Self-Inspection and quality audits

World Health Organization

Self-Inspection

Objectives

- To identify the role of self-inspection in the quality management system
- To review the way in which a self-inspection programme should be carried out
- To discuss what to inspect and verify in a company's self-inspection system

Self-Inspection

Principle (1)

- Purpose of self-inspection is to evaluate whether a company's operations remain compliant with GMP
- Assists in ensuring quality improvement
- The programme should
  - *cover all aspects of production and quality control*
  - *be designed to detect shortcomings in the implementation of GMP*
  - *recommend corrective actions*
  - *set a timetable for corrective action to be completed*

8.1

Self-Inspection

Principle (2)

- Performed routinely
- Also on special occasions such as
  - *Recalls*
  - *Repeated rejections*
  - *When a GMP inspection is announced by the national drug regulatory authority*

8.1

Self-Inspection

Principle (3)

- Self-inspection team should consist of personnel who:
  - Are objective and have no revenge in mind
  - Have no conflict of interest *(That is, normally not from the same department as the one being inspected)*
  - should have experience as observers of a self-inspection team before becoming a team member
- The team should be led by an experienced person
- Procedure should be documented
- Effective follow-up programme (CAPA implemented)

8.1

Self-Inspection

1. Self-inspection - informal (daily) — *Immediate correction*
2. Self-inspection - formal (quarterly) — *Improve systems*
3. QC - Internal (half-yearly) — *Confirm compliance*

Self-Inspection

Items for Self-Inspection (1)

- Written instructions provide minimum and uniform standard
- Covering all aspects of GMP:
  - *personnel*
  - *premises including personnel facilities*
  - *maintenance of buildings and equipment*
  - *storage of starting materials and finished products*
  - *equipment*
  - *production and in-process controls*
  - *quality control*

8.2

Self-Inspection

Items for Self-Inspection (2)

- *documentation*
- *sanitation and hygiene*
- *validation and revalidation programmes*
- *calibration of instruments or measurement systems*
- *recall procedures*
- *complaints management*
- *labels control*
- *results of previous self-inspections and any corrective steps taken*

8.2

Self-Inspection

The Self-Inspection Team

- Team appointed by management, with:
  - *authority*
  - *sufficient experience*
  - *may be from inside or outside the company*
  - *experts in their own field*
  - *familiar with GMP*

8.3, 8.4

- Frequency should be at least once a year
  - *Depends on company size, requirements, actrivities*
  - *Often, departments are inspected according to a calender – one department per month over a one year cycle*

Self-Inspection

- Report prepared at completion of inspection, including:
  - *results*
  - *evaluation*
  - *conclusions*
  - *recommended corrective measures*
- Follow-up action
  - *Effective follow-up programme*
  - *Company management to evaluate both the report and corrective actions*

8.5, 8.6

Self-Inspection

Quality Audit

- This is an examination of all or part of quality system
- The aim is to improve it
- Usually conducted by outside experts or team appointed by management
- Useful to supplement self-inspection programme with quality audits
- May be extended to suppliers and contractors

8.7

Self-Inspection

Suppliers' audits and approvals

- Quality Unit (e.g. QA or QC) responsible together with other relevant departments for approving suppliers
- Ensure that suppliers can reliably supply materials that meet established specifications
- Suppliers should be evaluated and approved before they are included in approved supplier's lists
- Should take into account the supplier's history and nature of materials to be supplied

8.8, 8.9

- Evaluation may also lead to an audit to assess compliance, e.g. with GMP

Self-Inspection

Inspecting the Self-Inspection Programme (1)

- GMP inspectors should preferably check self-inspection programme at end of an inspection

- Evaluate:
  - *SOP, team composition*
  - *Annual program / schedule*
  - *Checklists used by the company (are these up to date?)*
  - *Check that inspections are done as schedules*
  - *Reports are available*
  - *CAPAs are taken, implementation is verified, management involvement*

Self-Inspection

Auditing the Self-Inspection Programme (2)

- The SOP should describe teams, process, items covered, and the frequency of self-inspection
- Company policy may not permit GMP inspector to see actual deficiency reports and corrective actions
- GMP Inspectors should be looking for compliance with the self-inspection SOP - not necessarily at actual deficiencies recorded
- Seek objective evidence of reports and action

Self-Inspection

Auditing the Self-Inspection Programme (3)

- Ensure company is not just doing housekeeping or safety audits
- Check there are “Vertical” as well as normal “Horizontal” audits; both play valuable role in self-inspection

Self-Inspection

Group Session

- You are a GMP inspector in a large company with a diverse range of products
- You are given the SOP, deficiency report form, and the self-inspection schedule
- Prepare a report of your observations as to whether the company's approach to self-inspection meets GMP guidelines

Self-Inspection

Possible Issues

- Size of the factory; phased inspection
- Source of team leader
- Source of team members
- Reports and feedback