

SELF-INSPECTION

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Self-Inspection

Self inspection consist of,

- Periodic detailed examination of condition
- Working procedure by a team from production site,

with an aim of verifying that good pharmaceutical manufacturing practices are being applied and,

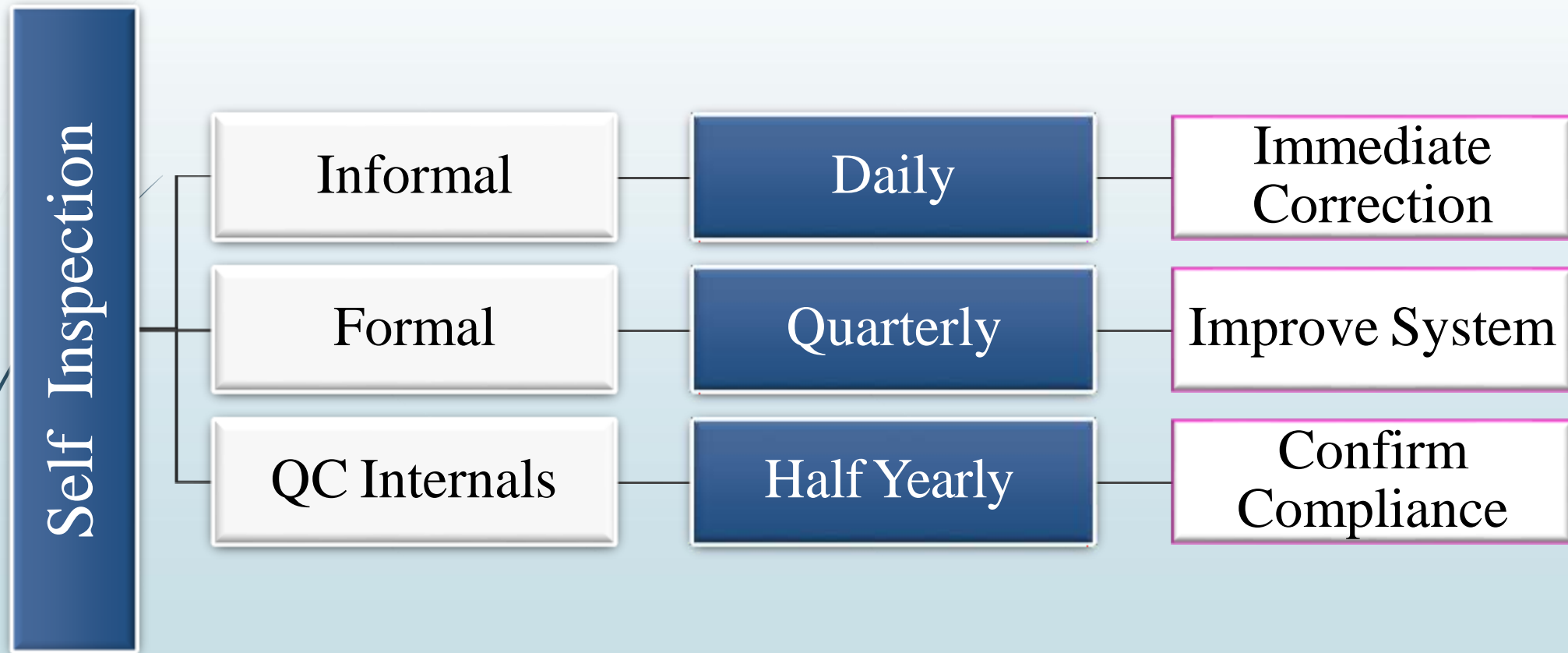
propose any necessary corrective measures to responsible management.



OBJECTIVES OF SELF INSPECTION

- Production workers are made to fill more responsible for the quality of their work
- Feedback on performances is immediate, thereby facilitating process adjustments.
- The cost of a separate inspection department can be reduced.
- Elimination of a specific station for inspecting all products reduces the total manufacturing cycle time.

TYPES OF SELF-INSPECTION



PURPOSE OF SELF-INSPECTION

- ❑ To evaluate whether a company's operations remain compliant with GMP.
- ❑ Assists in ensuring quality improvement.

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The programme should

- *Cover all aspects of production and quality control*
- *Being designed to detect shortcomings in the implementation of GMP*
- *Recommend corrective actions*
- *Set a timetable for corrective actions to be completed*

❑ Performed routinely also on special occasions such as :

- *Recalls*
- *Repeated rejections*
- *When a GMP inspection is announced by the national drug regulatory authority*



❑ Procedure should be documented for an effective follow-up programme.

❑ Self-inspection team should consist of personnel who:

- *Can evaluate the situation objectively*
- *Have no conflict of interest, have no revenge in mind*
- *Should have experience as observers of a self-inspection team before becoming a team member*
- *Can be lead self-inspector with experience as team member*



CRITERIA FOR SELF-INSPECTION

- ❑ Written instructions must 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*



- ↗ *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*

THE SELF INSPECTION TEAM

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- ❑ The team appointed by management, with:
 - *Authority and member from different areas of experience*
 - *Sufficient experience*
 - *May be from inside or outside the company*
 - *Experts in their own field*
 - *Familiar with GMP*

- ❑ Team members can be selected from:
 - *Quality assurance /Quality control*
 - *Production & Engineering*
 - *Planning & inventory control*



CARRYING OUT A SELF-INSPECTION

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- ❑ Frequency should be at least once a year.
 - *May depend on company requirements*
 - *Size of the company and activities*
- ❑ 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*

THANK YOU

