Guidance Document

Common Findings: ISO 13485:2016 Stage 1 Audit

NSAI have compiled a non-exhaustive list of ISO 13485:2016 quality management system audit findings which commonly occur during a stage 1 audit.

These findings cover a broad spectrum of the standard, and it is hoped that this document will assist in preparing for an audit of your quality management system. The table below indicates both the finding and the corresponding clause of ISO 13485:2016.

EN ISO 13485:2016 Clause	Findings
4.2.2	**Quality Manual:** Not all non-applications were correctly identified. Design was incorrectly identified as a non-application, while it is a permitted EXCLUSION. The Quality Manual does not outline the scope of the QMS and the roles of the company. The Quality Manual does not include a 'description of the interaction of the processes of the QMS'. There is no reference to many of the required procedures e.g., Risk management, Purchasing, Identification & Traceability, Preventive action etc.
4.1.2/ 4.1.3	**Process clause matrix/process approach:** The processes identified by the company, do not align with the proposed ISO 13485 cert scope e.g., Design is missing. Having identified the processes of the company, there is no evidence that each of the company process is monitored and measured e.g., there is no KPI/Quality Objective/metric (either direct or indirect) for the process of Design. The monitoring of the Design process, via the Internal Audit programme, is not in evidence e.g., the 2021 schedule did not include an audit of Design.
5.3	**Quality Policy:** As documented the policy does not address: (b) 'includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system' (c) 'provides a framework for establishing and reviewing quality objectives' The Quality Policy was not aligned to the purpose of the organisation e.g., Design was in the scope, but not in the Policy.
4.2.4 & 4.2.5	**Control of Documents & Records:** Retention period of documents and records has not been defined The retention period of records is defined but is not aligned with the retention period of related documents /procedures.
5.5.2	**Management representative:** The responsibilities and authority of the Management Representative are not clearly stated.
6.2	**Human resources:** Evidence that 'methods' are in use to determine the effectiveness of training were not available at the time of audit.
8.5.2	**Corrective and Preventive Action (CAPA):**

	There is no indication that 'corrective and preventive actions are required to be taken without undue delay'.
8.2.1	**Feedback:** At the time of audit, a documented procedure that describes the organisations methods for obtaining and using customer feedback have not been provided.
8.2.2	**Customer Complaints /Vigilance:** The company procedures and Quality Manual do not clearly identify the role of the company The definitions of the following are incorrect: complaints (as per ISO 13485:2016)
7.4	**Purchasing:** Supplier monitoring and re-evaluation is not formally documented. There is inadequate evidence of control of key suppliers • No quality agreements signed and in place • key supplier is not on ASL/AVL; ASL/AVL has not been approved • the<first> supplier evaluation review has not taken place • the supplier evaluation process consists in only one statement in the Management Review – "Key supplier A are ok" and this is not supported by any further data • The requirements for records of the results of re-evaluation were not documented Purchasing procedures have been documented to included Vendor Approval and Vendor rating requirements. However, at the time of audit these requirements have not been fully implemented.
4.1.5	**Control of outsourced processes:** Outsourced supplier relationships are unclear/not defined. The auditee is unaware that the outsourced service provider may/does further outsources key processes e.g., sterilisation. Contracts not signed / duties not clearly assigned to either party. **Expectation @ stage 1:** Ideally outsourced service provider(s) have been identified, the contract(s) has been drafted, and supplier evaluation process is under way. **Expectation @ stage 2:** Signed contract for outsourced processes must be available, and they are on the ASL/AVL.
5.6	**Management review:** The documented management review procedure does not include ISO 13485:2016 Management review does not conclude regarding "Continued suitability, adequacy and effectiveness of the QMS" in line with wording of EN ISO 13485:2016 **Expectation @ stage 1:** Management review has been completed and covers all applicable requirements. **Expectation @ stage 2:** As above, note arising from the Stage 1 audit, an updated Management Review may be necessary.

7.1	**Risk management:** From the procedure, it is unclear how the Risk Management File is kept up to date • Unclear what will trigger a Risk Management file review and/or update • The frequency of "periodic" review is unclear Note: annual review may not be adequate for some Tech Files.
8.2.4	**Internal Audit:** The procedure does not address adequately Training requirements or the records of training required to demonstrate that Internal auditors are suitably trained. A full round of Internal audits (considering ISO 13485:2016) was not completed/ or planned to be completed before Stage 2. Internal audit schedule was not conducted /aligned to the Processes of the company (The Processes recorded on the NSAI PCM are not reflected on the Internal Audit Schedule). [Particularly for small organisations] There is no evidence that the auditors are impartial/did not audit their own work. It is unclear that the company have followed their own procedure on how to handle an Internal audit finding e.g., the company SOP stated that all Major Internal audit findings should lead to a CAPA, however no CAPA was raised. **Expectation @ stage 1:** The audit schedule has been generated, and at least one audit has been conducted. **Expectation @ stage 2:** A full round of Internal audits (as per the schedule) has been completed.
4.2.1	**Change control:** Change control Procedure does not provide instruction on • How to identify a QMS substantial change and how to notify NSAI. The Design and Development Changes Procedure does not link with Change Control procedure.