Single Sourcing: The Cure for the Common Supply Chain

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Medical device OEMs can cure their supply-chain ills with suppliers that do more than supply.

The changing regulatory and political actions imposed on medical device OEMs are pressuring them to scrutinize their businesses to remain competitive. Industry reports estimate that it costs $31 million on average to bring a 510(k) product to market and $94 million to bring a PMA device to market. Further, more than 75% of those costs are directly related to clearing regulatory requirements. The Affordable Care Act’s 2.3% excise tax on all U.S. sales of medical devices—a projected $30 billion industry hit over the next decade—adds 33% to the medtech industry’s overall tax burden.

Although medical device OEMs cannot control regulatory costs and increased taxes, they can control both the production costs and selling of their products. Passing along increased costs and charging customers more is only a partial solution for OEMs. For sustained competitiveness, manufacturers must examine ways to streamline the manufacturing of their devices and lower production costs.

One practical way manufacturers can achieve these goals is to consolidate their supplier base. Part of the high cost of bringing product to market can be attributed to outsourcing component manufacturing from multiple—often hundreds—of suppliers. Managing these complex relationships can take a heavy financial and logistical toll. Having multiple suppliers slows
production time to market and drives up the cost for the OEM, and ultimately, its customers.

Instead of having one supplier doing specific things, medical device OEMs can select a partner that does more than just supply. A supplier that offers a vertically integrated supply-chain solution can add value to the OEM’s manufacturing process by doing more for them.

OEMs need to evaluate suppliers based on total-cost-of-purchasing criteria instead of the cost of the parts. It’s a bit of a shift to seek suppliers that combine manufacturing with services such as purchasing, engineering assistance, production, finishing, and assembly. Entrusting more of the product development processes to one supplier involves careful evaluation.

Any error in an OEM’s medical device can set the company back weeks and cost millions of dollars. Therefore OEMs have to be sure that their supplier can meet the exact specifications time after time.

Choosing the right supplier among the thousands is challenging. To make the right supplier choice, OEMs should consider the following supplier criteria:

- Manufacturing expertise.
- Medical industry expertise.
- Engineering savvy.
- Risk tolerance.

**Manufacturing Expertise**

A supplier might wow you with its myriad services, but it should be completely eliminated from your consideration if it is not exceptional in the most basic function of manufacturing. Whether it is extruding, machining, molding, finishing, or welding, a supplier must be able to respond to an OEM’s unique manufacturing needs.

Plenty of suppliers have exceptional manufacturing skills, so separating them from one another involves looking at their less-publicized capabilities and determining if they can add value to your process.

One such capability might be in-house toolmaking. Many suppliers can produce components, but they may be unable or unwilling to create the machine tools used to manufacture them. They must purchase tools from other suppliers, which not only extends the supply chain, but also can create the opportunity for inaccurate communication or even slight mismatches between tool and component specifications.

In an industry in which microns can make all the difference and risk mitigation is a must, the threat of even the slightest manufacturing inaccuracy must be eliminated. OEMs might want to look for suppliers that have chosen to keep toolmaking in-house. These suppliers can design both simple and complex tools that efficiently take OEM projects from design to production to significantly minimize the risk of error.

Because in-house toolmaking is an integral part of the supplier-OEM partnership, skilled suppliers often engage in continuous improvement activities. These activities include creating advanced tools and implementing new concepts that help machine devices more efficiently.
Other supplier capabilities, such as CNC, vertical- and long-bed precision machining, robotic pick-and-place technology, metal finishing, and multifunction manufacturing processes improve manufacturing and product details. Supplier operations with complementary component manufacturing services can also help improve accuracy and contribute to complete product manufacturing.

**Medical Industry Manufacturing Expertise**

Manufacturing expertise is fundamental because of the complexities of the industry. Suppliers should have medical industry manufacturing expertise and a proven track record. Without it, they are just taking orders and skimping on adding value to the overall process.

Proof can be found in a supplier’s robust internal auditing system, along with documented quality and delivery performance. FDA has not only stepped up the frequency and intensity of surveillance with large medical device manufacturers, it also is starting to directly interface with the supply chain as well.

Compliance with ISO 13485 standards and European medical device directives’ RoHS, WEEE and REACH (requirements for hazardous materials used in medical devices and disposing of electrical components and waste created during manufacturing), also add evidence of industry expertise.

Suppliers need to understand and collaborate with OEMs to help ensure their manufacturing processes adhere to proper tolerances, while meeting the functional and critical to safety requirements of the product. Machines that deliver x-rays and isotopes using mechanical movements, for example, can lead to severe patient injury if the functional components are not embedded in a fail-safe process. Such proper mechanics need to be established in the product development stage.

Suppliers who understand and comply with medical device regulatory guidelines can help OEMs ease the due diligence process. And those who go the extra mile by offering engineering design assistance, can provide additional value to OEMs.

**Engineering Savvy**

After a supplier has passed the capabilities and industry-expertise tests, the next thing to evaluate is engineering abilities.

Most suppliers offer engineering services to some extent, but relatively few have the resources necessary to allow OEMs to place most of their supply-chain needs from design to assembly in a supplier’s hands.

One such resource is 3-D modeling. By creating a 3-D, digital model of a component, engineers can make adjustments in real time. This capability enables suppliers to troubleshoot designs, create fabrication tooling fixtures, order custom dies, and program machining and inspection equipment without ever seeing the finished part.

This 3-D modeling allows for flexibility because engineers are able to use an active, working model to test the prototype components to help ensure they meet the required tolerance and...
dimension specifications. Supplier engineers can make real-time changes during the design cycle instead of waiting to see how the component turns out before going back to the drawing board. This function can lead to huge savings in time and resources.

A consolidated supply chain enables design for manufacturability. As the partnership develops, the supplier becomes more familiar with the parts and the context in which they are used. Supplier engineers can better understand each part’s essential functions, how the parts interact with the system, and the reasons behind aesthetic, durability, and weight requirements.

Such familiarity puts the supplier on the same page with the OEM design engineer and enables them to work together to create components that are easy to use and manufacture.

For example, one medical device manufacturer was having design problems with a component that was exhibiting unwanted breaks during testing and was difficult to assemble. Rather than ordering the same set of replacement components, the OEM decided to work with a supplier to seek an entirely new component. The new design jointly created by OEM and supplier engineers involved evaluating the component’s technical needs, including durability and ease of assembly.

Instead of using the original design and steel material, the supplier extruded and hard-coat anodized a new aluminum component. The component profile also was designed to snap fit with its mating components. This element eliminated the previous need to use hand tools during assembly, reducing assembly time from eight hours to one hour. Not only did the new component meet the requirements for durability, it helped the OEM be more competitive by lowering the manufacturing cost per part and reducing assembly time. Such a partnership can only work if the OEM and its supplier work together to determine the best approach to manufacturing components. In some cases, it may not be what the original design engineer intended.

Another service a good supplier will offer is customer training. New product design engineering assistance, on-site customized educational seminars, and tailored events help inform customers of the latest industry developments and manage expectations when it comes to manufacturing design.

OEMs should work with suppliers that want to be a part of the product development process and design for manufacturability.

Good suppliers want to know what the OEM is doing, why they are doing it, and how they can work together to do it better.

**Risk Tolerance**

With the high cost of creating medical devices comes a low margin for error. As in the manufacturing of parts, one small error at any point in the process is unacceptable.

OEMs should look for suppliers that embrace a zero-tolerance approach. Perhaps the easiest way to determine this is by looking at third-party certifications. These certifications, particularly those administered by ISO, are given to suppliers that meet the organization’s high standards for safety, reliability, and quality.

But these standards should just be a starting point. Suppliers deserving of an OEM's
consideration should go beyond this by minimizing risks throughout the entire product
development process, not just during the manufacturing stage.

One way to do this is through data-driven predictive maintenance. By analyzing manufacturing-
process control data, suppliers can predict how often a machine tool can be used before it
wears down and replace it before it reaches that point. This means not having to wait for new
components to be delivered and not having to worry about the components meeting
specifications because they were made with a worn-out tool.

Consolidating several manufacturing steps with one supplier also limits the risk of transit
damage. Instead of one supplier creating a component, boxing it up, and sending it to another
supplier that handles the next step in the manufacturing process, a single supplier controls and
manages the entire process. Fewer hands touch the product, leaving fewer opportunities for
freight or material-handling damage. Consolidation can also decrease shipping and packaging
costs.

Though significant, the risks pale in comparison to the greatest risk OEMs face: not delivering
their devices to the market on time.

Medical device patents last for only 20 years, and many of those years are spent researching
and designing the product. OEMs have a limited time to cash in on their innovations. Every
minute that production is delayed, money is wasted. To counter this time crunch, some suppliers
have adopted quick response manufacturing philosophies that strive to cut down lead times in all
levels of production.

The approach essentially combines the waste-eliminating focus of just-in-time, or lean, practices
and manufacturing with a heightened attention to timing for all steps in the supply-chain product
development process. Instead of waiting 30 days for a supplier to create a product, quick
response manufacturing can allow the same process to be performed in just four days—a
reduction of almost 90%.

Such speed allows OEMs to get their devices to market more rapidly, respond quickly to
changes, avoid potential breaks in the supply chain, and lessen downtime and the high costs
that accompany it.

**Supplier Relief**

For medical device OEMs, managing the logistical maze of hundreds, sometimes thousands, of
suppliers adds unneeded costs and time required to transfer partially finished components from
one supplier to the next.

Turning to a single-source supplier can remedy that problem. The right supplier can provide a
team of dedicated engineers, manufacturing specialists, and market experts to review designs
and discuss capabilities. It can work with OEMs to create real-time solutions that help simplify
their supply chain and get products to market faster.

OEMs must work with suppliers every step of the way, insisting on suppliers who can help limit
their costs while elevating product quality and taking some of the responsibilities off their plate.
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