

Standard Operating Procedure

Title: GMP Audit Procedure

The auditors should use the Housekeeping checklist for area audited. Non-conformances made during the inspection should be discussed with personnel at the time they are observed, so that observations are clearly understood by all involved. Non-conformances should be resolved as soon as possible, and are to be documented in the housekeeping checklist. Non-conformances are also captured using the Deviation Report system and are to be raised by the designated Housekeeping Auditor or Process Manager. DR number must be recorded on the Housekeeping Checklist.

6. Regulatory inspection

6.1. Schedule

Regulatory Agency inspections may be announced or unannounced. The Quality Assurance Manager is the primary contact for Regulatory Agency Inspections. Should the Quality Assurance Manager not be available on site, this responsibility will be defined in the letter of delegation issued prior to planned absences.

6.2. Planning

For Regulatory inspections, either announced or unannounced, the following should be identified and made available in a timely manner to facilitate the auditing process.

- An inspection team with specific roles such as runners, scribes and subject experts to be able to quickly respond to the needs of the auditor.
- An appropriate individual to assist the auditor in conducting the audit and be available at all times to the auditor to facilitate the timely gathering of information.
- A conference room or office available to the auditor for the purpose of reviewing notes, inspection of company documents and /or use of telephone to contact his/her office.
- The auditor should be made aware that the taking of photographs, use of tape recorders or other electronic equipment, the listening to, reading and signing of affidavits, the review of internal audit reports and the allowing of access to computer databases is **NOT ALLOWED** and requires consultation with the Quality Assurance Manager.

6.3. Audit Performance

Once the Regulatory Inspection has commenced, the following process should be followed:

- Senior management should be present at the opening and closing meeting of a regulatory inspection. It is suggested that the senior management give a brief introductory presentation to the Regulatory Authorities (with their agreement) covering the department, function or site being audited.
- Auditors should be accompanied at all times to meet the organization's EHS requirements and to facilitate the provision of documents, information and movement through the facility.
- Auditor's questions must be answered truthfully and honestly, in the most direct manner to ensure prompt provision of information and adherence to the audit schedule timeliness.
- Auditors must go through proper Induction Training Programs for areas audited should they request entrance into restricted areas of facility.
- Inspection team members should keep accurate detailed notes on issues, products, operations, documents reviewed and samples taken during the audit, to facilitate timely clarification and resolution of issues arising during the audit.
- Documents or copies of documents provided to the auditor should be stamped as "CONFIDENTIAL" to ensure company confidentiality and a duplicate copy of these documents must be included as part of the inspection file at QA Office to facilitate the timely resolution of any future queries from the Regulatory Agency relating to the audit, should they arise.
- Daily summary sessions (daily wrap-up meetings) with the auditors at the end of each day's activities should be requested for the purpose of clarifying any issues that may have been