



8 December 2022
EMA/INS/931781/2022 - Rev. 3
Inspections Office

Joint Audit Programme for EEA GMP inspectorates JAP

Audit notification template

EMA/

Amsterdam, 8 December 2022

Joint Audit Programme for EEA GMP Inspectorates

Preliminary/Updated JAP Audit Notification

Dear Colleagues,

I am writing to you on behalf of the Compliance Group to initiate an audit under the Joint Audit Programme of EEA GMP inspectorates.

In line with the JAP audit schedule adopted by the GMDP IWG and the decision of the Compliance Group, the following audit has been agreed:

COMPETENT AUTHORITY TO BE AUDITED:

Insert name

AUDIT SCOPE AND OBJECTIVES: (select accordingly)

- To check (compliance with) implementation of EU GMP legislation and guidelines
- To check compliance with compilation of Union procedures on inspections and exchange of information
- To check compliance with JAP requirements
- To conduct observed inspections (only if on-site audit is performed)
- To check compliance with international agreements, e.g. ACAA, MRA
- Initial audit in a distant assessment setting subject to change to on-site audit depending on the COVID-19 pandemic situation
- Re-audit (full scope)(reduced scope)

AUDIT REQUIREMENTS:

The requirements of the audits are those specified in the Joint Audit Programme documents.

LEAD AUDITOR:

Insert name – NCA (e-mail)

SUPPORTING AUDITORS:

Insert name – NCA (e-mail)

OBSERVERS:

Insert name – NCA (e-mail)

PROPOSED DATE OF THE ON-SITE AUDIT:

Insert date

AUDITEE CONTACT POINT:

Insert name (e-mail)

We kindly ask you to confirm that you accept the audit and the proposed dates for the on-site audit.

Please send this information directly to the lead auditor (insert e-mail) and copy to jap@ema.europa.eu.

On behalf of the Compliance Group,

Best regards,

Name

CG Secretariat

Inspections Office (H-QS-ISP)

Quality and Safety of Medicines Department

Inspections Office

Quality and Safety of Medicines Department

European Medicines Agency

Domenico Scarlattilaan 6 | 1083 HS Amsterdam | The Netherlands

Tel. +31 (0)88 781 xxxx

xx.xx@ema.europa.eu | www.ema.europa.eu

ADDITIONAL INFORMATION

Financing model

Following the HMA decision, at its 69th meeting in Copenhagen, to change the JAP funding model, the same funding model as for BEMA applies for the JAP audits:

“The audited agency pays for flights, accommodation and meal costs of the auditors and any subject matter expert. The agency pays for any night after the visit if the time that the visit ends does not allow the auditors to take a flight home at a reasonable time. Costs for trainees, observers and MRA partners are covered by their own agency”.

Financing within the Joint Action No. 101082515 (EU4H 11)

- Co-financing of the audited NCA
The audited NCA, if participant in the Joint Action, will be co-financed for the travel, accommodation and subsistence costs of the auditors and any subject matter expert. According to the provisions of the Grant Agreement, the unit costs fixed by Decision C(2021)3510 and set out in Annex 2a of the Grant Agreement must be applied (see attachments). 80 % of the unit costs will be co-financed. Only in cases the travel costs are not covered by the mentioned decision, actual costs can be declared (80 % co-financing). Please note that the unit costs given are for return journeys.
Please liaise with your NCA's participant contacts of the Joint Action to ensure correct declaration of costs within the EU4H11-Joint Action or contact eu4h11@ages.at for any further information.

- Co-financing of personnel costs of auditors / subject matter experts

If the auditors / subject matter experts (SME) are working for an NCA that is participant in the Joint Action, personnel costs will be partially co-financed. Auditors / SMEs must keep detailed time records supporting the working time for Work Package 4 / JAP activities. According to the provisions of the Grant Agreement, time records have to be signed monthly by the auditor / SME and their responsible supervisor (as an alternative, an electronic time-record system where such monthly approval is foreseen can be used). Please find attached a template as an example for the time recordings.

Please liaise with your NCA's participant contacts of the Joint Action to ensure correct declaration of costs within the EU4H11-Joint Action or contact eu4h11@ages.at for any further information

Translations

If translation for the auditors is needed, preferably an individual with technical expertise from the audited agency should provide the translation.

Guidance for observers of JAP audits:

The lead auditor will communicate these rules to the observers:

- All Observers (i.e. not limited to those observing GMP inspections) will be expected to sign a confidentiality agreement in accordance with the relevant JAP procedure.

- Observers should not interfere with the conduct of the audit. They should not ask questions of the auditee during the audit itself. Questions may be asked of the JAP auditor(s) but the observer and auditor(s) should agree how and when this can occur before the audit starts.
- Observers may not ask for copies of documents being assessed by the auditors before or during the audit. The final audit reports and observed inspection reports will only be shared with the agreement of the auditee. The preliminary audit report and observed inspection report(s) of the audit team and the GMP inspection report(s) of the auditee will not be shared under the terms of JAP.
- The number of observers should be limited in order to avoid disrupting the conduct of the audit. As a general guide there should be no more observers than JAP auditors and the maximum number of observers should be linked to the expected number of audit teams. The JAP Procedure for observing inspections limits the number of auditors participating in the observed inspection to no more than 2 therefore it is reasonable to limit the number of observers to 1 per observed inspection.
- JAP procedures lay down rules for the language in which the entire audit or different phases of the audits will be conducted and is designed for the efficient conduct of the audit. If translators are required by the observers, this should be clarified well in advance of the observed audit and arrangements agreed with the lead auditor and auditee, and if applicable the inspected company.
- Observers are responsible for their own travel and accommodation costs, as well as any translation costs.

More information on the Joint Audit Programme can be found under the following link:

<https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/working-group/joint-audit-programme>