ISO 13485 Audit Preparation Checklist

Background: This checklist provides program managers with an understanding of what to expect during an ISO 13485:2016 (ISO 13485) audit of a medical device manufacturing facility and what may be required of you during this process. Typically, ISO 13485 audits are coordinated by the product license holder's Quality Assurance (QA) department. As a program manager, you may be requested to support the QA department with the audit and act as a liaison between the QA department and the manufacturer.

Medical device manufacturers and suppliers are audited for adherence to the ISO 13485 standard for Quality Management Systems (QMS).[1] The ISO 13485 certifies that the medical devices meet safety, quality, and relevant regulatory requirements. Audits are either conducted by the National Regulatory Agency (NRA), or in some countries by external auditors from a conformity assessment body (i.e. EU Notified Body, International Medical Device Regulators Forum (IMDRF) through their Medical Device Single Audit Program (MDSAP), etc.) that issue ISO 13485 certificates.

- ☐ The QA team (reporting to the PM) will request the audit agenda from the auditor to determine the scope of the audit, as well as whether the audit will be remote or on-site. The PM will share the audit agenda and details with the manufacturer.

  NOTE: *Auditors may also make unannounced visits to conduct audits. There will be no notice of such visits in advance, but the auditor will share the objective of the audit upon arrival.*

- ☐ The manufacturer will locate prior audit history documentation to ensure that routine internal audits have been conducted according to an audit schedule and preventative actions have been taken to address findings.

- ☐ The manufacturer will prepare an audit plan, including information on the standards, policies, systems, and facility areas where the audit will be conducted and share it with involved staff to ensure that they are prepared to answer questions from the auditor.

- ☐ The manufacturer will brief the PM about the audit plan and their readiness for the audit.

- ☐ The PM will work with the QA team to support the auditors with their travel plans (if requested) by recommending hotels, airports, etc. closest to the manufacturing site.

- ☐ The PM and QA team will ensure that applicable audit fees are paid to the auditor prior to the audit.

- ☐ The QA team (working with the PM) will determine whether the manufacturer's site documentation is up to date, properly executed, and stored in a controlled location. The following list is an example of the standard site documentation that may be requested by the auditor before or during the audit:
  - Quality manual
  - Standard Operating Procedures (SOPs)
  - Company's organization chart

[1] https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice

- Promotional literature and website pages
- Previous audit findings and status of corrective actions
- Supplier agreements
- Information on the Key Performance Indicators
- Minutes from the management review meetings

☐ The manufacturer will ensure that the complaints file is available and that it contains information on product complaints, investigation, closeout, and any applicable recalls.

☐ The manufacturer will assess the organization against each of the clauses of the ISO 13485 standard to ensure adherence.[2] The clauses are listed below and detailed information may be found at this link: https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en

- Scope
- Normative reference
- Terms and definitions
- General requirements
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis, and improvement

☐ After the audit, there will be an audit closeout meeting. The manufacturer may be able to address and justify any identified non-conformities to be excluded from the audit report.

☐ The manufacturer will request closeout details from the auditor, including when to expect the audit report and what the timeline is for addressing the audit non-conformities with a corrective and preventive action plan. The manufacturer will share this information with the QA team.

☐ The manufacturer should be prepared for the auditor to conduct a follow-up audit to verify corrective actions were taken.

☐ The QA team (working with the PM) will work with the manufacturer to address and respond to any observations made by the auditor in the audit report.

☐ If the audit is taking place as part of the product registration process, the PM can expect that registration timelines may be affected, as registration approval may not be issued until the manufacturing facility has been ISO 13485 certified. Some regulatory authorities indicate that ISO 13485 certification is a registration pre-requisite.

☐ If the audit is a routine re-certification for a medical device that has already attained marketing authorization approval, and if the manufacturing site is does not pass the certification process, marketing authorization of the products manufactured at the site may be suspended.

[2] https://www.iso.org/standard/59752.html