Supply Chain Strategies for a Challenging MedTech Landscape

Posted in Supply Chain by bmichaels on March 7, 2014

Improving quality, manufacturing, and distribution efficiencies is essential for medical device companies to stay at the top of their game.

At the MD&M West 2014 Conference in Anaheim, CA, Vinay Asgekar, senior director of the global supply chain at Edwards Lifesciences, held a session on supply chain and procurement for medtech. He laid out a series of best practices for medical device companies as they grapple with how to reevaluate their operations and supply chain strategies in the face of regulatory, technology, and margin-pressure challenges, as well as legislative changes. MD+DI caught up with him before his presentation.

Q: You talk about transformational supply chain strategies? What does that term mean?

A: In the healthcare sector—in particular, the medical device subsector—companies are at a crossroads. Compared with the electronics industry, for example, there are many more regulatory forces. These regulatory requirements are becoming more detailed and more constraining. And as they lead to new products, breakthrough technologies are leading the global regulatory organizations into a new arena. In addition, there are increasing margin pressures and legislative changes. All of these different factors are forcing companies to reevaluate their operations and supply chain strategies.

Except for regulatory requirements, these factors are not much different from those that affected the electronics industry. In the beginning, innovation was the driver in the electronics industry. Then suddenly, companies started looking at how to make the industry more efficient. We are going through this same process today in the medical device industry. Medical device companies are and will continue to be driven by innovation. At the same time, operational and supply chain efficiencies are becoming a key factor, which is requiring a fundamental shift in how we manage the supply chain and operations. Understanding what took place in the electronics industry provides valuable lessons for the medical device industry as it prepares for the future. Thus, we need to look at transformational strategies for managing the supply chain. It's not going to be business as usual or just a matter of learning to operate more efficiently.

Q: What steps should medical device manufacturers consider to improve supply chain logistics, given all of the forces working on the medical device sector?

A: The answer is to be found in best practices. Focusing on quality and efficiencies is a must for medical device companies. Firms will continue to innovate, but by themselves, innovations will not be enough to enable medical device manufacturers to withstand future regulatory forces, legislative changes, and margin pressures. Quality, lean manufacturing operations, distribution efficiencies, inventory optimizations—these are all becoming essential factors in companies' ability to remain leaders in their field.

Imagine a car. You have a chassis and the interior, representing innovation. You also have the four wheels, representing quality, manufacturing, the supply chain, and cost efficiencies. You need to turn these wheels faster to make innovation go farther. Without the wheels moving in the right direction at a faster and faster speed, innovation alone won't get you very far.

Thus, from the best practices perspective, companies need to focus on a few areas. For example, they must focus on the global sales and operations planning platform, enabling them to most efficiently coordinate worldwide demand with the worldwide supply situation. They also must have a solid manufacturing improvement program, including such enablers as Six Sigma and lean manufacturing principles. It's probably going to be very important for medical device manufacturers to adopt this philosophy, which helps companies not only to improve their supply chain operations but also to apply them to their engineering and quality operations so that they can introduce quality products more quickly.

Another area of focus will be determining how to introduce new products to the market. To accomplish this task, companies will have to develop a more integrated approach to launch management, enabling them to optimize the links among the supply chain, the engineering community, and clinical management. Whether a company is launching a new product or opening up a new region, it must integrate supply chain operations into its launch planning.

As the medical device industry expands into different markets and regions and products begin to move very fast, supplier risk management will also take on greater importance from a procurement perspective. As supply chains drill deeper and deeper, two- or three-level supply chains can impact a company's ability to meet regulatory and compliance requirements. For example, meeting RoHS requirements is becoming increasingly important. Thus, having a good handle on supplier risk management is also becoming a best practice that medical device companies should assimilate.

Q: What role does outsourcing play as companies face new demands to improve logistics?

A: The strategic questions medical device companies face go beyond outsourcing. Whether a company runs its own manufacturing and distribution operations or outsources these functions, it still has to make improvements and align them based on changing industry needs.

In the electronics industry, outsourcing is very prevalent. It began to take root because it enabled companies to more easily modulate their capacities and respond to capacity and cost requirements. In the medical device industry, however, capacity is not necessarily that big of an issue. For example, in my previous life in the cellphone industry, we sold millions of chips. Demand of that magnitude is unthinkable for heart valves. We will not be selling a million heart valves in a month. And at the same time, the quality control and regulatory requirements are much more stringent in the medical device sector than they are in the electronics sector. Thus, the outsourcing of manufacturing operations is not as prevalent in the medical device sector as it is in the electronics field.

In the medical device area, outsourcing is used most prominently on the distribution side, and this makes a lot of sense. Large OEMs outsource their manufacturing operations less frequently and more selectively. Products and markets play a big part. For example, for Class III devices, the level of outsourcing is probably very low, while for Class I devices, it is probably much higher. Nonetheless, if a medical device OEM outsources its manufacturing operations, it must ensure that the outsourcing partner can follow the regulatory and product-quality requirements. The same is true for distribution facilities as well. Thus, the capabilities of outsourcing partners to meet OEMs' quality and product engineering requirements are of primary importance, with cost and capacity following closely behind.

Q: How can OEMs strike a balance between changing regulatory requirements, supply chain management, and profit margins?

A: Regulatory requirements should be considered a cost of doing business. Unfortunately, in most cases, it becomes a cost-driver to a certain extent either on a temporary or an ongoing basis. For example, for a company to comply with universal device identification or RoHS requirements, it will incur certain initial costs.

Manufacturers must adjust their supply chain operations to work within the constraints of regulatory requirements. The supply chain must be architected based to optimize delivery service and cost. This need takes on greater importance when a company develops an expansion perspective. When companies expand their global market reach, it is important for them to handle global demand complexities.

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