5 Ways to Turn a Medical Supply Chain into a Competitive Advantage

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Design engineers are charged with creating reliable, high quality, safe medical devices that easily (and quickly) pass U.S. FDA and other geographies' regulatory requirements. Because of the unique challenges that a medical device OEM must overcome to stay competitive, more and more OEMs are choosing to outsource manufacturing.

One of the greatest challenges a medical OEM faces is how to build a supply chain that meets and maintains ISO 13485 standards for components and systems and will support manufacturing through a medical product's end of life.

Following are five key elements for developing a robust, reliable medical device supply chain.

1. Partner with an ISO-certified and FDA registered manufacturer that has a staff of experienced engineers and supply chain professionals.

The outcome every OEM is looking for is a high-quality product produced on time. Successful manufacturing starts with having a partner with the professional talent and resources that can augment an OEM's team. For example, Tier 1 ISO-certified manufacturers typically have highly skilled engineers throughout their organization.

Top manufacturers heavily invest in their engineers—mentoring, educating, and challenging them by exposing them to a broad range of engineering and manufacturing problems associated with a wide range of products.

Over time, these engineers develop a collective knowledge base of how products should be manufactured in the most efficient way with modern processes, techniques, and sources. The engineers apply that knowledge in real time as they design products. The design is optimized for manufacturing and supply chain from the start. As a result, these manufacturing and design engineers apply years of experience to a new product. These are the types of engineers an OEM wants to work with to design and optimize its product and develop a robust supply chain.

2. Follow a proven design process

Instead of letting the supply chain just “happen,” medical OEMs should work with a manufacturer that has a proven, documented design process—a process that consciously integrates the creation of a robust, qualified supply chain when designing the product from the start. This way, control of the supply chain rests with the OEM, instead of with suppliers.

The best approach is to have the design engineers document their needs (e.g., 12 V power supply, 10-inch display with a certain viewing angle, etc.). The manufacturer communicates those needs to their component engineers. The component engineers come back to the design engineers with a list of recommended components and suppliers containing expected lifecycles, costs, and delivery lead times from ISO-qualified suppliers. In cases where there is no ISO-qualified supplier for a component, the manufacturer would take the actions necessary to qualify that supplier. It is from this list that the design engineers can confidently select their components and begin their design work, confident that the supply chain can and will support the product from launch to end of life. This makes the overall design process efficient and cost-effective, with significant potential cost avoidance.

3. Have multiple, ISO-qualified sources for critical and custom components

In any given medical device, there are usually four to five key technology areas or subassemblies that consume the majority of a manufacturer’s attention. Not every product has all of them, but they usually have several: subsystems or components with core IP or innovation, power supply and batteries, display, microprocessor and communications, motors and mechanisms, plastics or other custom mechanical items. These critical and/or custom items can take 80% or more of the effort in designing the supply chain for a medical device. And they also tend to be the key components from the FDA’s or CE’s point of view because they’re usually safety- or efficacy-related items.

A significant competitive advantage comes from having at least two qualified sources for each of these critical and/or custom components. With multiple sources, the OEM is less likely to experience adverse supply chain disruptions from natural catastrophes (e.g., earthquakes, tornados, and tsunamis) and economic/political interruptions or from a component going end of life.

4. To avoid potential product liabilities, select a partner with a successful track record and capacity for qualifying new component suppliers for custom parts and maintaining ISO quality standards

Whenever there is a custom-designed part that provides a critical function, there is the opportunity for product liability or a medical product not performing in a manner consistent with claims. This is a significant potential liability for OEMs. With the FDA's increased and renewed focus that all critical components in medical devices meet proscribed standards, managing a medical device's supply chain becomes a bigger challenge than ever before.

Experienced medical manufacturers help suppliers establish compliant processes and controls so they can produce the objective evidence and documentation set out by international standards and regulations applying to medical devices. Once the supplier has been qualified, the manufacturing partner continues to manage the supplier throughout the manufacturing life of the medical device to ensure the firm stays in compliance.

5. Secure the supply chain for custom components with appropriate contract mechanisms

Since most medical devices are usually in the market for a long period of time, one of the challenges is ensuring that the components will still be available two to ten years from product launch. It's not unusual for components to stop being manufactured, often because a company transitions to its next generation component as is the case for displays and processors.

If it's an off-the-shelf component, try to qualify multiple suppliers. But if it's a custom component, like a communications module or precision mechanical or optical assembly, different steps should be taken up front with the supplier contract. When this happens, the medical OEM has to find and qualify a new supplier or, worse, redesign the component, with a potential risk of having to re-submit the device to the FDA with a revised design through a 510(k) (or similar) process.

In these situations, it is crucial to negotiate at the outset for the rights to manufacture the component or license critical technology under certain conditions. For custom components, top tier manufacturers will require a supplier to put all design documentation, test information, and specifications into escrow at the beginning of the contract and before work starts. This way if the supplier is unable or unwilling to produce the component or raises its price, then the manufacturer has legal ownership of that design along with full manufacturing rights.

Following these 5 tips will help medical OEMs strengthen their supply chain for a substantial and lasting competitive advantage.

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