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Committees and Inspections

# Joint Audit Programme for EEA GMP inspectorates

## JAP Procedure for observing inspections

### 1. Scope

This procedure describes how to initiate, plan, conduct, report upon and follow-up an observed inspection during a Joint Audit Programme (JAP) audit. It identifies the key steps involved during an inspection in order to determine if the inspection process of the observed GMP inspectorate complies with European Union (EU) requirements.

### 2. Introduction

An observed inspection to determine compliance of inspection methods is initiated primarily to evaluate the system used by the auditee on routine inspections. The observing audit team members must respect the scope of such an inspection and the fact that it also is a regular event for the company and manufacturer/importer authorisation/licence holder and, in most cases, is one of a series of routine inspections. Any major disagreement therefore must be discussed or solved and recorded amongst the audit team and not in front of the inspected company.

### 3. Definitions

**Audit:** systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

**Auditee:** GMP inspectorate being audited.

**Auditor:** person carrying out the audit and responsible for preparing the audit report.

**Audit team:** one or more auditors observing an inspection performed by the auditee within the auditee's territory.

**Observed inspection:** assessment of the way inspections are carried out to determine compliance with the Compilation of Union Procedures on Inspections and Exchange of Information.

**Observed inspection report:** report issued by the observing audit team on the observed inspection.

**Inspection report:** inspection report issued by the auditee.

*Planning:* preparation of the inspection, including review of previous inspection reports and communication with the company, complaint and recall file, updated SMF/SRF.

*Pre-inspection meeting:* meeting that takes places immediately before the inspection and the scope is to present the inspection environment for the observing audit team.

*Closing meeting:* meeting with the company, according to the auditee's procedure.

*Companies:* companies holding a manufacturer/importer authorisation/licence issued by the auditee.

*Team leader:* trained auditor confirmed during the planning phase of the audit, leading the team during the observed inspection.

## **4. Audit team**

A JAP audit team observing an inspection should not include more than 2 persons (acting as auditors) who all must have a clear role. One auditor of the team is appointed as team leader.

The audit team can include auditors-in-training and/or observers. The observers can accompany the audit team but do not act as part of it. There should be not more auditors-in-training/observers than JAP auditors.

In any case, the expected maximum number of audit team members should be not more than 3 persons.

## **5. Choice of sites**

The observing audit team should be offered inspection sites in principle from any of the companies within the auditee's territory. In practice the selection should be made from companies which are scheduled to be inspected during the period the audit is planned. The auditee provides the auditors with the inspectorate's inspection schedule, that lists name and address of the manufacturing site, general typology of the pharmaceutical dosage forms manufactured (e.g. sterile, non-sterile), and, if already established, allocated inspector(s) and inspection dates. The inspection to be observed should be selected from this list and agreed with the auditee.

## **6. Inspection planning**

The auditee is responsible for planning the observed inspection in close co-operation with the audit team and the company. Initiating, planning, conducting, reporting and leadership of the inspection will always be done by the auditee.

It is not necessary for the auditee to plan a full inspection of the selected site. The observed inspection can cover only limited aspects of a routine inspection, provided that it reflects the auditee's inspection procedure in a coherent way. All final decisions should be taken by the auditee.

The auditee should make proper agreements with the companies, including informing the company about the scope and purpose of the inspection. Names of audit team members should be communicated to the company, preferably in advance of the inspection.

The auditee should make, well in advance, proper arrangements with the company and observing auditors regarding entering requirements, e.g. protective clothing, vaccination or microbiological tests.

## 7. Pre-inspection meeting

A pre-inspection meeting should be arranged for the audit team. It takes place immediately before the inspection and the scope is to present the inspection environment for the observing audit team. Such a meeting is expected to last no more than half a day to one day.

The agenda for such a meeting includes:

- introduction to the auditee's inspectorate and normal inspection practice for the scheduled inspection;
- introduction to the company to be inspected (past inspection history, products authorised, recalls, etc.);
- introduction of the proposed plan for the inspection;
- methods of communication between the auditor(s) and auditee during the inspection. This could include, for example, meetings in private in the designated inspectors' room, use of notes.

## 8. Observed inspection

The observed inspection should be performed in English or an official language as formally agreed between the auditee and the audit team and with consent from the company. In case that it is not possible to perform the inspection in English, arrangements for interpretation should be planned for as necessary including any document translations. In this case, in order not to burden the company, an individual with technical expertise from the audited agency should provide translation as required.

The auditee should inspect in accordance with normal practice and must evaluate deficiencies in accordance with EU GMP.

The auditors should evaluate if the inspector's skills match with required skills, the inspection methodology as described in the auditee's inspection procedure is followed, critical activities are covered, and observations are factual and based on GMP requirements.

During the inspection, the auditors should not interfere with the inspector's activity and should not ask questions to the company. Only with the agreement of the auditee's lead inspector, the auditors may ask questions related to observations made or not made by the auditee in accordance with the agreed method of communication. The purpose of such questions should be to evaluate the inspection process rather than to further evaluate the company. The auditee's lead inspector may at his/her own discretion refer other questions to other occasions for example, to the wrap-up meeting with the company.

A short daily follow-up meeting can be scheduled between the auditee and the audit team, where inspection matters can be discussed in confidence within the teams.

Use of cameras, video, tape recording etc. should be with the auditee's normal practice.

## 9. Confidentiality

All auditors must obey legal requirements such as not to disclose any proprietary information obtained during an inspection.

The auditee and observing audit team must be aware of the company's rights regarding proprietary rights and trade secrets.

A confidentiality agreement shall be signed by all auditors and observers prior to the inspection if requested by the company, using the JAP Confidentiality agreement for audits template.

## 10. Reports

Two sets of reports should be issued: an inspection report from the inspection (by the auditee) and an observed inspection report (by the observing audit team).

The inspection report should be written and issued by the auditee in accordance with normal practice. The observing audit team should not take part in writing of this report. The inspection report may include a statement about the scope of the inspection, referring to the JAP audit. Observing audit team members must be mentioned. A copy of the inspection report should be sent, if required, to the audit team.

The inspection report should be written in the auditee's language. If both auditee and company accept it, the report may be issued in English.

The observed inspection report is issued by the observing audit team in English, using the JAP Observed inspection checklist.

## 11. Roles and responsibilities

<b>Auditee responsibility</b>	<b>Shared responsibility</b>	<b>Observing audit team responsibility</b>
Planning		
Information to the company		Confirmation of participating auditor(s)
Inspection	Pre-inspection meeting	Observing inspection process
	Daily follow-up meeting	Evaluate observed inspection
Write inspection report		Write observed inspection report