

Standard Operating Procedure

Title: Housekeeping Audit Procedure

- Calibrations
- Safety.
- Clothing worn correctly/No jewellery
- General maintenance of area i.e. chipped or flaking point
- GMP procedures
- Environmental, health and safety issues

Each area will also have items that are only applicable for that area.

2.4. Housekeeping audits by QA Staffs will be conducted in the presence of the Process Manager.

2.5. At the end of the audit any action items will be discussed with the area manager.

3. Checklists

3.1. There are prepared checklists for the following area to keep record of the audit.

Form-425 Analytical Laboratory
Form-430 Production Services
Form-435 Electrical and Mechanical Workshop
Form-440 Warehouse
Form-475 Dispensary
Form-485 Production

3.2. The Checklists are divided into 3 sections: GMP Items, EHS Items and Area Specific Items.

3.3. All Process and Support teams should utilise the checklists as specified above for each individual team.

3.4. The Housekeeping Auditor should complete all Sections as indicated in each audit checklist.

4. Audit Reporting

4.1. Audit details including action items and general comments are entered in the audit report. Any deviation for non compliance a deviation report to be raised and report forwarded to appropriate manager/s.

4.2. It is the responsibility of the area manager concerned to take action to rectify any findings of the audit. DR must be completed within one week of the audit or a work order submitted. If something has to be made or it is a big job, an action plan must be put into DR follow up tasks to complete the action item.

5. Non-compliances

5.1. A Deviation Report (DR) will be raised by the Housekeeping Auditor/QA Representative/Process Manager:

5.1.1. For GMP non-compliance if a cross (X) is recorded. Comment must be made in the Comments column and a DR rose immediately following the completion of the audit, if the non-compliance cannot be corrected during the same shift as the audit.

5.1.2. For an EHS non-compliance - immediately following the completion of the audit, if the non-compliance cannot be corrected during the same shift as the audit. An EHS item is identified and Reported to the EHS team immediately.