Perspectives on Supplier Differentiator, Part II

Deborah Kacera, Daniel Rudolf, Dan Walsh, Christine Forcier, and Bill Leverich

As ISO 13485 certification has become virtually a requirement for medical device suppliers, what is/will be the next significant differentiator?

Deborah Kacera
Regulatory and Industry Strategist, Pilgrim Software Inc.

ISO 13485 is a certification that is sought after up and down the Medical Device OEM's product/process global value-chain. However, as with any quality standard, the first step is "certification." After that, the organization has to work on truly changing the culture within the organization so that people embrace the quality culture in their day-to-day business processes.

The next evolution is the focus on the supply chain and ensuring the detailed processes are in place and that products/processes provided by downstream suppliers are validated and real. With globalization as the post facto now, it will require more stringent supplier controls from the initial selection of suppliers through the monitoring phases. How will suppliers select and monitor their supplier base? They are dealing with different cultures that have developing regulatory guidelines/understanding in addition to the "virtual" supplier base that is growing, and of course, suppliers have to do this with fewer resources than their OEM customers.

Daniel Rudolf
Director, Continuous Improvement, Precipart

The advantage will be with the OEM that has the strongest supply chain. Optimizing the value chain by applying aggressive continuous improvement practices that support ISO quality standards and other administrative regulations will lead to the device manufacturer being significantly more competitive across the board.

Precipart prioritizes continuous improvement as a philosophy weaved into our corporate culture. We are constantly increasing organizational effectiveness, not just as a means to meet current customer demands; we take it one step further, anticipating future needs of the device manufacturers, so that we may prepare and position ourselves to be responsive.

When quality regulations flow down to us at the supplier level, we are so familiar with them that we're already working on the automation of the processes. For example, we apply PPAP principles across all our product lines, not solely to the jobs that require them. We chose to become ISO 13485 registered in order to operate to the same quality standards as our customers. In doing this, we achieved efficiencies such as streamlining audits and reducing the time it takes to get on approved supplier lists, while increasing consistency and overall product satisfaction.

Continuous improvement of our quality management systems and those of our suppliers is a strategic imperative for Precipart because we understand that competition today is not company to company, rather it is supply chain to supply chain.

Dan Walsh
Life Sciences Industry Expert, PA Consulting Group

The next significant differentiator for medical devices suppliers will be related to connectivity and convergence. To provide the level of convenience and flexibility that consumers demand, medical devices and diagnostics will increasingly begin to converge or integrate with other devices and information systems. These will likely include smartphones, tablets, other medical devices, and cloud-based repositories and monitoring solutions. The basic technology aspects are relatively straightforward; however, the increase in this connectivity will also significantly raise the bar with regard to both HIPAA privacy issues and data integrity/availability issues. As the information stream grows to a flood, the best medical devices available will have connectivity and will be able to protect the data of their users and patients.

Christine Forcier
North American Business Assurance Program Manager, Medical Sector, Intertek

After certification to ISO 13485, there will be three main differentiators for medical device manufacturers.

Medical device manufacturers who have already implemented a quality management system that meets ISO 13485 requirements can take advantage of having a platform already in place to implement the additional requirements of ISO 9001:2008. While the focus of ISO 13485 is on the provision of safe and effective

devices, ISO 9001:2008 focuses on continual improvement and customer satisfaction. Many manufacturers certified to ISO 13485 have already recognized the benefits of implementing the additional requirements and gaining recognition through certification to ISO 9001:2008.

Effective supply chain management will be another key differentiator for medical device manufacturers. Taking responsibility for their supply chain and implementing controls over it will enable manufacturers to consistently obtain the best possible quality of products and services and see returns in terms of brand protection.

Lastly, while medical device manufacturers were not previously pressured to implement environmental management systems (ISO 14001), they are now becoming increasingly relevant in the industry with the RoHS Directive (2011/65/EU). Also known as RoHS 2, it will restrict the use of hazardous substances in medical devices by July 22, 2014. Manufacturers of electro medical devices now also have access to a resource that did not previously exist, IEC 60601-1-9, which provides requirements for environmentally conscious design.

Bill Leverich
Director of Manufacturing, RBC Medical Innovations

Supporting device launches outside of the United States (OUS). The robust due-diligence process within the FDA regulatory pathway has prompted some medical device companies to launch OUS first. This trend is especially present within start-ups, as venture capitalists are reluctant to invest in initial U.S. launches due to higher risks and delayed returns. OUS launches provide the opportunity for faster market approvals and potential revenues to recoup R&D investments. Established medical device companies are also participating in the trend as OUS launches provide opportunities to rapidly gather clinical data for new applications, which is also often utilized to support subsequent FDA regulatory approval for the U.S. market. In order to effectively support this trend, U.S. medical devices suppliers will need to have a very good working knowledge of the myriad of U.S. and OUS government regulations and how they affect medical device companies in the various cultural and political environments. This is a very large task, but one that is necessary for U.S. medical device companies to bring products to market as quickly as possible so that they can remain competitive in the global marketplace.

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