - KPI metrics
  - Financial stability
  - Cultural compatibility
  - Quality agreement

Collaborating with the right device contract manufacturer can improve the likelihood for success. It is imperative to choose an experienced partner that can ensure that the products provided are of the highest quality, minimize disruptions to the supply chain and bring safe, effective drug products to patients quickly and efficiently.

About West

West Pharmaceutical Services, Inc. is a leading manufacturer of packaging components and delivery systems for injectable drugs and healthcare products. Working by the side of its customers from concept to patient, West creates products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply. West is headquartered in Exton, Pennsylvania, and supports its customers from locations in North and South America, Europe, Asia and Australia. West's 2016 net sales of $1.5 billion reflect the daily use of approximately 112 million of its components and devices, which are designed to improve the delivery of healthcare to patients around the world.

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