Most Common NCRs in ISO 13485 Audits

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Today's Agenda

- Scope and Importance of ISO 13485 Certification
- Most common reasons an organization is deemed "Not ready to proceed" after Stage 1
- Most common nonconformities written during Stage 2, Surveillance and Recertification audits
- Questions & Answers, including concerns about 13485 audits during the COVID-19 pandemic

Scope of 13485 Certification

13485 contains "*requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the lifecycle, including design and development, production, storage and distribution, installation or servicing of a medical device and design and development or provision of associated activities (e.g. technical support).*"

"This standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations." --ISO 13485:2016, Section 1 Scope

Importance of ISO 13485 Certification

- During this critical time, many organizations will be looking to diversify their manufacturing. Obviously, there is more demand for medical device manufacturing right now than for manufacturing for other sectors.
- There are many similarities between ISO 9001 (and derivative standards) and ISO 13485.

Most Common Reasons an Organization is Deemed Not Ready to Proceed to Stage 2

Poor Planning

Time between Stage 1 and Stage 2 is not adequate for concerns identified.

This can be mitigated by allowing a minimum of six weeks, but not more than 90 days, between a Stage 1 and Stage 2 audit.

During the COVID-19 pandemic, PJR is allowing more than 90 days between the Stage 1 and Stage 2 audit.

Issues Identified on a Facility Tour

Tour of facility reveals very poor identification and traceability of components and products.	• This is not typically a Stage 1 criterion, but if the issue is so pervasive that it is noticed on a site tour, then this might indicate lack of preparedness for Stage 2.
Tour of facility reveals multiple companies in a shared space with no delineation.	• Scoping is very important. Multiple companies can share a space, but the boundaries of the medical device management system must be clear. The certificate issued by PJR **will** be clear.

Not all the management system pillars are in place

- Organization has not documented all of the required procedures.
  - Control of documents
  - Control of records
  - Management review
  - Human resources
  - Infrastructure
  - Work environment
  - Contamination control
  - Design and development/Design and development transfer/Design and development changes
  - Purchasing process

Not all the management system pillars are in place

- Organization has not documented all of the required procedures.
  - Production control procedures
  - Cleanliness/contamination control documentation
  - Documentation for installation activities
  - Procedures for servicing activities
  - Procedures for validation of processes (including software)
  - Procedures for validation of processes for sterilization/sterile barrier systems
  - Procedures for identification
  - Procedures for traceability
  - Procedures for preservation of product

Not all the management system pillars are in place

- Organization has not documented all of the required procedures.
  - Procedure for Monitoring and Measurement Equipment
  - Procedure for Feedback
  - Procedure for Complaint Handling
  - Procedure for Reporting to Regulatory Authorities
  - Internal Audit Procedure
  - Control of Nonconforming Product Procedure
  - Procedure for Issuing Advisory Notices
  - Rework Procedures
  - Procedure for Analysis of Data
  - Corrective Action Procedure
  - Preventive Action Procedure

Not all the management system pillars are in place

- You will note that there are many more procedures than are required for ISO 9001.
- Additionally, an organization may not have implemented all required processes.

Immaturity of the Management System

- The organization has no (or poor) quality objectives or no or limited data analysis for objectives.

Lack of Commitment

- The top management team does not exhibit good commitment and there are a number of tasks yet to be done.

Most Common Nonconformities Written During Stage 2, Surveillance and Recertification Audits

Most Common NCRs

- Issues with the Quality Manual
  - Improper Scope – declaring NA when not allowed
  - Not clearly defining the scope
- Regulatory requirements
  - 21CFR Part 820 in the United States
  - Need to identify, implement and maintain applicable requirements
  - Regulatory requirements are applicable for component and contract manufacturers as well.

Most Common NCRs

- Software validation
  - Depending on its purpose within the organization, this may include off-the-shelf software, such as Microsoft Excel.
  - Validation has to take place prior to use and after changes to the software or its application.

Purchasing

- Supplier control not based on risk.
  - Criteria need to be developed for the evaluation and selection of suppliers. The criteria shall be proportionate to the risk associated with the medical device.
- Service providers are not included in the scope.
  - Secondary/finishing services
  - Laboratories
  - Sterilization service providers

Preservation of Product

- Shelf life issues
- Other special requirements
  - Preservation shall apply to constituent parts of a medical device.
  - Preservation may be accomplished through packaging and shipping containers.
  - Organization has to document requirements for special conditions if packaging alone is not sufficient. These conditions shall be controlled and recorded.

Identification and Traceability in Production

- Documented procedure
- Identification of product status shall be maintained throughout production, storage, installation and servicing to ensure that only product that has passed required inspection/test or is released on authorized concession is released.
- If required by the applicable regulatory requirements, the organization may need to assign a unique device identification to the medical device.
- Devices returned from the customer are identified and distinguished from conforming product.

Contractual Requirements

- Product requirements shall be defined and documented.
- When product requirements are changed, relevant documents need to be amended and relevant personnel need to be made aware of the changed requirements.

Customer Complaints/Corrective Action Timeliness

- This is fairly straightforward. Timeliness is key when responding to complaints or other corrective action requests.

Document Control

- Issues are fairly similar to what we are seeing in ISO 9001 audits.

Conducting 13485 Audits During the COVID-19 Pandemic

- We have the option of conducting the Stage 1 audit virtually, with the exception of high-risk medical devices.
- Portions of the Stage 2, surveillance and recertification audits can be conducted virtually as well.
- PJR believes that tremendous benefit is gained from face-to-face interaction with clients.
  - Entirely virtual audits post-pandemic are unlikely.
  - Partially virtual audits can save clients money/improve auditor quality of life.

Questions? Comments...

THANK YOU!