QUALITYDIGEST

WHITNEY ANDREWS | 09/09/2014

ISO 13485 Certification for Temporary Labor and Staffing Services

Temp employees need to be held to the same training rigor as full-time staff

Medical device manufacturers are facing mounting pressure to better manage the quality of their supply chain. One approach they've taken to improve risk management and increase efficiency is to partner with suppliers who are ISO 13485 certified.

ISO 13485 is an internationally recognized quality standard that outlines the quality management system requirements for companies involved in the design, development, and production of medical devices. The standard is based on ISO 9001 with additional focus on regulatory requirements specific to the medical device industry.

Most service providers to the medical device industry understand that the primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. What isn't always well understood is what they need to do to meet the requirements of ISO 13485—or even why they should try.

This was the predicament that Operon Resource Management found itself in a few years ago. As one of the few staffing companies in the United States specializing in temporary labor for medical device and life-science companies, Operon was keenly aware of the importance of having an effective quality management system to ensure both compliance to the specific regulatory requirements of the industry, as well as assuring customer satisfaction. Operon also appreciated how complex, time-consuming, and daunting the process was, having supported many of its clients during their own ISO 13485 certification and recertification process.

What solidified Operon's decision to pursue ISO 13485 certification was the feedback garnered from multiple medical device companies, including many of Operon's clients. The overwhelming response to an independent survey was that partnering with a staffing company—or any service provider—that was ISO 13485 certified would significantly improve risk management and ensure a more seamless integration with their systems and procedures. Certified medical device manufacturers must be able to ensure that the quality of supplied materials, products, or services meets the requirements of the their quality management system. Interestingly,

the benefit to the client is often equal to that of the service provider, including increased supplier control, audit support, improved risk management, and more efficient supply chains.

There are a select number of service providers certified to ISO 13485 that are not actually involved in the direct manufacture of medical devices, including companies involved in translation, logistics, packaging, and sterilization services. It occurred to Operon that if companies that do not directly manufacture the product need to be ISO 13485 certified then why shouldn't temporary labor working on the manufacturing floor also be held to the same standard?

Temporary workers not only manufacture the product, they are taking measurements and recording data. They need to know how to assure compliance to the 21 CFR, Part 820 requirements mandated by the Food and Drug Administration. These temporary workers are as vital to the safety and efficacy of the product as any other. Often, temporary workers are the last people to touch a product before it's shipped. Medical device manufacturers should recognize the critical importance of ensuring those workers are fully trained to all quality and regulatory requirements.

If a company is using temporary labor, there is significant risk if those workers don't have thorough training on current good manufacturing practices (cGMPs), clean-room protocols, and other regulatory requirements. However, many manufacturers don't recognize the need, or want to take the time, to provide the same level of training to temps as they do for full-time staff; it's time-consuming and costly. But if ignored, it can be very risky because ISO 13485 requires companies to maintain training records for all employees.

This conundrum is at the center of Operon's value proposition. Operon has developed a unique and comprehensive training program for temporary workers that can be tailored to any medical device manufacturer. The result is a trained workforce that is familiar with ISO 13485 requirements and trained to the company's quality and operational requirements. Operon maintains thorough records of all training and makes these records available to clients to support their own internal and external audits. Through this training program, Operon helps their clients mitigate the major risk associated with the use of temporary labor.

In 2013, Operon was certified by BSI, a global leader in conformity assessments and quality management certifications. Although some of Operon's certification obstacles were unique (due to the type of services provided), the majority of the challenges would apply to any service provider seeking ISO 13485 certification.

Suppliers and service providers seeking 13485 certification first need to educate themselves on the requirements of regulators and customers, as well as what a 13485-compliant management system will entail. Then the organization needs to implement a quality management system that conforms to the standard's requirements. Many service providers are not exposed to a formal quality management system, so implementing one of their own can be a big undertaking.

Developing a robust quality management system that aligns with ISO 13485 requires significant time, energy, resources, patience, and leadership. To help keep the process efficient and productive, it's essential for senior management and subject-matter experts to work together early on to define and map out every single business process. This includes challenging the need of each process, examining how each process could be enhanced, and assigning responsibilities for carrying out all procedures.

Many service organizations may not have been exposed to a formal quality management system, so not only do they need to develop a well-documented and controlled system, but they may also need to undergo a significant culture change. The entire organization must accept a new quality-focused culture and understand that, in addition to new requirements such as internal audit and a corrective and preventive action system, the day-to-day business processes have to change as well.

During Operon's ISO 13485 certification journey, a few notifying bodies strongly encouraged the company to pursue ISO 9001 in lieu of ISO 13485 because it was less expensive and time-consuming. In addition, there was no precedent for a temporary staffing provider certified to ISO 13485. It was clear that a service provider pursuing ISO 13485 must have some compelling proposition that would bring value to medical device manufacturers and the end-user. In Operon's case, that was its on-boarding process including temporary-worker training and orientation to prepare workers for the regulatory, systems, facility, and operational requirements of medical product manufacturing. Operon stayed the course through the arduous certification process because it's committed to delivering the most value to its medical device partners.

John Witkowski, the general manager of Nypro Healthcare's Drug Delivery & Diagnostics Operations, says that as the demands for medical and pharmaceutical products continue to grow, increasing pressure is being placed upon the company to bring in a flexible and skilled workforce. "Operon has been a key strategic partner in helping us meet this requirement," says Witkowski. "Their ISO 13485 certification is another way of demonstrating to our customers that we hire qualified people to work on their products." More and more manufacturers are seeing the benefits of working with an ISO 13485-certified staffing firm.

Service providers who do obtain ISO 13485 certification demonstrate their dedication to maintaining quality within their own system and helping their customers strengthen the overall quality of their supply chain. This unique value proposition sets service providers apart in the medical device marketplace and makes them a better industry partner.

Link: http://www.qualitydigest.com/inside/health-care-article/iso-13485-certification-temporary-labor-and-staffing-services.html#