Appendix 5.5.2
More Information About ISO 13485

Background

The International Organization for Standardization (ISO) was founded in 1947 as a means for developing international technical standards. Interestingly, ISO is not an acronym. Rather, it is a name derived from the Greek word "isos" meaning "equal"—the idea being that if two objects meet the same standard, they should be equal. Given the global nature of the organization, this name also eliminates the need for different acronyms as International Organization for Standardization is translated into various languages.[1]

ISO is a voluntary organization whose members are recognized standard-setting authorities from its member countries. In 2013, the organization had 162 members.[2] The American National Standards Institute (ANSI) is the U.S. representative to ISO (one representative is allowed from each member country). ISO standards are developed by technical committees made up of experts "on loan" from relevant industrial, technical, and business sectors. These experts may be joined by others with pertinent knowledge, including representatives of governments, testing laboratories, consumer associations, environmentalists, and so on. Every year, as many as 649 international organizations participate in the development of ISO standards.[3] As of the end of 2013, ISO had developed more nearly 20,000 standards applicable to a broad spectrum of industries around the world.[4]

Overview of ISO 13485:2003

ISO 13485, published in 2003, is a standard that specifies requirements for quality management systems in the medical devices industry. Importantly, all requirements of ISO 13485:2003 are specific to organizations providing medical devices. Within this industry, the standards are applicable to all medical device companies, regardless of the type or size of the organization.

The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems around the world.[5] While ISO 13485 is a stand-alone standard, it is generally consistent with ISO 9001. A few fundamental differences, many of which make the ISO 13485 standard more consistent with the FDA's QS regulation, are listed below:[6]

- While ISO 9001 requires the organization to demonstrate continuous improvement, ISO 13485 only necessitates that it demonstrate that the quality system is implemented and maintained. It was not written to be a business improvement model, but rather as a tool for maintaining effective quality processes
- ISO 13485 explicitly positions awareness of (and adherence to) regulatory requirements as an executive management responsibility, consistent with U.S. QSR requirements. As a result, it is less focused on customer satisfaction.

- ISO 13485 institutes controls in the work environment to ensure product safety.
- ISO 13485 maintain a focus on risk management and design transfer activities during product development.
- ISO 13485 includes specific requirements for inspection and traceability for implantable devices.
- ISO 13485 includes specific requirements for documentation and validation of processes for sterile medical devices.
- ISO 13485 includes specific requirements for verification of the effectiveness of corrective and preventive actions.

Because of these types of difference, organizations whose quality management systems conform to ISO 13485 cannot claim conformity to ISO 9001, unless they have specifically taken extra steps to ensure compliance with all requirements of ISO 9001.[7]

Why Become ISO Certified?

In the United States, medical device companies are in no way obligated or required to implement ISO 13485 to manufacture, sell, and distribute their devices domestically. However, if they intend to enter international markets, the ISO quality system becomes significantly more important. As mentioned, compliance with ISO 13485, as granted by a conformity assessment body (CAB), is seen as a first step in achieving compliance with European regulatory requirements and being granted a CE Mark.[8] ISO 13485:2003 certification is also required for a company to market a medical device in Canada and Japan. Furthermore, ISO certification can be a competitive differentiator, particularly for companies working with (or seeking to become) contract manufacturers or outsourcing partners. In the long run, many companies also believe that implementation of an ISO 13485 quality system saves them time, money, and problems over time.

Fortunately for companies seeking ISO 13485: 2003 certification, approximately 85 percent of the requirements overlap with the FDA's QSR. TR 14969 is a guidance document for the use and implementation of ISO 13485:2003.

ISO Audits

To become ISO certified, a company contracts with a third-party auditor and forms a relationship that is both consultative and compliance-based—first, the auditor helps the company make improvements to its quality systems and prepare for the audit, then certifies the company once it has successfully met all requirements outlined in the standards. Upon conclusion of the audit, the major findings are written up and the company is given time (as well as corrective advice) to fix any problems before a re-audit occurs. In contrast to the FDA, ISO-accredited auditors have no authority to impose fines, initiate product recalls, halt operations, or enforce other corrective penalties. Their objective is to identify problems and help companies fix them. Generally, it is a "friendlier" process than an FDA audit, with the auditor more motivated to help the company become successful. As a result, a company may choose to handle the audit in a more open manner. On the other hand, the company may choose to use the ISO audit as "practice" for an FDA audit and conduct it in the same way it would a visit from the FDA.

[1] Cynthia J. Martincic, "A Brief History of ISO," February 20, 1997, http://www.sis.pitt.edu/~mbsclass/standards/martincic/isohistr.htm (March 21, 2014).
[2] "ISO Members," International Organization for Standardization, http://www.iso.org/iso/about/iso_members.htm (March 21, 2014).
[3] "ISO in Figures for the Year 2013," International Organization for Standardization, http://www.iso.org/iso/home/about/iso-in-figures.htm (March 21, 2014).
[4] Ibid.
[5] "ISO 13485:2003," International Organization for Standardization, http://www.iso.org/iso/catalogue_detail?csnumber=36786 (March 21, 2013).
[6] "ISO 13485," www.wikipedia.org, http://en.wikipedia.org/wiki/ISO_13485 (March 21, 2014).
[7] "ISO 13485:2003," op. cit.
[8] "ISO 13485," op. cit.

