1. **Purpose**

This document defines the policies and procedures for performing quality audits to ensure the effectiveness of the quality management system and compliance with the applicable regulatory requirements. These policies and procedures include auditor selection, audit planning, execution, reporting, and closure.

1. **Scope**

This procedure applies to all Quality Management System audits including internal quality audits and supplier quality audits.

1. **General** 
   1. **Definitions** – N/A
   2. **Responsibilities**

**Quality Auditors** – Auditors are responsible for executing the following procedures and submitting all records to the Quality Department.

**Quality** – Quality Management is responsible for the planning, execution, and continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – Internal Auditors shall be trained to the procedures specified in this document. Auditors shall meet audit qualification requirements listed in this procedure.
  4. **Record Management** – Audit records are managed and maintained by the Quality Department.
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**ISO 13485** Medical Device Quality Management Systems

**ISO 19011** – Guidelines for Auditing Management Systems

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**GHTF/SG4/N28R4** – Guidelines for Regulatory Auditing of QMS of Medical Device Manufacturers

**QP-0012** – Corrective and Preventive Action (CAPA) Process

**QP-0023** – Supplier Management Process

1. **Internal Audit Schedule**

The internal audit schedule is developed and maintained by the Quality Department. The audit schedule shall cover all areas of the quality management system on an annual basis. The schedule shall include:

* The areas to be audited with appropriate references to the applicable regulatory requirements (e.g. FDA CFR 21 Part 820, ISO 13485 sub clauses, MDD, etc)
* Linkage to the associated QMS documentation for regulatory requirements
* The planned month of execution
* The name of lead auditor and date of audit once completed

1. **Quality Audit Procedure**

The following audit procedures are utilized to ensure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the Quality Management System. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Audits shall be as detailed as necessary to determine the effectiveness of the implemented systems considering the associated risk and importance of the area to be audited.

* 1. **Auditor Selection**

Auditors may be chosen from within any department in the company or utilize third party auditors based on their qualifications and independence from the subject/area to be audited. Auditors shall not audit their own work. Auditor qualifications include the following and all records are maintained by the Quality Department:

* Candidate has completed internal/external auditor training or has previous auditing experience (e.g. previous job, auditor/training certificate)
* Candidate has knowledge of applicable regulatory requirements (FDA CFR 21 Part 820, ISO 13485, MDD, etc.)
* Candidate has participated in all phases of Internal Auditing (planning, execution, reporting, and closure)
* Candidate has demonstrated auditor competencies to a qualified auditor
  1. **Audit Preparation**

Audits are scheduled by the lead auditor with the area management during the designated month on the audit schedule. During the planning stage, the lead auditor shall complete the following items and documents as appropriate:

* Identify the audit objective, scope, applicable regulatory requirements, and participating auditors
* Review previous audit reports for the subject/area
* Identify all corrective actions from previous audits that require follow-up
* Send the audit plan to participating auditors and auditee representatives
  1. **Audit Execution and Report**

An audit is initiated by an opening meeting and concluded by a closing meeting. The following items are completed during the audit and documented on the report:

* An Opening Meeting (formal or informal) with auditor(s) and area management to communicate the audit objective and scope
* Documentation of the names/titles of all participating parties and date of the audit
* The auditor(s) shall take notes and obtain evidence of auditee’s conformance to the established requirements
* All objective evidence, checklists, and any other audit material shall be included in the audit report
* A record of all findings (see following section) along with the statutory requirement with which the area is not compliant
* Appropriate follow-up to any corrective actions from previous audits. If found insufficient, a new finding shall be created
* Closing Meeting with the area management to discuss the results of the audit and any findings

Quality Management shall review the audit report and send the final audit report to auditee representative. Any audit disputes or issues shall be resolved by Quality Management.

* 1. **Audit Findings**

Upon completion of the audit, the auditor shall provide a report of the results to the management responsible for the area/organization audited. The report shall include all findings (nonconformities or deficiencies) of the audit and any opportunities for improvement. All findings shall reference the QMS/Regulatory requirement that is not fulfilled.

All findings are rolled into and managed by the CAPA/SCAR Systems. Opportunities for improvement do not require corrective actions. Area management shall review all findings and submit responses including root cause and corrective action plan to the Quality Department for approval within 30 days. Corrective actions for audit findings are required to be implemented within 90 days. An extension may be granted at the Quality Management’s discretion with justification.

* 1. **Audit Closure**

Once all corrective actions have been completed, area management shall submit verification of the corrective actions to the auditing body. Once all corrective actions are approved the audit shall be closed. Notification of closure shall be communicated to appropriate management.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0015 |  |  | Initial implementation of the Quality Audit Process |