Shedding Suppliers

OEMs rethink the number of suppliers they use amid increasing federal scrutiny.

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The greatest lessons in life are not always the most evident. Often, they are hidden in great challenges, awaiting discovery only by individuals able to overcome these challenges. In some cases, the struggle to surmount such daunting obstacles can lead folks down a path of self-discovery.

Last fall, executives at Stryker Corp. wandered down this path after the company issued a voluntary recall of its System 6 and Cordless Driver III Hand Pieces. According to a safety notice posted on the Internet, the surgical tool could potentially "continually run" even when the trigger was not depressed. As a result, the company took about 26,000 of the Cordless Driver III Hand Pieces off the market.
Product recalls are always a challenge for medical device manufacturers: Not only are they costly and time-consuming, but they also sully companies' reputations and trigger an avalanche of bad press. Stryker had already overcome this challenge in January 2008, when it recalled two Trident hip implant cups over concerns about potential "manufacturing residuals" contaminating the parts. Memories of the first recall were just starting to fade when the second one came about.

Though it quickly resolved the issue and resumed shipping the surgical tool, Stryker took advantage of the recall to conduct some self-discovery. And what the company discovered was a need to improve its quality systems.

"What we realize is we've got a lot of good quality product," Stephen MacMillan, Stryker's president and CEO, told investors and analysts during a conference call in November. "But we haven't had the compliance systems all the way through the company as rigorous as we would like. And therefore we're looking not just at the facilities—but going obviously much broader across the entire company."
The lesson Stryker learned from its two bouts of recalls last year is the same lesson other OEMs are beginning to comprehend: stepped up enforcement of quality systems by the U.S. Food and Drug Administration (FDA) is forcing medical device manufacturers to more closely scrutinize their suppliers and make contractions in their supply chains.

"Many OEMs have very large supplier lists, and I am aware of quite a few OEMs that are trying to reduce their lists," said Kelly Lucenti, president of Millstone Medical Outsourcing, a company in Fall River, Mass., that provides customized outsourcing solutions to the medical device industry. "The OEMs are recognizing that it's becoming too much to manage all their suppliers. The feedback they are getting from the FDA is that they are responsible for the performance of all their suppliers and that they need to take on a more active role in managing their supply chain."

Several years ago, executives at Millstone Medical created a program to help OEMs better manage their supply chains. The program works through a partnership between Millstone Medical and OEMs that emphasizes Millstone's strengths as an outsourcing partner and a competent supply chain manager.

OEMs interested in whittling down the number of suppliers they use are encouraged to visit Millstone Medical's facilities to familiarize themselves with the company's capabilities and quality systems. These first few encounters enable OEMs to educate themselves about the company and determine whether Millstone Medical has the appropriate validations in place to manage the supply chain. Once the initial "education" period is over, OEMs must decide whether to hire Millstone Medical as a contracted supplier and allow the company to manage its supply chain.

"The OEM is truly responsible for managing the supply chain and managing the quality coming from the supplier," Lucenti noted. "At the end of the day, the OEMs know it's their product coming through the pipeline and they are responsible for those products. The FDA is going to hold them [fully] accountable. We help OEMs determine what they truly want to focus on."

Raising the Bar

After its second product recall last year, Stryker executives decided the company needed to spend more time focusing on quality standards and less time on managing suppliers. One company official estimated that Stryker was considering eliminating 60 percent to 70 percent of its supply chain in order to ensure that its suppliers are FDA-compliant. The Kalamazoo, Mich.-based firm has not provided any estimates on the number of suppliers it wants to shed, and executives have not discussed a timetable for undertaking such a task.

Contractions in the supply chain could be troublesome for manufacturers in other industries that want to diversify and enter the lucrative medical device market. But the trend also could bring more business to companies that already meet FDA-recognized quality certifications such as ISO 13485:2003 and product labeling restrictions.

In an effort to avoid repeating its mistakes of the past year, Stryker is spending at least $50 million through 2010 to standardize quality throughout its 12 divisions and across its supply base. Katherine A. Owen, vice president of strategy and investor relations for the $6 billion firm, said Stryker will spend between $60 million and $90 million this year on compliance efforts, which include validating its vendors, stepping up facility inspections, and monitoring key quality data.

"We are introducing a more formal quality system, which sets minimum consistent standards across all of our locations," Owen told investors during a quarterly earnings conference call last fall. "That's an area like compliant investigation, design controls for new product development, and production processes. We have been working across the divisions to improve the control and efficiency of our supplier base by sharing vendor audits and performance metrics."

Stryker is not alone in its struggle to prune its supply chain base and improve quality control systems. Most OEMs have huge supplier lists, thanks to years of double-digit growth and the rising popularity of outsourcing.

As the medical device industry grew in the 1990s and early part of this decade, OEMs formed outsourcing partnerships with companies based not on their medical device expertise but on whether or not those companies could meet timing and price demands.

The partnerships helped OEMs meet demand, but it also left them with a bloated supply chain base. "The OEMs brought in companies that maybe they should not have partnered with," Lucenti explained.
"Maybe the supplier or vendor was not ISO [13485] certified or maybe it did not have a quality system that the OEM would expect from a medical device contract manufacturer. A lot of OEMs were growing, they had certain needs and they got on board with a company that didn't have a history of medical device manufacturing but fulfilled a need at the time. I think OEMs are all fixing past sins now."

To fix those past sins, however, OEMs will have to acquire a new mindset: work strictly with suppliers that have the best quality systems, and funnel business only to the most trusted outsourcing partners. OEMs can no longer afford to choose an outsourcing partner that does not have much experience in the medical device industry or does not have a top-notch quality system.

OEMs that want to reduce the number of suppliers face a daunting challenge. In many ways, the thinning of bloated supplier lists is almost like choosing a supplier or outsourcing partner from scratch. OEMs must re-evaluate the companies to determine which ones would make the best partners. "Past performance is a true indicator of future performance. You have to do your homework...check references. Look for financial stability," said Clay Anselmo, president and CEO of Reglera, a Lakewood, Colo.-based regulatory compliance and quality assurance consulting and outsourcing firm for the medical device industry. "Conduct an audit. Go visit the company and have a face-to-face meeting—make sure you are convinced this company knows what it is doing. Also, make sure the company you are outsourcing with is a cultural match. Does that company share your value system? If not, it will come back to haunt you."

Besides being a good cultural match and financially fit, the ideal outsourcing partner also must possess a thorough understanding of the OEM's product, industry experts said. Preferably, the partner should only be utilized for its core competency.

Jeff Grabow, supply chain director at Medtronic Spinal & Biologics in Memphis, Tenn., said process and systems integration is essential when considering an outsourcing partner. “The single key to effective supply chain management is process and systems integration,” he noted. “Without process and integration, demand and supply synchronization is difficult to achieve. Without demand and supply synchronization, overall supply chain performance is negatively impacted from both a customer service and cost perspective.”

Other factors OEMs must consider in evaluating a supplier’s quality system include regulatory history, the supplier’s key customers’ regulatory histories, its handling of complaints (including investigations), adverse event filing, internal audits, corrective and preventative action procedures, QMS certifications, and the maintenance of other certifications.

Certainly, the superiority of a supplier’s quality system has become increasingly important as the FDA places a renewed focus on preventing product recalls and improving medical device companies’ regulatory compliance. But the ability of an outsourcing partner to spot a need within the industry and fulfill that desire is perhaps just as important as maintaining first-rate regulatory compliance.

Millstone Medical tested this theory six months ago. Noticing a need among customers for inspection services, the company expanded its inspection division, adding state-of-the-art equipment including two new 30-inch comparators. One of the 30-inch comparators is equipped with a 5X lens. Millstone also added a 14-inch comparator, a vision system, and a micro-hite. In addition, the company increased the total number of inspectors to 25 and hired a 20-year quality management veteran as inspection manager.

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The FDA’s continued onslaught on quality systems is going to lead to a major reorganization in OEMs’ supply chains. Companies that want to enter the medical device market may find it more difficult to cross the threshold without experience in the industry and a long list of quality certifications. Even experienced contract manufacturers that already meet the FDA’s compliance regulations may find the welcome mat pulled out from under their feet by OEMs looking to contain costs and reduce their chances of experiencing a product recall.

In many ways, the contraction taking place in OEMs’ supply chains is necessary. As they experienced astronomical growth, OEMs—like most other companies in the device industry—were forced to form outsourcing partnerships with firms that could fulfill their short-term needs and get their product to market quickly.

Now, as pressure mounts because of growing FDA attention to outsourcing in the medical device industry, OEMs are realizing the value of working with suppliers they know and trust. They also are discovering the benefits (both financially and logistically) of using fewer suppliers. As Millstone Medical’s Lucenti put it: “OEMs are realizing that the most effective way of conducting business is by partnering with fewer companies but making the most of those partnerships.”