Issue Reports, which have been completed since e.g. last audit.

Investigational Products and/or QA from the site that is responsible for the investigational products for which study drug documentation will be reviewed during the audit, should be contacted ahead of the audit for any relevant input (including, for example, information on compliance issues).

If the DS audit is in conjunction to planned investigator site audit(s) or systems audit, activities should also include, where possible, a review of study drug supply information. For example, information on study drug supply as stated in the clinical study protocol, monitoring reports.

- Prepare appropriate working documents (checklists)

5.3 Conducting the Audit

5.3.1 Opening / Introductory Meeting

The Auditor(s) will:

- Hold an opening meeting to introduce the audit team, and to provide information on the purpose and details of the DS audit.

  The Lead Auditor will also inform the auditee on the issuing of a (draft) audit report and requirements for responses to the draft report. This information may also be provided during the feedback meeting (see section 5.3.3).

5.3.2 Audit Activities

The Auditor(s) will continue with:

- Interview(s) with the DS management and other appropriate personnel of the concerning organization, personnel of the facilities, DS documentation, and non-routine operations.
- A tour of facilities at the DS.
- A review of DS documentation.
- A review of selected Study Drug (if applicable) Documentation.

5.3.3 Feedback Meeting

At the end of the audit, the Lead Auditor will:

- Present audit observations to the DS management at the DS site.
- Discuss any follow-up corrective actions, where appropriate
- Thank those involved for their assistance during the audit

5.3.4 Follow-up Activities

