

Audit Report <Date>

1. General Information

Purpose of audit:	Internal audit
Auditors:	Enter names of your internal auditors

2. Internal Participants

Name
Team
Position/Role
Audit date
Start
End
Scope
Audit Criteria

3. Audit Activities

See IAU - Internal Audit Plan section 4 and copy the audit schedule here.

4. Methodology

During the audit, the auditor gathered, using appropriate sampling, information relating to the audit objectives, scope and criteria, including information relating to the interfaces between functions, activities and processes, and verified it. Only verifiable information constituted audit evidence. Audit evidence leading to audit findings was recorded.

Relevant documentation from the auditee was reviewed in order to:

- Determine the compliance of the system, based on the available documentation, with the audit criteria, and to
- Gather the information necessary to support audit activities.

In addition, information related to the audited process was gathered through interviews of the auditees by the auditors.

5. Classification of Non-Conformities

The classification of audit findings is established as follows:

- **Major Non-Conformity (MNC):** A deviation in the system, practices and processes that could result in significant effects that violate the law, patient safety or well-being, or could result in a public health risk or indicates a major deviation from current regulations.

- **Minor Non-Conformity (mNC):** A deviation in the system, practices and processes that is not expected to result in an adverse effect on the safety or well-being of patients.
- **Opportunities for Improvement (OFI):** A commentary indicating a process for improvement either by improving quality or reducing the occurrence of deviations.

6. Audit Protocol

Requirement	Audit Question	Audit Record & Evaluation / Finding
ISO 13485:2016, chapter 4.2.3	For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to:	State here the audit record (e.g. the Quality Manual) and the audit finding.
Continue with the requirements that are listed in the audit plan and programme.		

7. Audit Conclusions

7.1 Major Non-Conformities

MNC			
No.	Requirement	Audit Proof	Finding
1	State the requirement here.	List the audited record.	Describe the MNC.

7.2 Minor Non-Conformities

mNC			
No.	Requirement	Audit Proof	Finding
1.	State the requirement here.	List the audited record.	Describe the MNC.

7.3 Opportunities for Improvement

OFI			
No.	Requirement	Audit Proof	Finding
1	State the requirement here.	List the audited record.	Describe the MNC.

8. Follow-up of Actions from the last Audit

Describe the follow-up of actions from the last Audit. Where there any gaps needed to be closed? Are there delays in the closing of non-conformities?

10. List of Documents and Information collected during the Audit

List the documents that have been audited here.

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