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ISO 13485: Top NCRs and Need-To-Knows

The Scope and Importance of ISO 13485

With consumer demand on the rise despite production slowdowns worldwide, it's natural for organizations to be interested in diversifying their manufacturing. Medical devices and other related items are even more in demand than products from other sectors, but with the industry comes more stringent requirements. On a basic level, ISO 13485 is quite similar to ISO 9001 and its other derivative standards.

The scope of ISO 13485 includes requirements for a quality management system (QMS) for organizations to demonstrate their capabilities in providing medical devices and services that consistently meet not only regulatory requirements but customer needs as well. From design and development, production and distribution, or installation or servicing of devices, ISO 13485's umbrella covers a wide array of businesses operating within (and related to) the medical device industry.

What Changes Were Made in the Last Revision?

The 2016 revision of ISO 13485 made a number of changes to the standard as well as the addition of several new requirements and the removal of others. Alterations to the standard include (but are not limited to):

- Adding further detail (e.g. clarifying life-cycle stages, types of organizations, etc.)
- Addition of new terms (e.g. authorized representative, risk, complaint, distributor, etc.)
- Added emphasis on the process approach to quality management
- Removal of italicized font previously used in ISO 13485:2003 to identify medical device-specific requirements

For a more detailed overview of what was changed between ISO 13485:2003 and 2016, check out a recording of our ISO 13485:2013 Overview webinar, available at www.pjr.com/webinars/past-webinars.

What's the Hold Up? – The Most Common Reasons for Delays Between Stage 1 & 2

The first and foremost common reason for an organization being unable to proceed to Stage 2 is simply poor planning; that is, a lack of adequate time between the Stage 1 and scheduled Stage 2 for concerns and nonconformances to be rectified. This issue can be mitigated by allowing a minimum of six weeks between each audit. That said, the period between audits may not exceed 90 days – exceeding this allowed window will result in the Stage 1 needing to be repeated.

Problems identified in a facility tour are another regularly-seen problem in ISO 13485 audits. While an issue like poor identification and traceability of components and products may simply point to a lack of preparedness for Stage 2, one more notable problem that is found on occasion is the discovery of multiple companies operating in a shared space with inadequate delineation. Scoping is crucial in all certification schemes, but is especially so in ISO 13485. While multiple companies *may* share a space, the boundaries of the medical device management system must be made very clear, as the certificate issued *will* be clear.

As previously mentioned, ISO 13485 has some similarity to ISO 9001. However, a major difference that sets the two apart is the requirement for proper documentation of procedures; there are *far* more procedures that require documentation in ISO 13485. They include: control of documents and records, management review, human resources, infrastructure, work environment, contamination control, design and development, purchasing process, production control, cleanliness/contamination control, installation activities, and many more.

An immature management system can also lead to hang-ups in the certification process. Having no (or poor) quality objectives or inadequate data analysis for said objectives are telltale signs that the management system is underdeveloped. Similarly, lacking management team buy-in – demonstrated by a lack of good commitment and unfinished tasks – is an obstacle to certification that should be rectified before the Stage 1 audit.

Most Common Stage 2, Surveillance, and Recertification NCRs

Once the Stage 1 audit has been completed successfully, the work is far from over. Stage 2 audits and surveillance audits pose their own challenges. The most common of these include quality manual issues – particularly improper scope or a lack of clear definition – and regulatory requirements; the latter must be identified, implemented and maintained (this includes component and contract manufacturers as well). As manufacturing worldwide becomes more and more technology-reliant, ensuring software validation is another issue that has come to the forefront. Validation must take place prior to use as well as after changes to the software or its application, and may include “off-the-shelf” software such as Microsoft Office programs depending upon the purpose of use.

For companies with complex supply chains, a common area of concern is purchasing. Lacking risk-based supplier controls developed for the evaluation and selection of suppliers is a must-have, with criteria consistent to the degree of risk associated with the medical device in question. Similarly, not including service providers such as secondary/finishing services, laboratories, or sterilization service providers in the scope of certification can pose difficulty.

Side-by-side with supply chain issues, problems with identification and traceability in production may lead to a number of NCRs. A lack of thorough documentation is a straightforward (and very common) issue, but other problems include maintaining identification of product status throughout to ensure inspection/testing, the assignment of unique device identification (if required by regulation), and the necessity of identifying and distinguishing items returned by a customer separately from conforming product.

Careful observation of product preservation, such as shelf life and other item-specific special requirements can trip up organizations during certification, especially where special conditions are needed; these conditions must be controlled and documented. The specific contractual requirements laid down for each product must also be clearly defined and documented, with relevant documents being amended following any requirement changes.

ISO 13485 is rightfully considered one of the more complex and demanding ISO standards; given the sensitive nature of the products it governs, that reputation is thoroughly deserved! If you're considering ISO 13485 certification and need to know where to start or are looking to transfer your existing ISO 13485 certificate, reach out to PJR – call **(248) 358-3388** or visit **www.pjr.com.**