The Cure for the Common Supply Chain

By Gordon Knott & Jim Sartell

Medical device original equipment manufacturers can cure their supply-chain ills with suppliers who do more than supply.

The changing regulatory and political actions imposed upon medical device OEMs are pressuring them to further scrutinize their businesses to remain competitive. Industry reports estimate that more than 75 percent of the average $31m cost to bring a low-to-moderate 510(k) medical device to market, and 75 percent of the average $94m cost to bring a high-risk device that requires pre-market approval to market, are related to clearing regulatory requirements. Added to that is the impact of the Affordable Care Act's 2.3 percent excise tax on all U.S. sales of medical devices—a projected $30bn industry hit over the next decade and a 33 percent increase in the medtech industry's overall tax burden.

While 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 should re-examine how they streamline the manufacturing of their devices and lower production costs.

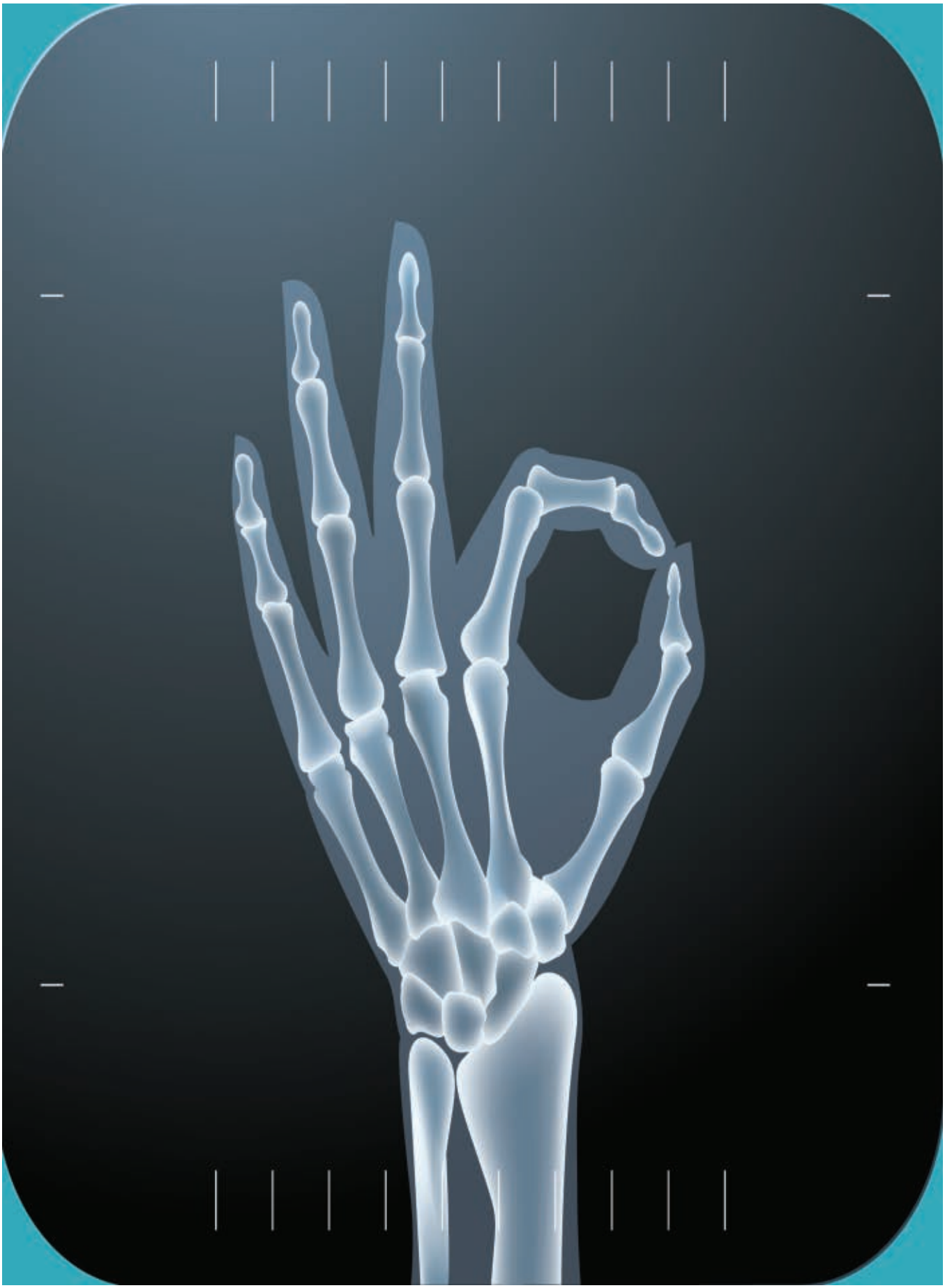
One practical way manufacturers can do this is to consolidate their supplier base. The high cost of bringing product to market can be attributed to outsourcing component manufacturing from multiple—often hundreds—of suppliers. Managing these complex relationships can take a heavy financial and logistical toll—slowing product time to market and driving up the cost for the company, and ultimately, its customers.

Instead of having one supplier doing specific things, medical device OEMs should 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 of it for them.

That means OEMs need to evaluate suppliers based on total-cost-of-purchasing criteria instead of the cost of the parts—seeking suppliers that combine their manufacturing expertise with value-added services like ease of purchasing, engineering assistance, production, finishing and assembly.

A vertically integrated design-engineering and product-manufacturing model simplifies the supply chain, helping OEMs bring their products to life more successfully and economically.

But 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

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

Plenty of suppliers can do these things, 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 is in-house toolmaking. Many suppliers can produce your components but they may be unable or unwilling to make the machine tools used to manufacture them. This type of outsourcing from other suppliers 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 where microns can make all the difference and risk mitigation is a must, the threat of even the slightest manufacturing inaccuracy must be eliminated. OEMs should look for suppliers that have chosen to keep toolmaking in-house—designing both simple and complex tools that efficiently take OEM projects from design to production in order to significantly minimize the risk of error.

With in-house toolmaking as an integral part of the supplier-OEM partnership, skilled suppliers will often strive for continual improvement, such as creating new, advanced tools and implementing new concepts that can help OEMs make their 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 under one roof can help improve accuracy and provide complete product manufacturing solutions.

Medical Industry Manufacturing Expertise

Manufacturing expertise is fundamental but 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. The 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 adds evidence of industry expertise.

Suppliers also 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, will continue to build successful relationships with their OEM customers.

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Engineering Savvy

After a supplier has passed the capabilities and industry-expertise tests, the next thing to evaluate is their 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 their supplier's hands.

One of these resources 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 tremendous flexibility, as 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. If they do not, 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 can be a huge savings of time and resources.

A consolidated supply chain further heightens these benefits. As the partnership develops, the supplier becomes more familiar with the parts and the context in which they are used. It can better understand each part's essential functions, how it interacts with and impacts other parts of the system, and why its aesthetic, durability and weight requirements are what they are.

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

For example, one medical device man-

ufacturer that was having design problems with a component worked with a supplier to seek an entirely new component solution instead of ordering the same set of replacement components and perpetuating the problem. The new solution 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 eliminated the previous need to use hand tools during assembly, which reduced assembly time from eight hours to one. 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.

This sort of partnership will only work if OEMs and their suppliers work closely together to determine the best approach to manufacturing components, which may not be what the original design engineer intended. Often, to know the best approach requires customer-training services of some kind. The best suppliers are willing to do that—offering new product design-engineering assistance, on-site customized educational seminars, and tailored events to inform customers on the latest industry developments. All at no cost.

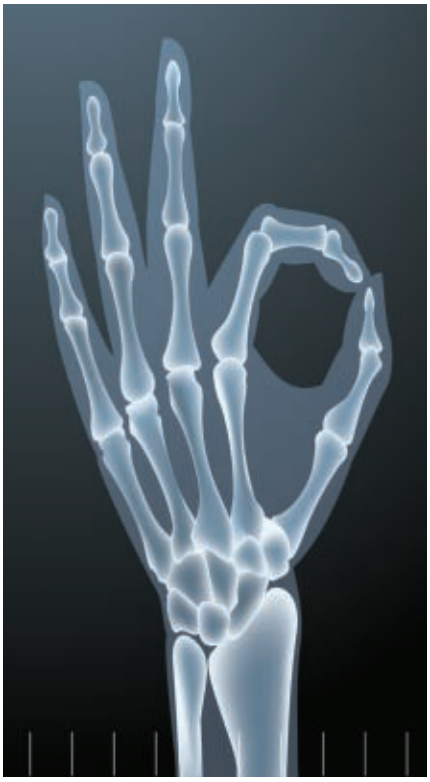
OEMs should work with suppliers that want to be a part of the product development process and design for manufacturability. Good suppliers will need to know what the OEM is doing, why they are doing it, and how they can work together to do it better.

Low Risk

With the high cost of creating medical devices comes a low margin for error. Like in the manufacturing of parts, one small error in any part of the process is unacceptable. OEMs should look for suppliers that embrace the same 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 your consideration should go beyond this by minimizing your risks throughout the entire product development process, not just during the manufacturing stage.

One way they can 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 no waiting for new components to be delivered and not worrying about them 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 another 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. This also means decreased shipping and packaging costs.

Though significant, these risks pale in comparison to one of the largest risks OEMs face—not getting their medical devices to market in time.

Since medical device patents last for only 20 years—many of those years are spent researching and designing the product—medical device OEMs have a limited time to cash in on their innovations. Every minute that production is delayed is money wasted.

To counter this, certain suppliers have adopted Quick Response Manufacturing (QRM), a manufacturing philosophy that strives to cut down lead times in all levels of production. This approach essentially combines the waste-eliminating focus of just-in-time, or lean, manufacturing with a heightened attention to timing for all steps in the supply-chain product development process—from purchasing and engineering-design assistance to product development and delivery. Instead of waiting 30 days for a supplier to create a product, QRM can allow the same process to be performed in just four days—a reduction of almost 90 percent.

This 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 in time and money to transfer partially finished components from one supplier to the next.

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

OEMs need to work with their 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 of their plate. It may not be a miracle drug, but it's close.

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