

Best Practices in Selecting a Medical Device Contract Manufacturer

Contract manufacturing is on the rise in the medical device industry, but finding an ideal partner to manufacture your device isn't always easy.

Why use a contract manufacturer?

Contract manufacturers have played a significant role in the medical device industry for decades, and that role will be expanding in the years to come – some analysts expect the volume of devices built by contract manufacturers to double in the next five years. There are many reasons for using a contract manufacturer, but several stand out in today's industry:

- Downward price pressure, a continuing trend in foreign markets and an increasing trend in the United States market
- Limited venture capital funding
- Increasingly complex device designs leading to a need for increasingly complex manufacturing technologies

Although using a contract manufacturer can benefit almost all medical device companies, the primary benefit recognized often varies depending on company size. For a small company, the key benefit of using a contract manufacturer is often efficient use of limited funds; with a strong manufacturing partner, a small company can minimize or even eliminate the need for direct capital investment. For more moderate size companies, contract manufacturing provides an opportunity for the company to focus on their core technology or core therapy by outsourcing the day-to-day concerns of manufacturing. Large companies can benefit from the lower overhead that contract manufacturing provides; this can be particularly important for manufacturing of legacy products.

Contract Manufacturing Challenges

The benefits of working with contract manufacturers are myriad, but there can also be difficulties. Some of the more common issues in the medical device industry include:

- Identifying a partner with a robust quality system. Some contract manufacturers have made the transition to medical devices after getting their start in telecommunications or other less regulated industries. The quality system and quality culture may be insufficient, particularly for manufacturing Class II and Class III devices.
- Finding a manufacturer with both breadth and depth in manufacturing techniques for fabrication of complex devices. The industry is seeing a surge in development of mechanically and electrically intricate minimally invasive surgical devices, high-risk implantable devices, and miniaturized monitoring devices among other complex designs. To build these types of devices, a manufacturer must be competent in more than basic electro-mechanical assembly.
- Selecting a supplier who can support your entire product life cycle. Contract manufacturers often have a specialty – they may work primarily in a high mix/small volume mode or in a low mix/high volume mode. This may mean that as your product transitions from small development and clinical volumes to higher commercial volumes, you will need to move to a new manufacturer. This kind of change can be costly, risky, distracting to your in-house resources, and can create regulatory delays for your product launch.
- Obtaining the right resources to support your project. Many contract manufacturers work primarily in a “build to print” mode. While this helps you achieve the primary goal of getting your device fabricated, it won’t help you improve your device design for manufacturability, reduce the cost of your manufacturing process, or lean out your supply chain.

CIRTEC Quality System

ISO 13485: 2003 certified

FDA Registered

Focus on Class II and III devices

*Support for CE Mark, 501k, and
PMA submissions*

Selecting the Ideal Contract Manufacturer

How can you avoid these common pitfalls and develop a relationship that provides all the benefits that contract manufacturing can offer? There are some simple steps that will help keep you on the path to contract manufacturing success:

Step 1: Understand the quality system requirements for your product and research potential suppliers to find a match.

- Determine the regulatory path and classification for your device. Look for manufacturers with experience working with devices of that class.
- Will the contract manufacturer deliver you a finished device, or will you perform final operations at your facility or a third party? If the device will be finished by the contract manufacturer, limit your search to suppliers who are appropriately registered with the FDA.

- How will your quality system mesh with the system at your supplier? Your contract manufacturer should have a robust method for documenting and executing quality system interfaces.
- How will you approach process risk management and qualification? A manufacturer with existing procedures for these activities could streamline your project.

Step 2: Identify a manufacturing partner with the right combination of capability and expertise for your device.

- Understand the key manufacturing processes required for fabricating your device. This might include extrusion, mechanical joining, plating or coating, overmolding or adhesives work, sealing, complex packaging, or other processes.
- Determine which key processes require high value capital equipment. Focus your search for a contract manufacturer on companies with the appropriate high value equipment already in place. This is particularly important for processes that should be completed in a cleanroom environment
- Identify key processes that require customized process parameter development. Look for contract manufacturers with demonstrated expertise developing and qualifying those types of processes.
- Will your device include a power source? Seek a manufacturer with experience handling and shipping power sources safely; in some cases, the manufacturer may need to be specially certified for shipping.
- How will your device be tested for safety and functionality? Complex designs may require a variety of test techniques, including power up and power supply recharge testing, air and water ingress testing, mechanical strength testing, electrical function testing, pressure response testing, or package seal testing. The contract manufacturer you select should have sufficient expertise to help you determine which tests should be performed and implement those tests.

<i>Electromechanical assembly</i>	<i>Silicone molding, backfilling, adhesion</i>
<i>Laser ablation</i>	<i>Coil winding</i>
<i>Laser welding</i>	<i>Thermal bonding</i>
<i>Laser marking</i>	<i>Resistance welding</i>
<i>Pultrusion</i>	<i>Ultrasonic welding</i>
<i>Epoxy molding and backfilling</i>	<i>Packaging and labeling</i>

Table 1: Selection of CIRTEC manufacturing capabilities

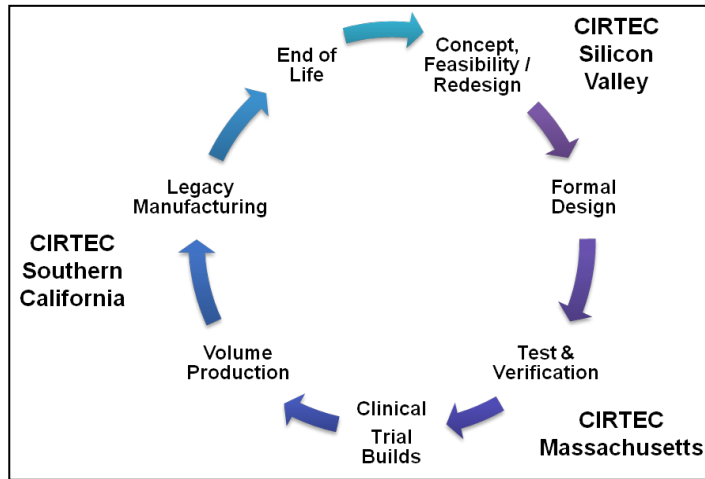


Figure 1: CIRTEC facilities support complete product lifecycles

Step 3: Outline your product life cycle both in time and in manufacturing volumes. Use that outline to determine a suitable manufacturing partner.

- What range of volumes do you expect to build over the life of your product? Look for a supplier with the facilities and the organizational structure to support you through clinical trials, initial production, and the ramp of commercial manufacturing.
- How will you ensure continuity in the team throughout the product life cycle? An ideal contract manufacturer will have a history of customer service and will provide a consistent point of contact through your entire product life cycle.

CIRTEC Customer Service

Every product has a consistent account manager throughout its lifecycle

Eight current clients have been with CIRTEC for over 10 years.

Step 4: Determine your strategy for in-house resources and identify a contract manufacturer who will complement your team.

- A full service contract manufacturing can provide design for manufacturability input for your product, helping to increase yields and decrease costs.
- If your product design isn't fully mature, a contract manufacturer with prototyping and design capabilities can be a tremendous asset to your team. This is particularly true for design aspects outside the core technology of your product, which may be a distraction to your in-house team.
- Will your product require custom test systems as part of the manufacturing process? If so, a supplier with test engineering capabilities could be ideal.
- How will your supply chain be managed? You may benefit from a contract manufacturer with the engineering and materials management personnel to provide supplier development and materials management. Early stage companies may further benefit from a contract manufacturer with a strong Approved Vendor List to help build an initial supply chain.

CIRTEC Manufacturing Support Services

Manufacturing Engineering

Fixture Design and Fabrication

Quality Engineering

Quality Control

Test Engineering

R&D Engineering

Material Planning

Material Management

Conclusion

Working with a contract manufacturer offers a range of benefits, including lower cost, reduced capital expenditure, more options for complex manufacturing processes, and freedom from day-to-day concerns allowing greater focus on your company's core technology.

There can be challenges in working with a contract manufacturer, but by keeping the following key factors in mind during your selection process, you can find a partner who will help you succeed:

- Match the quality system requirements for your product to the capabilities of your contract manufacturer.

- Identify a manufacturing partner with the right combination of process capability and expertise for your device.
- Understand your product life cycle both in time and in manufacturing volumes and select a manufacturer with a corresponding business model.
- Identify a contract manufacturer who will complement your in-house team.

CIRTEC Medical Systems is a full service contract manufacturer of Class II and III devices and can support your product through its entire life cycle.