Perspectives on Supplier Differentiator, Part I

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

Joe Rotino
VP of RA/QA, Acting VP of Engineering, Pro-Dex Inc.

While ISO 13485 is considered the international gold standard of a medical device supplier's quality management system, the certification, by itself, is not a significant differentiator.

This is due, in part, to the increased pressure on medical device original equipment manufacturers (OEMs) to be fully engaged with what their suppliers are doing. Therefore, a subsequent differentiator is how an OEM's manufacturing partner mitigates risk along their supply chain.

Just as medical device OEMs must audit their manufacturing partners to ensure their standards for validation and process controls are being met, a manufacturer needs to have controls in place to objectively confirm that their suppliers can capably and consistently deliver high-quality parts.

A critical element when maintaining supplier control is to clearly stipulate in the supplier quality agreement that if the supplier changes anything, or deviates from their process in any way, then they are contractually obligated to notify the

manufacturer. This gives the manufacturer the opportunity to conduct the same approval process again and re-verify the supplier's quality, capability, repeatability, and reproducibility.

Holding an ISO 13485 certification is significant, but it's only one of many important capabilities that a medical device supplier needs to possess in order to demonstrate the value and expertise they bring to the supply chain.

Alan Walsh
Director of Software Development, Logic PD

There are a few areas that stand out as currently lagging in medical devices compared to consumer devices that will need to be addressed as medical devices become more connected and experience greater penetration into the consumer market (e.g., glucose meters, heart monitors, etc.). One of these will almost certainly be the next great differentiator when a smart manufacturer creates a branded solution that achieves industry acceptance. Data security enhanced with bioinformatics is one area. A secure data cache that can only be unlocked by an app with an iris scan or voiceprint or fingerprint would certainly be a differentiator, could gain wide acceptance, and could easily be a USP or KSP for home devices. The other key area is upgradeability, particularly software. When a device manufacturer succeeds in building a secure and efficient ecosystem to deliver fixes and new functionality to your personal medical device, they will own the market.

Aidan Petrie
Chief Innovation Officer and Co-Founder, Ximedica

As external industry influences like excise taxes, longer approval process time, and reimbursement pressures bear down on device manufacturers, development partners must look to areas of opportunity and how to best support medical firms in these pursuits. While opportunities such as the growing and aging population and emerging markets are getting a lot of play, it’s also important to realize that progress (i.e., technological advances) poses perhaps the most significant area of opportunity in transforming healthcare. It will become critical that development partners are equipped with the expertise and capabilities to develop and produce integrated, intelligent, and connected platforms within the next two to five years, and for those OEMs who can demonstrate these capabilities sooner, this will set them apart.

Michelle Lott
RAQA Director, Xeridiem

Recognizing that customer demand drives market requirements, current regulatory expectations are moving toward additional means of control between the legal manufacturer and supplier. Medical device suppliers who voluntarily contract with customers on quality system responsibilities and choose to implement applicable elements of ISO 14971 will find themselves with a competitive advantage in tomorrow’s market. The following examples highlight emerging expectations.

- Customer-Supplier Quality agreements delineating
    - Product and quality system responsibility matrix
    - Permission for customer’s notified body to audit the supplier
    - Requirement for change notification including materials and process

- According to ISO 14971, one tool a legal manufacturer can use to demonstrate manufacturing process and risk control is a Hazard Analysis of Critical Control Points (HACCP). To complete an analysis for an outsourced component or process, the legal manufacturer partners with the supplier to define:
    - A process flow diagram
    - A hazard analysis worksheet—The customer must provide the hazards but the supplier must identify the critical control points affecting the hazards.
    - A HACCP plan—Plan execution is the responsibility of the supplier.

Suppliers who proactively engage with their customers in these areas will have a strategic advantage in this competitive environment.

Carol Tucker
Quality & Regulatory Manager, Product Development, Vention Medical

The next step for medical device manufacturing suppliers to exceed the increasingly strict regulatory expectations is supply chain control. It is imperative that the manufacturers who are responsible for the suppliers have controls in place to enforce standards throughout the supply chain. Monitoring the suppliers on a continual basis is the key to ensuring a high quality supply of medical device components and services. An experienced and vigilant quality group is the necessary vehicle for the success of this program as they will expertly perform inspection and auditing of suppliers to ensure compliance.

Patient safety is the most important motivator in the medical device industry today. The FDA has voiced their concerns that patient safety can be compromised by failures of components or services used in medical devices. As an example, in 2011 the FDA issued 30 warning letters to medical device manufacturers for inadequate supplier controls. For these reasons, medical device manufacturers need to develop a close partnership with their suppliers and monitor them regularly.

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