1 Purpose

This Procedure defines the procedure for performing Distribution Site (DS) audits and includes selecting, preparing for, conducting, reporting and documentation archiving of DS audits.

The primary purpose of these audits is to evaluate the operational use of the DS for compliance with the company procedural documents, GMPs, GCPs, and applicable (local) regulatory requirements.

2 Scope and Applicability

It should be in the policy that each DS, used for distribution of Study Drug, will be audited as part of the quality assurance process. This includes any DS located within the same premises, as well as any DS at a Contract Research Organization

Audits of Distribution Sites should be carried out by QA group working for contracts.

3 Definitions

3.1 Critical Observation

"Deficiencies with Company Standards, and/or current regulatory expectations that provide immediate and significant risk to product quality, patient safety or data integrity, or a combination/repetition of major deficiencies that indicate a critical failure of systems."
Immediate corrective action and reporting to Management is required

3.2 Major Observation

"Deficiencies with Company Standards and/or current regulatory expectations that provide a potentially significant risk to product quality, patient safety or data integrity, or could potentially result in significant observations from a regulatory agency, or a combination/repetition of "other" deficiencies that indicate a failure of system(s)."

3.3 Minor Observation

Observations of a less serious or isolated nature that are not deemed Critical or Major, but require correction, or suggestions given on how to improve systems or procedures that may be compliant, but would benefit from improvement (e.g. Good Practice seen elsewhere).

3.4 DS

Distribution Site

5 Procedure

5.1 Frequency of the Audit Program

The frequency of DS audits will be one every 3 years, as initial assessment. Thereafter the assessment may be based on audit (i.e. visits), questionnaire, or other information.

5.1.1 Prioritization of Audits

Prioritization of audits is potentially based on:

- Clinical study activities (number of studies) at DS
- External inspections
- Scope of licensed activities, e.g. manufacturing license or distribution activities
- Compliance risk, based on previous DS audits, reported compliance issues, or other knowledge

5.2 Preparing for the Audit

5.2.1 Planning the Audit

The Lead Auditor and Co-Auditor will:

- Decide the practical arrangements for conducting the DS audit

5.2.2 Initial Contacts and Confirmation

The Lead Auditor will:

- Inform the responsible DS Manager or the responsible person at the DS.

Once the audit date is confirmed, the Lead Auditor will:

- Confirm the planned audit to the DS contacts via electronic mail or by letter. The e-mail or letter, will introduce the audit team, confirm the agenda of the audit, and state the documents to be sent to the auditors preceding the audit.

5.2.3 Preparatory Reviews and Preparation of Working Documents

The Auditor(s) will:

- Complete preparatory work before the DS audit will be performed.

Activities should include, where possible, a review of supplementary SOPs, organization chart(s), and job descriptions. Activities should also include, where

- Incorporate responses into the report

  When only minor observations have been reported, the audit will be considered closed, and the Final Audit Report will be issued.

  When major or critical observations have been reported, the audit will be considered closed after the lead auditor has obtained confirmation that follow-up commitments to major or critical observations (as specified in the action plan) have been completed. The Final Audit Report will be issued after obtaining the required confirmation.

  If longer term corrective/preventative actions will be transferred to a Compliance Improvement or Enhancement Plan for the DS, the Final Audit Report may be issued after receiving the Compliance Improvement or Enhancement Plan.

- Obtain confirmation that follow-up commitments to major or critical observations have been completed (or obtain the Compliance and Enhancement Plan for longer term corrective/preventative actions).

- Issue the Final Audit Report.
  The Final Audit Report will be issued, as an attachment to an e-mail. The recipients will be the same as for issuing the Draft Audit Report.

5.4.4 Annual summary of audit observations

The head of the QA Systems/Support and the DS Subject Matter Expert will review the audit observations on an annual basis, and prepare a summary of the observations.

The summary will be shared within QA, and DSs to facilitate learning, and to promote enhancements in compliance within the DSs.

Summaries of audit observations should be made available on the DS website.

5.5 Archiving of Audit Documents

The audit report and all relevant documents will be archived.

The following documents will be stored electronically, according to QA routines, on a shared drive:

- E-mail for issuing Final Audit Report
- Final Audit Report

The following documents will be archived locally, according to local routines, for at least 15 years:

- Copy of E-mail for Confirmation of DS Audit

