YR = Present year

Scope:

This procedure defines the general 1st party audit system also called the internal audit system, at the Pharma A/S production plant in Lyngby, Denmark.

This procedure does not apply for 2nd and 3rd party external audits.

Summary of internal audit system

The Pharma A/S internal audit program is managed by QA who coordinates the internal audit plan, trains internal auditors and facilitates the resolution of the findings from the audits.

It is the intention that each Pharma A/S function or department is audited internally at least once per year.

Any full time Pharma A/S employee with more than one year of employment can become internal auditor. The employees superior must approve.

To become an internal auditor the training will consist of an introductory theoretical training program and the participation as observer in a number of internal audits.

To become an internal lead auditor the person must have participated in a number of internal audits as assistant auditor and have passed an external course as lead auditor.

An auditor training plan template is attached as Attachment 1.

The internal audit program

QA will during the start of every year issue an audit plan for the internal audits at Pharma A/S for the coming year. All departments / functions should be audited at least once during the year. A proposal for the plan will be distributed to all managers and function responsible persons in January who must acknowledge their part of the plan or negotiate a change with QA.

The final plan is distributed to all managers, engineers and supervisors.

Any later request of change to the plan must be announced to QA at least one month before the planned audit.

Internal auditor training and certification

Convocation as an internal auditor may happen either as a request from QA to a specific employee or as a request from an employee to QA.

Any full time Pharma A/S employee with more than one year of employment can apply to become an internal auditor with their superiors approval.

QA may reject or put on hold any candidate for training as internal auditor.

Assistant auditor:
The candidate will be assigned a QA employee as tutor. The training will start with a theoretical course in the general audit process and auditor behavior administered by QA personnel. The course has a duration of 2 hours.
The auditor candidate will participate in minimum 3 internal audits as an observer.

After completion of 3 audits as observer, the candidate will participate in one audit as assistant auditor. After completing of the first audit as assistant auditor, the auditor candidate, the lead auditor from the audit and the QA tutor will meet to evaluate if the candidate is interested and competent to become internal auditor. If agreed the person is announced internal auditor.

Lead auditor:
To become lead auditor for internal audits, the person must participate in minimum 3 internal audits as assistant auditor.
Furthermore the candidate must participate in an external lead auditor course indicated by QA.

Fulfilment of these requisites, the person will act as aspirant lead auditor in an internal audit. After this first audit as lead auditor, the lead auditor candidate and the QA tutor will decide if the auditor is ready to become lead auditor or need more training.

Approved auditors:

QA will keep and maintain a list of all internal auditors approved and in training.

Handling of internal audit findings

All internal audits must generate an audit report with a detailed registration of the findings. Findings for internal audits are divided in Observations for Improvement and Non-conformities. It is also recommended in the reports for internal audits, to emphasize subjects for sharing of better practices.

The audit report with its findings, must be sent to QA by the lead auditor maximum 30 days after the audit. The lead auditor must ensure the approval of the report by the assistant auditor(s) before the official issue.

When receiving the audit report QA has the responsibility to assign a responsible function or person to resolve each finding. QA has responsibility to follow up on the action plan and its completion. All findings from internal audits are compiled and presented by QA in the quarterly Management Review meetings.

Responsibilities:

This document: Quality Unit Manager
Yearly internal audit plan: Quality Unit Manager
Internal auditor training plan and certification: QA engineer and auditors superiors
List of approved internal auditors: QA engineer

Change Log

Version	Description	Initials	Date
01	This is first version	QA person	15.10.(YR-1)

Attachment 1

Training plan Internal Auditor

Internal Auditor Training Plan Pharma A/S, Lyngby Site

Full Name: Date:
Department:
Is to start training as internal auditor. Approval by (initials / date):

Superior:_____ QA:_____

Introduction to auditing
Date:_____

Initials/ Date; Employee:_____ QA:_____

Certification as Assistant auditor: Lead auditor: Initials / Date:

Observer 1st audit: _____

Observer 2nd audit: _____

Observer 3rd audit: _____

Assistant auditor audit: _____

Employee approved as internal assistant auditor:

Initials / Date Employees:_____ QA:_____

Certification as Lead auditor Lead auditor: Initials / Date:

Assistant auditor 1st audit: _____

Assistant auditor 2nd audit: _____

Assistant auditor 3rd audit: _____

External lead auditor course completed: _____

Employee approved internal lead auditor

Initials / Date Employees:_____ QA:_____