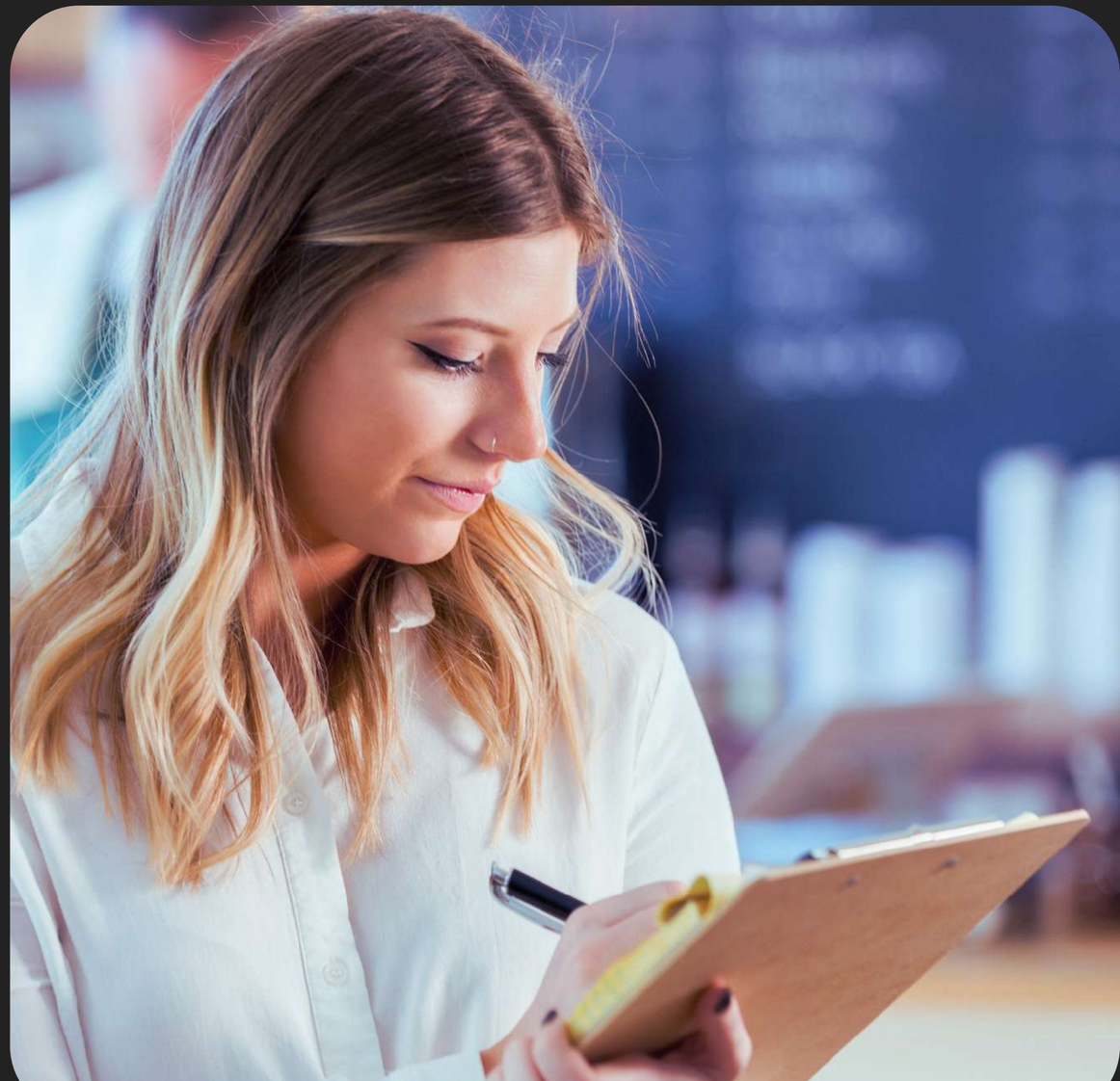
ViTres
Quality Consulting

01

SELF-INSPECTION TRAINING



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"Without continual growth and progress, such words as improvement, achievement and success have no meaning"
Benjamin Franklin

04

What is self-inspection?

Quality Control

A method in which a company monitors its own compliance with regulations and standards throughout the entire operation.

Implementation monitoring

GWP/SAHPRA guidelines are adhered to and CAPAs are effectively implemented.

Positive and objective

Self-inspections should be done objectively and the inspection must be a positive apprach to improve one's QMS and processes.

Purpose of Self-inspections

05

A systematic approach to impartially evaluate one's own operations in their entirety

Correct problems before they cause serious damage

Identifying defects in the QMS

Avoid costly regulatory non-compliances such as recalls or penalties

Purpose of Self-inspections

06

Promote quality awareness within the department/organisation

To ensure that the necessary corrective measures are taken

Check if internal procedures are being followed

Support the continuous improvement of the QMS

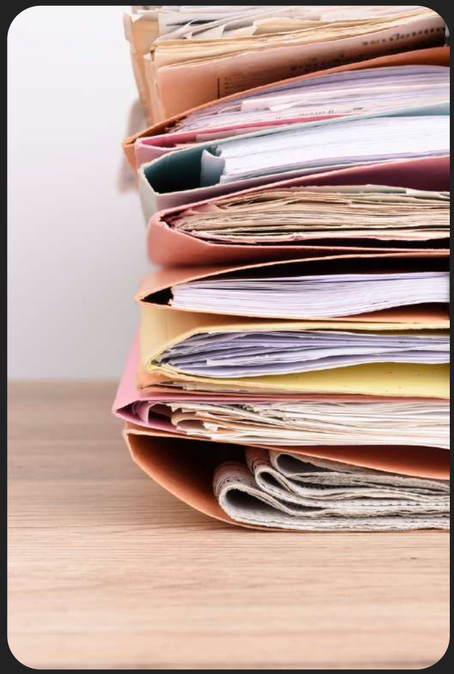
Principles of Self-inspections

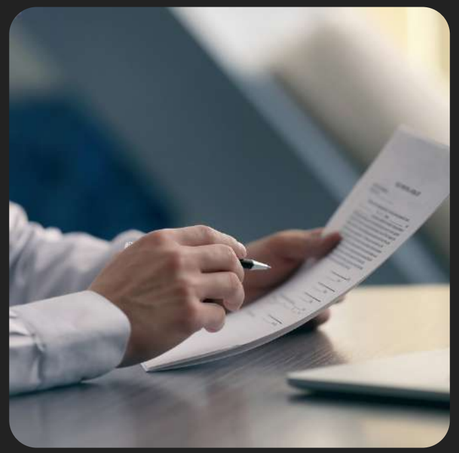
07

There should be a procedure in place for regularly monitoring all aspects within the company.

A method should exist for correcting any problems that are found.

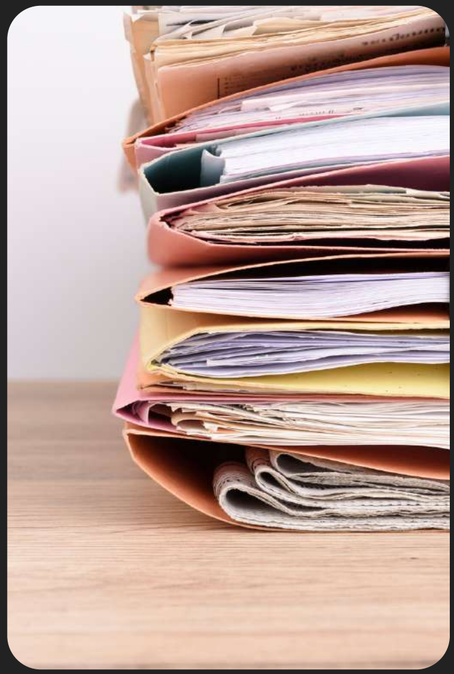
Should be conducted in an independent way by competent individuals from the company.

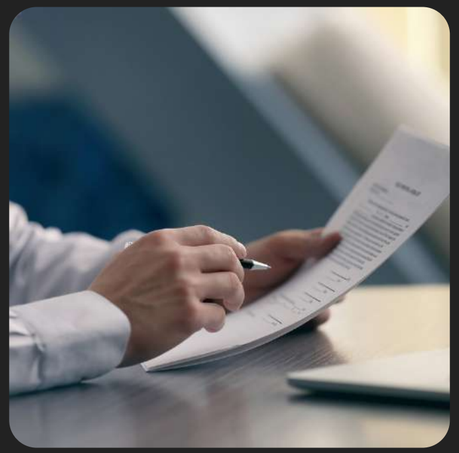




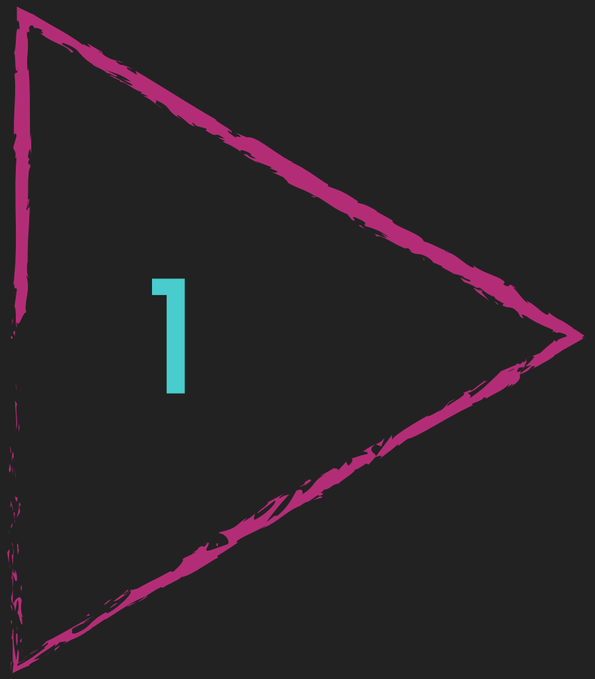
Principles of Self-inspections

- Must be recorded
- Reports must contain all observations made (good and bad)
- Must be done at reasonable intervals
- Should cover an area/function/operation at least once a year
- Findings must be reported to senior management



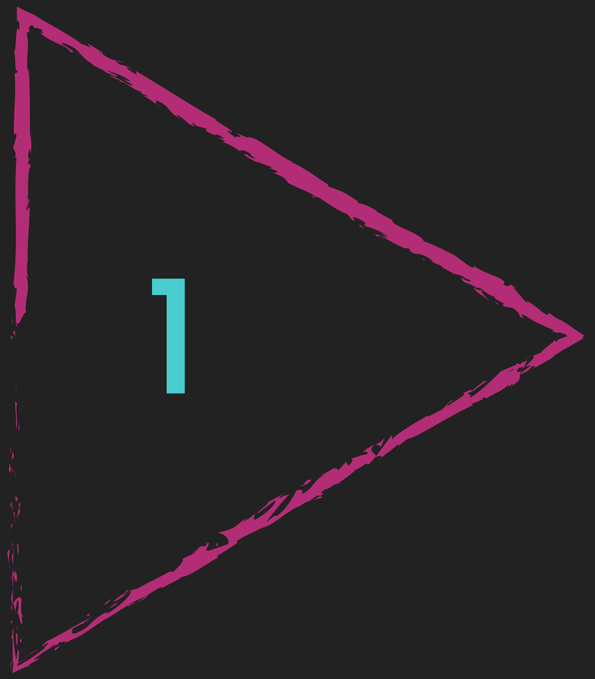


SELF-INSPECTION PROCESS



Self-inspection program

- Shall be prepared in January **for each calendar year**
- Must be prepared and managed by Head of QA
- All areas should be covered **at least once a year**, but the schedule can be djusted/updated
- Approved by operation managers and Responsible Pharmacist
- Should be communicated **in advance** to the departmental managers



Self-inspection program

The following processes should be included in the self-inspection program (not limited to):

- Personnel
- Premises and equipment
- Maintenance
- Receipt and storage of finished goods
- Quality control
- Documentation
- Sanitation and hygiene
- Validation and re-qualification program
- Dispatch and distribution
- Product complaints and recalls
- Change controls, deviations, CAPAs
- Training
- Data integrity
- Calibration
- Labels control

1 Self-inspection program

Area/Procedure to be Inspected	Frequency	Date Planned	Inspection Leader
Area 1	Monthly	Jan - Dec	Responsible Person
Area 2	Quarterly	Mar/Jun/Sep/Dec	Responsible Person
Area 3	Bi-Annually	Jan/Jun	Responsible Person
Area 4	Annually	May	Responsible Person

Approvals:

DC Manager: _____ Responsible Pharmacist: _____

Date: _____ Date: _____

1 Self-inspection program

Area/procedure to be inspected	Jan	Feb	Mar	Apr	May	Jun
Area 1	Inspection Leader					
Area 2		Inspection Leader				
Area 3			Inspection Leader			Inspection Leader
Area 4		Inspection Leader		Inspection Leader		Inspection Leader

Approvals:

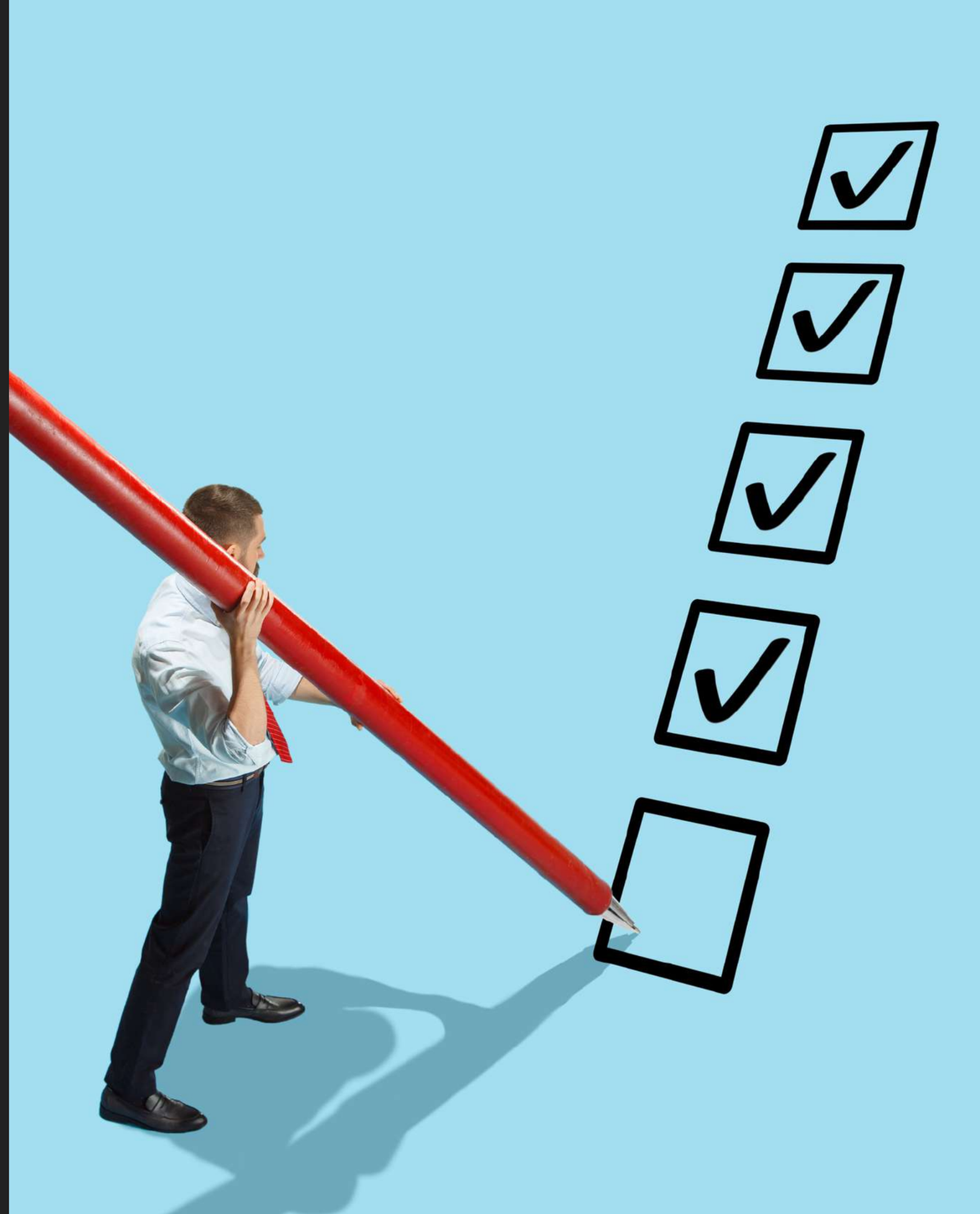
DC Manager: _____ Responsible Pharmacist: _____

Date: _____ Date: _____

SELF-INSPECTION PROCESS

The quality of assessors is critical to the quality of the assessment result

– Pearl Zhu



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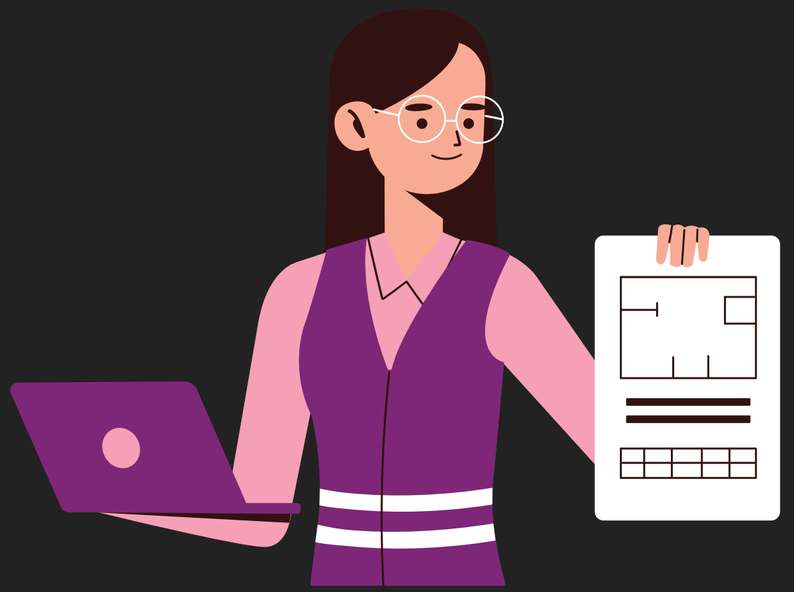
Self-inspection team and agenda

- Members are appointed by company management (Head of QA)
- Should be selected from different departments within the company, such as Quality, Receiving, Dispatch, Operations, Administrators, etc.
- Should consist of a technically competent employees with a high conscience in quality assurance
- Should have a good understanding of all relevant regulations and standards
- Should be independent and objective

2 Self-inspection team and agenda

Head QA



- Prepares self-inspection program
- Prepares self-inspection checklist
- Appoints Inspection Leader (IL) and team members
- Conducts a meeting with the IL to discuss the checklist and regulatory requirements of the area being inspected
- Provides guidance and assistance with self-inspections
- Ensures compliance towards corrective action completion
- Reports to senior management

2 Self-inspection team and agenda

Inspection Leader

- Conducting of self-inspections in the area assigned
- Completion of self-inspection checklist
- Shall conduct a meeting with the team working in the area to explain the procedure (where and when applicable)
- Creating self-inspection report and provide recommendations
- Ensures that CAPA feedback is received
- Reporting to Head of QA

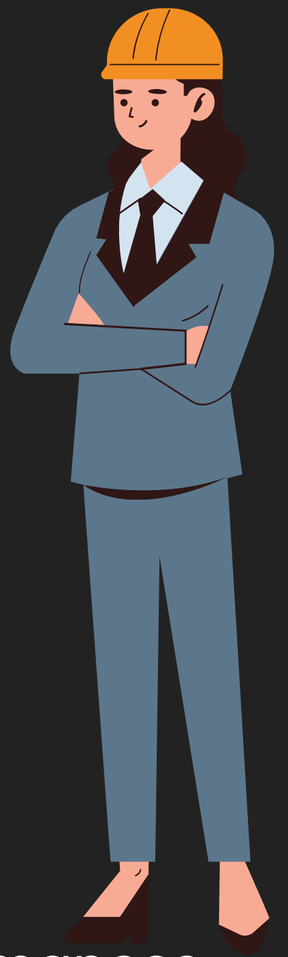
2 Self-inspection team and agenda

Inspection Team

- Assist with conducting the self-inspection
- Assigned when required
- Execute any activities required by the IL
- Report to IL

2 Self-inspection team and agenda

Inspectee



- Assists the inspection team when the self-inspection is being conducted
- Provides a CAPA plan after the report has been issued
- Must be honest
- This is not personal!
- The purpose is to aid the department in identifying non-conformances

2 Self-inspection team and agenda

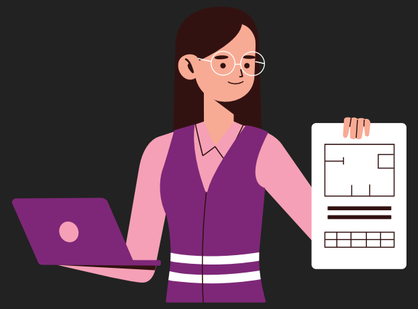
Agenda

- Should be issued to the departmental manager of the area being inspected
- Should contain details of the date of the planned inspection
- Does not have to be an official document - can be communicated via e-mail
- Should state the individuals who will be participating in the inspection

SELF-INSPECTION PROCESS

3

Self-inspection meeting



- The Head QA and IL should be meeting before the inspection can start
- The Head QA should ensure that the IL is familiar with the inspection area and the regulatory requirements applicable to the area
- The IL should understand the checklist applicable to the area
- The IL should understand the classification when deciding between Critical, Major, Minor findings
- The IL should have the opportunity to clear out any uncertainties

3

Self-inspection meeting

- The IL should be meeting with the inspectee before the inspection can start
- The IL should explain to the inspectee how the process will work and what is expected of them
- The inspectee should have the opportunity to clear out any uncertainties

SELF-INSPECTION PROCESS

4

Conducting the Self-inspection

- Identify deviations from the **current** authorized procedures
- Check the procedures, forms, and work instructions for their revision and updated dates
- Detect any **shortcomings** in the implementation of GWP
- Detect any data integrity issues
- Check for **incomplete** forms and checklists
- Check logbooks and schedules

SELF-INSPECTION PROCESS

5

Preparing the Self-inspection report

- Self-inspection is looking for **improvement** and not only fault finding
- The Inspection team should give **recommendations** for solving encountered problems
- After completion of self-inspection, the Inspection team shall prepare the inspection report within X working days
- The inspection **report number** shall be provided by QA (unique numbering format)
- Should be done by the **Inspection leader**
- Head of QA must **review for Critical Non-conformances** before issueing the report

5 Self-inspection report

Inspection report of: _____

Inspection report no.: _____

Date of inspection: _____

Name of auditors: _____

Name of inspectee: _____

Reference no.	Area	Observation	Classification

Approvals:

Head of QA: _____

Date: _____

Classification of findings

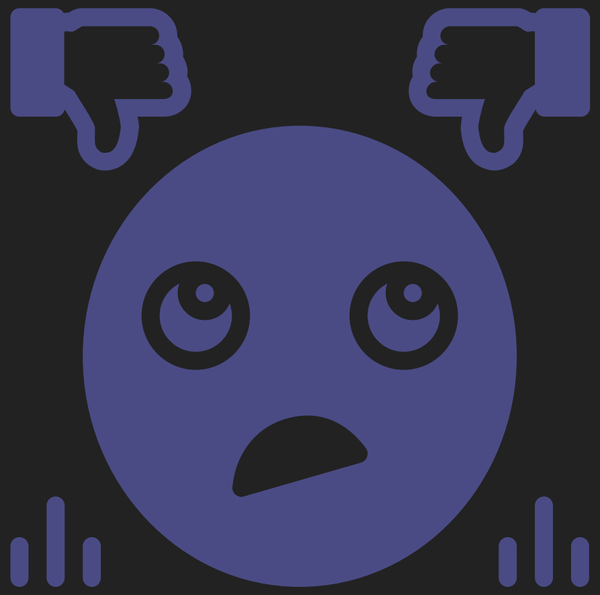
Satisfactory

When processes are effective in mitigating risks.

Should be mentioned in the report as positive points.

Classification of findings

Critical finding



May result in a significant risk of storing/distributing a finished product that is seriously harmful to the users.

Affects the purity, strength and/or safety of a finished product.

Classification of findings

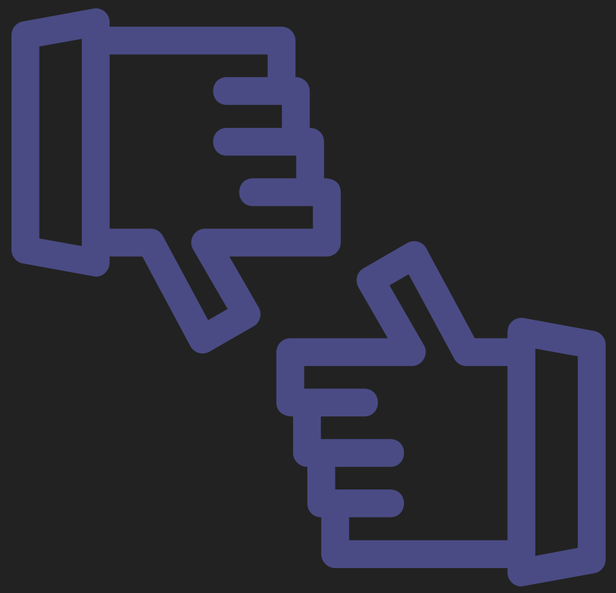
Major finding

Deviation from the validated or established procedure, process, system, or practice.

Can affect the purity, strength and/or safety of a finished product.

Classification of findings

Minor finding



Any deviation related to documentation from controlled SOP or GWP norms.

Multiple minor findings can be grouped as a major finding.

No effect on the purity, strength and/or safety of a finished product.

Classification of findings

Recommendation

When an observation is made that can possibly result in a future finding.

Should be mentioned in the report to make the inspectee aware of the observation.

SELF-INSPECTION PROCESS

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Self-inspection log

- The Inspection Leader will send the self-inspection report to the **Head of QA** for compliance.
- Self-inspection log should be updated after each self-inspection by the **Head of QA.**
- **Summary** of the self-inspections completed and the progress of each self-inspection documented.

5 Self-inspection log

Date	Department	Inspection no.	Target completion date	QA sign/ date	Final review	Sign/Date	Remarks

SELF-INSPECTION PROCESS

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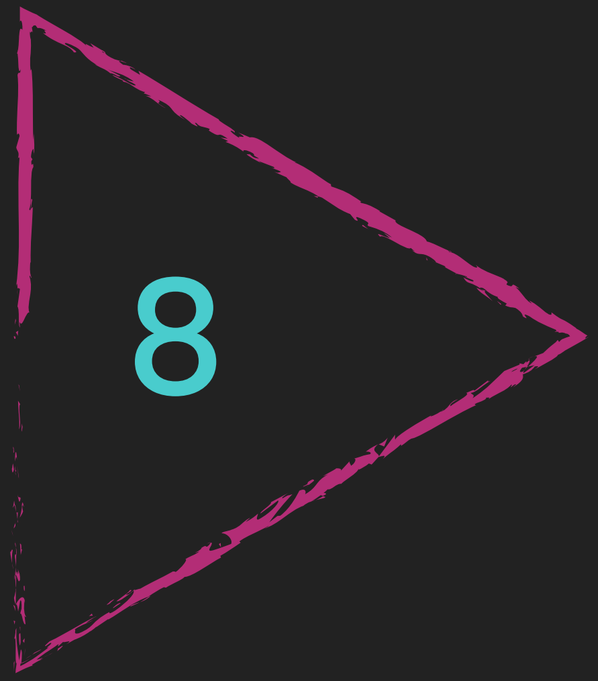
Issue of Self-inspection reports

- The report should be distributed to the **Inspectee.**
- Should be done by the **Inspection leader.**
- The IL should brief the **Head of the Department** about the findings.
- An opportunity must be made available if the **Inspectee** needs clarity over any point or if any finding must be disputed.

SELF-INSPECTION PROCESS



Compliance reports

- **Inspectee** shall produce a compliance report and its compliance status within X days.
- Should include an **action plan** with:
  * Target date of completion
  * Responsible person
- If a deviation or change control is required, the internal SOPs should be followed.
- Action plans consist of **Corrective** actions as well as **Preventative** actions (where applicable).

8 Compliance report review

Inspection compliance report of: _____

Inspection report number: _____

Ref no.	Observation	Category	CAPA	Status	Target date	Review comments

8 Compliance report review

- Self-inspection team shall review the **compliance** report and proposed CAPAs.
- Must give **feedback** if not satisfied with the measures suggested.
- Where the implementation of the proposed CAPA requires major capital investment, the Head QA shall get **approval from management.**
- If CAPA is planned in a phased manner, the inspection report shall be kept open until the action is completed.

SELF-INSPECTION PROCESS

9

Follow up and close out of CAPAs

- The Self-inspection team shall **verify** the implemented CAPAs.
- Regular **follow-up meetings** should be conducted with the Head of the department until all the open actions are completed.
- If deemed justifiable, the Head of QA has the authority to **extend** the target dates.

SELF-INSPECTION PROCESS

10

Review of reports and self-inspection close out

- Once all the inspection observations are closed and implemented successfully, the Head of QA shall **close** the self-inspection.
- Inspection Leader may decide to perform a **follow up inspection** to check for compliance with some observations.
- The self-inspection report and compliance report are **confidential** and should only be distributed internally.

Inclusion of current guidelines, standards, and regulations as criteria

The corporate structure and operational activities of a company have the potential to undergo changes, despite the fact that policies, standards, and regulations are updated over time.

It is vital to include current guidelines, rules, and laws as criteria in a self-inspection to show that your QMS is efficient and compliant.

Documentation of corrective and/or preventive actions

Results of a self-inspection should always be documented in a written report .

Review the self-inspection procedure.

Lack of action...

- missed opportunities
- risk of non-compliance
- "erosion" of confidence
- persistant issues and escalation

Get to know the departments better

Being "on-site" with the inspectee.

Ask detailed questions.

Increase understanding among inspectees

Try to set out some time to discuss the rationale behind specific procedures.

A better relationship with the quality department will undoubtedly arise from more understanding, which is advantageous to both parties.

Collect feedback from auditees and spot opportunities

You can do this by recording any feedback

Check compliance before external audit

Self-inspections can also be utilized as a readiness check.

Display the required corrective and preventive actions.

List of Services:

- Training
- Cold room & freezer mapping
- ISO 13485:2016 implementation
- QMS Implementation
- Gap analysis
- Risk Assessment
- Validations
- SOP creation
- Route Profiling
- Inspection preparation
- Licence applications
- General pharma consulting
- Mentoring

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THE END