

**ASEAN Guidelines on GMP for Traditional Medicines & Health Supplements
(TM/HS)**

**CHAPTER 10 –
SELF-INSPECTION**



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OUTLINE

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- Importance and Benefits of Self Inspection
- What is needed
- Scope
- How can self-inspection be conducted
- Inspection Techniques
- Example of Self-Inspection Plan
- Who should be involved
- Self-inspection report
- Points to consider when performing self-inspection
- Stages of Self-Inspection
- Example of Self-Inspection Checklist
- Advantages & Disadvantages of Checklist
- References



PRINCIPLE

Self-inspections shall be conducted to monitor the implementation and compliance with Good Manufacturing Practice (GMP) principles and to propose necessary corrective measures.



IMPORTANCE AND BENEFITS

- To monitor and identify the shortcomings in implementation and evaluate compliance with the Good Manufacturing Practice principles and quality management system
- Company is able to address any issues internally and sooner therefore avoid potentially bigger problems



WHAT IS NEEDED

A pre-arranged programme at regular interval is needed to examine the compliance with the Quality Assurance and shall cover:

- Personnel matters
- premises, equipment
- documentation, production
- quality control
- distribution of the products
- arrangements for dealing with complaints and product recalls
- self-inspection



SCOPE

- All chapters/requirements in the GMP Guide [including Appendix 2 (Verification)] and;
- All aspects that might influence the quality of products shall be included in the scope of the self-inspections.
- Self-inspections shall assess and look at adequacy and compliance of systems, processes, premises and equipment, documents, etc.
- Areas for improvements could also be recommended.



SCOPE

- SOP needs to be established as per clause 5.43.10 which states the following:
 - frequency (and possible need to establish an audit plan)
 - the scope and standard to be used
 - how to record/report the self-inspection carried out
 - training and experience for personnel involved in self-inspection,
 - the need to review previous reports classification of Non-Conformities (NCs) with corresponding desired timeframe to close out the NCs

Annex 1 - Sample SOP on Self Inspection

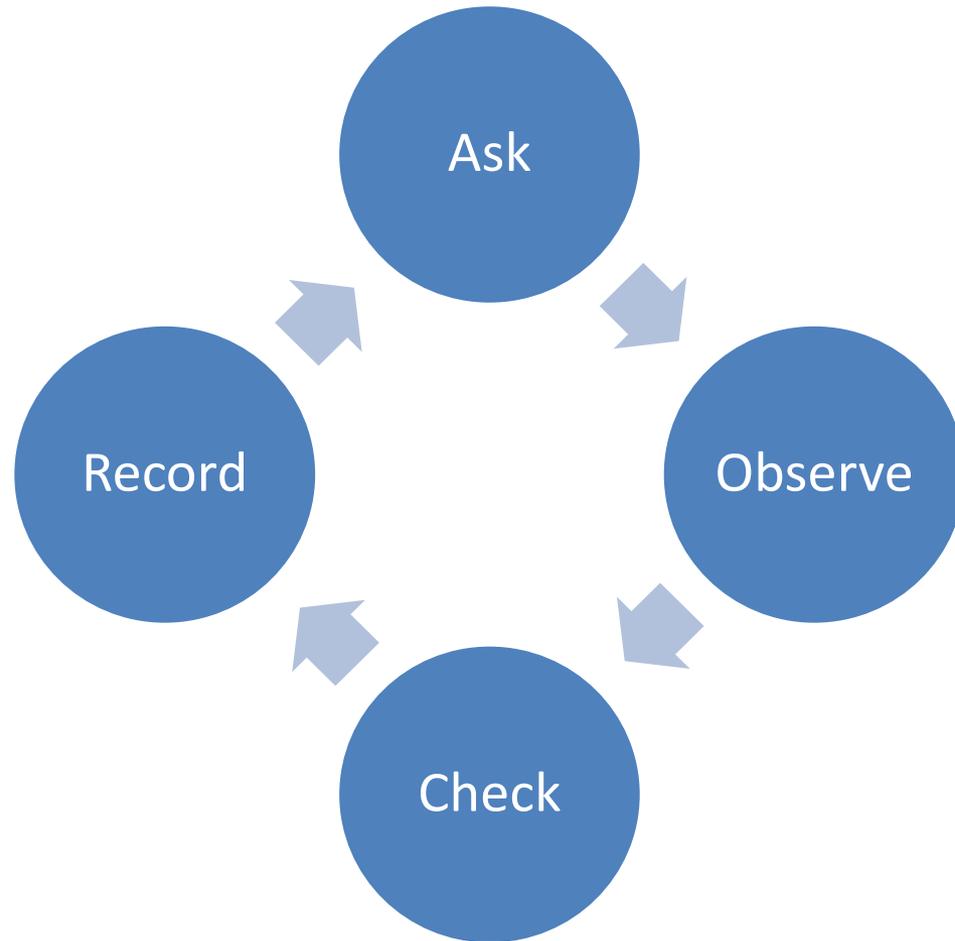


HOW CAN SELF-INSPECTION BE CONDUCTED

- Self-Inspection program / plan may cover:
 - all areas/chapters in one single self-inspection (annually) or;
 - have several self-inspections within a year (i.e. split the areas/chapters and perform self-inspections on several occasions)
 - Provide report for each self-inspection.



INSPECTION TECHNIQUES





EXAMPLE OF SELF-INSPECTION PLAN

Periode	Chapter	Should Cover
January	Quality Management (Chapter 1)	Quality Assurance, Quality Control and Product Quality review
	Personnel (Chapter 2)	Organisation, Qualification and Responsibilities, and Training
	Premises and Equipment (Chapter 3)	Premises (including Production areas, Storage areas, Quality Control Areas and Ancillary areas) and Equipment



EXAMPLE OF SELF-INSPECTION PLAN

Periode	Chapter	Should Cover
April	Sanitation and Hygiene (Chapter 4), Documentation (Chapter 5) Production (Chapter 6)	Personnel, Premises, Equipment and Utensils Quality Control Documents, Specifications, Production Documents, Packaging Instructions, Batch Processing and Packaging Records, SOPs and records Verification, Prevention of Cross-contamination, Starting Materials, Processing Operations, Packaging Materials, Packaging Operations, Finished Products, Rejected, Recovered and Returned Materials



EXAMPLE OF SELF-INSPECTION PLAN

Periode	Chapter	Should Cover
July	Quality Control (Chapter 7)	Sampling, Testing and On Going Stability
	Contract Manufacture and Analysis (Chapter 8)	Contract Manufacture, Contract Analysis, Contract Giver and Acceptor, and the Contracts
	Complaints and Product Recall (Chapter 9)	Product Complaints, Product Recalls and Complaints on Adverse Product Reactions
October	Self-inspection (Chapter 10)	the robustness of self-inspection programme
	Verification (Appendix 2)	Documentation, Verification of Machinery and Equipment, Verification of Process, Change Control system



WHO SHOULD BE INVOLVED

- *Clause 10.2 - Self-inspection shall be conducted in an independent and detailed way by designated competent person(s) from the company. The independent audits by external experts may also be useful.*



WHO SHOULD BE INVOLVED

- Should consider having a self-inspection team with multiple representatives from different areas of work/responsibility.
- Self-inspection should be conducted in an independent manner:
 - no conflict of interest
 - one shall not inspect his/her own work or area of work
- Should conduct thorough inspection that is objective and evidence-based.
- Can consider using the approach used by regulatory inspectors.



WHO SHOULD BE INVOLVED

- Qualification of self-inspection team:
 - Trained
 - Competent
 - Independent

- With the training and knowledge, self-inspection team members can then explore matters with the view to improve the system or address any gaps.

- Independent audits by external experts who have more experience in inspecting more companies can help to identify blind spots and suggest good practices for further improvement of the system.



SELF-INSPECTION REPORT

- *Clause 10.3 - All self-inspections shall be recorded. Reports shall contain all the observations made during the inspections and, where applicable, proposals for corrective actions and preventive actions, and corresponding time frames. Statements on the actions subsequently taken shall also be recorded.*



SELF-INSPECTION REPORT

- Provide Evidence
- Can be various formats depending on the company's preference
- Allows traceability to all the follow-up actions to be taken
- If company decided to use a checklist, must make sure that the checklist is appropriately designed and in a way to allow the recording of any Non Conformance (NCs)

Annex 2 – Sample Record of Self Inspection



SELF-INSPECTION REPORT

- Root cause identified for each Non Conformance (NCs) and there should be corresponding Corrective / Preventive Actions (CAPAs)
- NCs that have higher impact to quality of product shall be addressed sooner
- Should be followed through and closed-out within reasonable timeframe
- Record all objective evidence and what has been observed



POINTS TO CONSIDER WHEN PERFORMING SELF-INSPECTION

- Shall ask appropriate and right questions during self-inspections and shall focus on identifying flaws/gaps of processes and systems rather than finding faults on an individual or nitpicking.
- Use “who”, “what”, “where”, “when”, “why” and “how” rather than “closed questions” which will end up getting a “Yes” or “No” as an answer.
- Superficial questions often produce superficial findings.



POINTS TO CONSIDER WHEN PERFORMING SELF-INSPECTION

- Shall create win-win situation with the view to help company/organisation to improve the processes and systems
- Don't just focus on hardware and documents, should also interview different personnel to verify effectiveness of established systems or processes
- Good and legible notes are essential to good inspection as you will never remember everything without notes
- Use “trace-back” method
- Include positive observations
- Keep the report simple and clear



STAGES OF SELF-INSPECTION





STAGES OF SELF-INSPECTION

Planning

- Risk based Inspection Programme
- Management appoint self-inspection team
- Initiate self-inspection:
 - prepare inspection schedule
 - Notify / brief self-inspection team and auditee of the inspection plan
 - Allocate documents to team members for review and creation of checklists
 - Liaise with Management on inspection timing (including changes to timing)
 - Study documents and develop checklists (where applicable)



STAGES OF SELF-INSPECTION

Performing

- Conduct Opening Meeting
- Conduct on-site self-inspection and record findings following suitable audit techniques
- Document Review
- Conduct Closing Meeting



STAGES OF SELF-INSPECTION

Reporting

- Prepare self-inspection report **and classify the NCs by the team**
- Draft of report reviewed by auditee
- Send inspection report to auditee
- Request corrective and preventive actions (CAPA) to address the NCs
- Assigned personnel to identify the root cause to establish appropriate CAPA
- Set time frame



STAGES OF SELF-INSPECTION

Follow-up

- Verification of CAPA, especially for critical and major NC
- **Present findings at Management Review meeting**
- Ensure follow-up on NCs until they are satisfactorily close-out **by Lead Inspector.**



EXAMPLE OF AN SELF-INSPECTION CHECKLIST

Date:		
Inspector:		
Location:		
Auditee:		
Description	Parameter	Finding
Personnel:	Organization structure	
	Personnel hygiene	
	Training Record	
Storage area:	Design and layout of defines area	
	Flow of personnel and goods	
	Structure of the storage area (does it comply with GMP)	
	HVAC System	
	Storage condition monitoring	
Sanitation:	Pest Control	
	Bait map	
	Cleanliness of store	
	Cleanliness of equipment	
Documentation	Records of maintenance and calibration of equipment	
	Pest Control p+B60rocedure and records	
	Premises Cleaning procedure and records	



ADVANTAGES OF CHECKLIST

Advantages of a Checklist:

1. Serve as a good inspection planning tool
2. Help to focus on the essential parameters
3. Serve as aids to memory
4. Provide a useful means for quick recording of findings
5. Help to maintain inspection direction



DISADVANTAGES OF CHECKLIST

Disadvantages of a Checklist:

1. Inhibit flexibility
 2. Become a Questionnaire
 3. Encourage copy-cats inspection
 4. May discourage probing and investigation
- The quality of an inspection depends to a great extent of the quality of the checklist.
 - There is a need to incorporate “impromptu questions in response to auditee’s responses. This requires much skill and experience.



REFERENCES

1. ASEAN Guidelines on Good Manufacturing Practices for Traditional Medicines.
2. ASEAN Guidelines on Good Manufacturing Practices for Health Supplements.

THANK YOU!



ONE VISION, ONE IDENTITY, ONE COMMUNITY