Procedure: Internal Quality Audits

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This procedure is a typical approach to internal audits but it should be expanded to reflect the actual practices of the company.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for conducting internal audits of the Quality Management System (QMS) and other related systems.

The internal quality audit system reviews the effectiveness of the individual elements of the Quality Management System.

# Scope

The scope of this procedure includes all processes and activities of the QMS, the areas where it is implemented and related procedures and systems at [Company].

# Responsibilities

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| Role | Responsibility |
| All personnel | Actively participating on an as needed basis in the audit and performing follow up activities |
| Department Manager |  |
| Quality Manager | Preparation and issue of the audit schedule  Performing Audits as required, issuing of audit reports  Oversight of Quality Audit Program including appropriate closure of any corrective actions as a result of audits  Maintaining completed audit reports |
| Senior Management | Ensuring adequate resources are assigned for the timely closure of audit actions and to maintain the internal quality audit schedule |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## Audit plan

Planning of internal audits is based on the Quality System Process Map (refer Quality Manual Section 4). The quality system process map defines the major quality system elements. Using this as a basis:

* define component sub-processes that require auditing
* list pertinent sections of the quality manual and related operational procedures
* specify areas to be audited
* reference relevant sections and clauses in ISO 13485

QA is responsible for planning and scheduling internal audits of the QMS, manufacturing processes and products. The audit frequency is based on the criticality of the process, product or area being audited. Previous audit results, non-conformities and customer complaints are also considered. Each QMS element must be audited at least annually.

The variation in audit frequency should reflect the criticality and importance of the area or activity.

Internal audits cover all QMS (sub) processes. They are conducted in relevant departments, functions and areas and cover all operational shifts.

Ensure the audit plan also reflects the requirement to cover all shifts.

The QMS audit plan is documented in a matrix (refer to Form *FM802-1: Internal Audit Plan*; the x-axis lists audit dates and assigned auditors; the y-axis lists processes of the QMS to be audited).

A more detailed scope, along with ISO 13485 references, should be developed for each audit.

Internal audit plans and cycles are synchronised with management reviews of the QMS (refer to Procedure *QP501: Management Review*), so that the complete results from a full auditing cycle is available for the management review meeting.

## Audit team

The QA Manager is responsible for training and assigning internal auditors. Personnel assigned to perform audits must be independent of those responsible for the activity or function being audited.

Internal auditors are qualified on the basis of their education, experience and training. Minimum requirements are:

* satisfactory completion of year 12 schooling
* two years in this or a related industry
* eight hours external or in-house training

Training should be at an accredited external course or by in-house training provided by a qualified consultant/trainer. If training is provided in-house, the trainer must have appropriate, documented, qualifications and experience.

ISO 13485 requires internal auditors to be qualified but does not specify the qualification.

## Preparing for audit

Auditors must be able to demonstrate adequate preparation for the audit; check lists are useful for this purpose. Notes taken during the audit should also be retained as evidence.

Auditors prepare for an audit by:

* reviewing the Quality System Process Map and Section 4 of the Quality Manual
* identifying relevant clauses of ISO 13485

...or other relevant standard or regulatory code.

* refreshing their knowledge of the quality manual and relevant operational procedures
* reviewing non-conformity reports, customer complaints and corrective action files
* reviewing previous audits of the area/function
* preparing questions/checklists

The audit may be a broad, looking across the whole area, or it may track a particular product or activity through its life-cycle.

## Conducting the audit

Notify the manager responsible for the area being audited at least a week before the proposed date. The manager should respond by confirming or proposing alternative dates.

During the audit, auditors seek objective evidence to demonstrate whether the activities conform to the requirements of the QMS and/or standard and whether the system is effectively implemented and maintained.

When a non-conformity is noted, it is brought to the attention of and discussed with the responsible manager or supervisor. Form *FM802-2:* Audit Non-Conformity Report may be used for this purpose.

## Reporting the audit

At the conclusion of the audit, an informal verbal report is given to the area or function manager. The manager is then given the opportunity to refute, correct or comment on any points or inaccuracies.

Within one week of completion of the audit, the auditor must submit a formal audit report listing and rating the findings.

|  |  |
| --- | --- |
| Audit Ratings | Description |
| Critical | Non-compliance with regulations or likely to result in a device that will cause a serious harmful effect to the user |
| Major | May result in a GMP non-compliance or a device failure that could have a minor effect on the user |
| Minor | Deviation from procedure that is unlikely to effect the final product |
| Comment | Suggested improvements in systems or practices. |

The audit report will generally indicate a period within which the auditee should respond and when any deficiencies should be resolved and closed out.

## Corrective actions and follow up

In this procedure, corrective actions from audit findings may be tracked directly through the response to the audit or, if the deficiency requires a longer time to rectify, through the general corrective and preventative action system (refer QP810 Corrective and Preventative Action and FM810-1 Corrective Action Request).

The manager of the area or function audited is responsible for responding to the audit report within the time frame specified. The response should address each of the points in the report:

* simple deficiencies that have been addressed immediately and resolved should be closed out in the audit report
* where deficiencies are more complex or will take longer to resolve, a CAR should be raised (*Form FM810-1: Corrective Action Request*)

Deficiencies transferred to a CAR are processed according to Procedure *QP810: Corrective and Preventative Actions*. The responsible manager investigates the problem and proposes a corrective action to be taken and proposes a suitable time frame. The auditor reviews and approves the proposed action.

The auditor is responsible for following up all deficiencies (both minor deficiencies and ones resulting in a CAR) to determine if they have been resolved effectively. Where there is objective evidence the action is effective, the non-conformity report is closed out. If additional work is required, a new follow-up date is agreed.

## Documentation and records

Internal audits, implementation of resulting corrective actions and follow-up audits are documented and records retained by QA.

Pending CARs are kept by the auditor. Closed-out CARs are filed by QA.

At the end of an auditing cycle, all CARs raised during the cycle are compiled and analysed. They are presented annually to the management review meeting (refer to Procedure *QP501: Management Review*).

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP501 | Management Review |
| QP810 | Corrective and Preventative Actions |
| FM802-1 | Internal Audit Plan |
| FM802-2 | Audit Non-Conformity Report |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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