Guidance Document

Common Findings: (EN) ISO 13485:2016 (Including Regulatory Requirements) Stage 1 Audit

NSAI have compiled a non-exhaustive list of (EN) ISO 13485:2016 & Regulatory (EU MDR 2017/745 & MDSAP) quality management system audit findings which commonly occur during a stage 1 audit.

These findings cover a broad spectrum of the standard and associated regulatory requirements 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 (EN) ISO 13485:2016 where relevant.

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. Quality Manual doesn't claim compliance to applicable regulatory requirements e.g., MDR, MDSAP TGA: TG(MD)R ANVISA: RDC ANVISA 16/2013 Health Canada-CMDR MHLW/PMDA: MHLW MO169 FDA: 21 CFR 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 or is not aligned with MDR /MDSAP participant's regulatory requirements

	The retention period of records is defined but is not aligned with the retention period of related documents /procedures. Key SOPs not updated in line with MDR /MDSAP participant's regulatory requirements.
5.5.2	**Management representative:** The responsibilities and authority of the Management Representative are not clearly stated. PRRC- role and responsibility are not clearly stated/defined.
6.2	**Human resources:** Evidence that 'methods' are in use to determine the effectiveness of training were not available at the time of audit. No evidence that relevant staff were trained in MDR/ applicable regulatory requirements.
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, with respect to Economic Operators as per MDR i.e., Manufacturer, Importer and /or Distributor AND/OR Sponsor/ Local representative etc in MDSAP participants regulatory requirements. The timelines for investigation of vigilance reports are undefined/ unclear. The definitions of the following are incorrect: complaints (as per ISO 13485:2016), FSCA/FSN/ (as per MEDDEV 2.1201 Rev 8 and updated guidance of July 2019). It is unclear who is performing reportability decisions and that they are appropriately trained. It is unclear if/when clinical involvement occurs in reportability decisions. The procedures for Adverse Events and FSCA/FSN do not correctly identify • When a report is necessary • What form to use • Which Competent Authority(s) to submit to • Timelines for submission • Initial/follow-up and final reports
7.4	**Purchasing:** Supplier monitoring and re-evaluation is not formally documented. There is inadequate evidence of control of <u>key suppliers</u> • 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 parties. In cases where the Manufacturer delegates some of the requirements of the MDR to another party, there is inadequate evidence of the systems/controls in place e.g. the activity of complaints handling and Adverse Event reporting is delegated, and there are no procedures available for review; there is no evidence that the Manufacturer has fully assessed the supplier for his ability to do this job. **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 & MDR/applicable regulatory requirements in its purpose. Management review does not conclude regarding "Continued suitability, adequacy and effectiveness of the QMS" in line with wording of EN ISO 13485:2016 and MDR /applicable regulatory requirements. **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:**

	Internal audit Procedure/ schedule/report did not reference MDR/applicable regulatory requirements. The procedure does not address adequately Training requirements or the records of training required to demonstrate that Internal auditors are suitably trained. Auditors were not trained to MDR/applicable regulatory requirements. A full round of Internal audits (considering ISO 13485:2016 & MDR/ /applicable regulatory requirements) 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.
MDR 2017/745	**Clinical:** The company have not distinguished between Clinical Investigation and Clinical Evaluation. The company procedure on Clinical Evaluation • is not aligned with MDR expectations • does not consider the three pillars of equivalence - clinical, biological, and technical per Part A Annex XIV section 3. • does not consider frequency of update of the CER. Within the Clinical Evaluation Plan/Report, the organisation is utilising a literature review only. It is unclear how this meets the requirements of article 61 or Annex XIV Part A. The company have not completed a CER (or justification for not having one as per MDCG 2019-15).
MDR 2017/745	**Insurance policy:** The insurance policy provided did not cover all the activities of the company e.g. Manufacturer, Importer, distributor, Manufacturing site.
MDR 2017/745	**Common Specifications (CS):** While it is acknowledged that currently there are no agreed Common Specifications, the company have not provided evidence of how changes to current Common Specifications or the publication of new Common Specifications are monitored.

MDR 2017/745	**UDI:** No process or procedure for basic UDI-DI creation, maintenance, application, and update. The UDI procedure does not reference the UDI timelines as outlined in MDR.
MDR 2017/745	**EUDAMED:** While it is acknowledged that currently not all parts of EUDAMED are operational, the company was unaware of the relevant EUDAMED timelines and requirements.
MDR 2017/745	**Declaration of Conformity (DoC):** The DoC template does not include the requirements of annex IV or article 19 • Does not say identify Regulation 2017/745, EC council directives and standards • No statement that it is in conformity with this regulation. • Does not include area for CS. • Approval/approval signature – place and a date of issue • Signed on behalf of whom • SRN • models/variants covered by the DoC. The requirement for language/translations of DoC has not been addressed or evident in the documentation provided.
MDR 2017/745	**Technical Documentation:** The name and/or address of the Manufacturer on the labelling (labels and cartons) is not aligned to name and/or address in this QMS application.
4.2.1	**Change control:** Change control Procedure does not provide instruction on • how to identify a product significant change and how to notify NSAI/ appropriate authority, • how to handle a non-Significant change, • how to identify a QMS substantial change and how to notify NSAI. The Change control procedure does not cite /consider the appropriate guidance documents e.g., NBOG, MDCG etc The Design and Development Changes Procedure does not link with Change Control procedure.