Joint Audit Programme report

Audit of <name of audited GMP inspectorate> (<abbreviation>) <Country>

<Preliminary><Final> report – <date>
*Template revision 3, 11 January 2022*

Please complete the different sections of the report. Guidance and proposed wording are provided. Please adapt the wording or add more information if and as required.

Delete the green drafting notes from the report.

1. Reference

This JAP audit was notified to the auditee and the auditors by an EMA letter dated <date audit notification letter> (see Annex 1).

1. Introduction

Please provide a short description of the following topics:

* Country information.
* Regulatory authority description (overall description of the GMP/ licensing/handling of quality defects, organisational charts, etc.).
* Laboratory information (overall description of the official laboratory, the analytical capability and product-on-the-market testing system).
* Pharmaceutical industry information.
* List of the applicable legislations.

<text>

Organisational chart:

See Annex 2.

Offices:

The Agency is located at <address>

List of applicable national legislation:

* <title legislation>

Documents submitted by the Agency:

* <title document>

<It should be noted that prior to and during the audit, <abbreviation auditee> was entirely transparent and provided the auditors with full and open responses to all requests.>

1. Audit date(s)

<date(s) of audit>

The audit plan can be found in Annex 3.

1. Composition of the audit team

Lead auditor: <title, name, surname, name NCA>

Co-auditor(s): <title, name, surname, name NCA>

<Auditor(s)-in-training: <title, name, surname, name NCA>>

<Observer(s): <title, name, surname, name NCA>>

1. Personnel met during the audit

Please list only key personnel met in the NCA and not all participants (in a list or tabular format).

* <title, name, surname, function/role>
1. Audit scope and objectives

Please describe the scope and objectives of the audit, in line with the audit notification.

The purpose of this <full><reduced> scope <initial audit><re-audit><follow-up audit> was to assess the compliance of <abbreviation auditee> with EU GMP legislation and guidelines (directives 2001/83/EC, 2001/82/EC, 2003/94/EC, 91/412/EEC, 2001/20/EC and 2005/28/EC or where relevant the superseding legislation), the compilation of Union procedures on inspections and exchange of information and the JAP requirements <, as well as with the <ACAA><MRA>international agreements>. The audit <included><did not include> observed inspections.

1. Previous audits

Please give information about the last 2 or 3 audits carried out, including previous OMCL audits .

The last <JAP><MRA><PIC/S> audit was conducted in <year> with an onsite-visit <and observed inspections> from <date audit> by <name and NCA auditors>.

The last audit report was reviewed ahead of this JAP audit.

<additional information of the outcome of the last audit, if necessary>

1. On-site / Desktop audit/ Distant assessment evaluation at the GMP inspectorate and the laboratory(ies)

Please report on the audit at the GMP inspectorate and any relating entities, as well as at the laboratory(ies). The aspects to be covered should be the following:

* Quality system, including implementation of Compilation of Union Procedures.
* Implementation of legislation related to the GMP supervision system.
* Authorisation/licensing system for manufacturers.
* GMP guidance.
* GMP compliance certification.
* Administration of inspections (e.g. frequencies, resources, procedures).
* Qualifications and training of inspectors.
* Inspections (planning, performance, reporting and follow-up system).
* Complaints - Rapid alerts system.
* Obligations as EU Member State.
* Internal audits.
* Observed inspections (if carried out).

The detail in the narrative of this section of the report may be reduced if detailed information is included in the completed audit checklist which is a mandatory annex to the report. In this case, the narrative should be used for summarising the topics of the different components and to justify the observations raised and opportunities for improvement identified.

Clearly mention for each indicator if it is fulfilled or if it is not or partially fulfilled.

Give a clear description of the findings for observations and opportunities for improvement.

The full details supporting this section are available in the completed audit checklist and the report of the observed inspection(s) (see Annexes 4 and 5). Observations raised are denoted as OB and identified opportunities for improvement as OI. <A summary table is provided in section 11.> <<abbreviation auditee>’s proposed CAPAs/responses to the OBs and OIs are detailed in Annex <#>.>

* 1. Component 1: legislative and regulatory: requirements and scope

<text>

<The JAP requirements as stated in indicator 1 to 23 were found to be met.>

<Regarding component 1, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

|  |
| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| <OB><OI><#><details on observation/opportunity for improvement> |
| *Reviewed document reference (if not already mentioned in the self-assessment):* |

* 1. Component 2: regulatory directives and policies

<text>

<The mechanisms for designating inspectors and managing the code of conduct were both found to meet the JAP requirements as stated in indicator 24 and 25, with examples seen.>

<Regarding component 2, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

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| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Reviewed document reference (if not already mentioned in the self-assessment):* |

* 1. Component 3: GMP standards

<The legislative provisions enabling the application of GMPs were found to meet the JAP requirements stated in indicator 26 and 27.>

<text>

<Regarding component 3, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

|  |
| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 4: inspection resources

<The JAP requirements as stated in indicator 28 to 33 were found to be met.>

<text>

<Regarding component 4, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

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| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 5: inspection procedures

<The JAP requirements as stated in indicator 34 to 51 were found to be met.>

<text>

<Regarding component 5, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

|  |
| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 6: inspection performance standards

Included under sub-component 11A Quality Management system – Quality Management

system.

* 1. Component 7: enforcement powers and procedures

<The JAP requirements as stated in indicator 52 to 57 were found to be met, with examples seen.>

<text>

<Regarding component 7, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

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| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 8: alert and crisis systems

<The JAP requirements as stated in indicator 58 and 59 were found to be met, with examples seen.>

<text>

<Regarding component 8, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

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| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 9: analytical capability

<text>

<The JAP requirements as stated in indicator 60 to 65 are fulfilled.>

<Regarding component 9, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

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| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 10: surveillance programme

<text>

<The JAP requirements as stated in indicator 66 to 71 are fulfilled.>

<Regarding component 10, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

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| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

* 1. Component 11: quality management system

<Key elements of the Quality Management Systems were reviewed and found to fulfil the corresponding JAP requirements as stated in indicator 72 to 78: Compliance with GMPs, Key Performance Indicators, implementation of and adherence to the QMS, documentation system, internal audit and performance review.>

<text>

<Regarding component 11, <#> observations (OB <#>) and <#> opportunities for improvement (OI <#>) were noted. All other indicators of this component (<x>-<y>) are fulfilled.>

|  |
| --- |
| **Indicator <#>**<text indicator>*<not><partially> fulfilled* |
| **<OB><OI><#>**<details on observation/opportunity for improvement> |
| *Document reference (if not already mentioned in the self-assessment):* |

1. Report(s) on the observed inspection

Please list the sites of the observed inspections and if not done already in section 8, summarise the outcome of the observed inspection(s), in particular observations raised and opportunities for improvement identified.

<text>

The observation of the <company 1> inspection is reported in Annex 5:

<Name and address of inspected company 1>

<The observation of the <company 2> inspection is reported in Annex <#>:>

<Name and address of inspected company 2>

1. Annexes attached

Annex 1: Audit notification letter

Annex 2: Organisational chart

Annex 3: Audit plan

Annex 4: Completed audit checklist

Annex 5: Observed inspection report

<Annex x: Best practices>

Annex 4 is the JAP audit checklist as completed by the auditee (self-assessment) and assessed by the audit team with a clear indication for each indicator if it fulfilled, partially fulfilled or not fulfilled and with comments and observations as required. The conclusion on fulfilment of indicators in annex 4 should be the same as in the audit report.

Add additional annexes if required, ensuring correct numbering in this section and in the entire report.

1. Observations and opportunities for improvement identified during the audit and audit team review of the auditee’s proposed corrective and preventative actions (CAPAs)

In the preliminary report, please list the observations raised and the opportunities for improvement identified during the audit at the inspectorate and laboratory(ies) and the observed inspection(s).

Please request the auditee to provide a CAPA plan and include the proposed action(s) in the table in the final report. The CAPA should be clear and addressing the finding and a deadline for the implementation of the CAPA should be given. Any comments raised by the auditee on the observations or opportunities for improvement during the audit or the closing meeting can be included here.

In the final report, please add an evaluation of the proposed CAPA for each indicator and conclude (a) if the CAPA was implemented successfully and hence that indicator can be considered fulfilled or (b)if the successful implementation of the CAPA by the proposed deadline will support the fulfilment of the indicator.

In case multiple correspondences are required on the CAPA plan and its evaluation, for each of reading and to have the full chronology, an overview or table in an additional annex can be provided. Once the report is finalised, please add the following sentence ‘The final audit report was transmitted to the auditee and the Compliance Group on <date>.’.

The preliminary report was transmitted to the auditee and the Compliance Group on <date>.

The auditee provided responses and a CAPA plan to the audit team on <date>.

<Additional discussion on the CAPA plan and its review took place between the audit team and the auditee on <date>.>

The Compliance Group provided feedback on the audit report to the audit team on <date>.

|  |
| --- |
| **Observation*** Indicator <#>: <text indicator>

<not><partially> fulfilled*<concern raised>** Indicator <#>: <text indicator>

<not><partially> fulfilled*<concern raised>* |
| **Proposed CAPAs (provided by <auditee abbreviation> on <date>)** |
| **Conclusion of the audit team after review of the proposed CAPAs*** <CAPA acceptable>

<Documented evidence supporting the implementation of the CAPA received and reviewed. The indicator is now considered fulfilled.><CAPA when implemented will support the fulfilment of the indicator.>* <CAPA acceptable>

<Documented evidence supporting the implementation of the CAPA received and reviewed. The indicator is now considered fulfilled.><CAPA when implemented will support the fulfilment of the indicator.> |

|  |
| --- |
| **Opportunity for improvement*** Indicator <#>: <text indicator>

<concern raised>* Indicator <#>: <text indicator>

<concern raised> |
| **Proposed CAPAs (provided by <auditee abbreviation> on <date>)** |
| **Conclusion of the audit team after review of the proposed CAPAs*** <CAPA acceptable>

<Documented evidence supporting the implementation of the CAPA received and reviewed. The indicator is now considered fulfilled.><CAPA when implemented will support the fulfilment of the indicator.>* <CAPA acceptable>

<Documented evidence supporting the implementation of the CAPA received and reviewed. The indicator is now considered fulfilled.><CAPA when implemented will support the fulfilment of the indicator.> |

1. Recommendation for the Compliance Group

Please provide a recommendation to the Compliance Group on the outcome of the audit in line with the audit scope and objectives, as well as issues to be followed-up by the Compliance Group.

<The JAP requirements were fulfilled in the preliminary audit report, with the exception of the not fulfilled indicators <#> and the partially fulfilled indicators <#> for which observations were raised. <#> opportunities for improvements were identified. The received responses and proposed CAPAs relating to the observations were considered satisfactory. <Abbreviation auditee> provided documented evidence on the implementation of the CAPAs for indicators <#> and the indicators can now be considered fulfilled. Documented evidence for the implementation of the CAPAs for indicators <#> is awaited by the agreed deadline.>

<The audit team recommends the follow-up of the outstanding CAPAs by the audit team <or the Compliance Group> after the finalisation of the audit report as listed in the JAP Follow-up on CAPA implementation in Annex <#>.>

If applicable, please refer to best practices identified during the audit for which the auditee agreed to share them with the inspectorate network.

<The audit team noted best practices in place at the auditee and obtained agreement from the auditee to share these best practices with the EEA inspectorate network. The best practices are listed in annex <x>.>

1. Summary and conclusion

Please provide a clear statement on the conclusion of the audit regarding the compliance with EU and JAP requirements in line with the audit scope and objectives, as well as the next steps to be taken.

If no conclusion on compliance of the auditee or agreement on a CAPA plan can be reached by the audit team, please describe this clearly and indicate clearly if and for which indicators and reason the conclusion on compliance and/or the follow-up on the CAPA plan is referred to the Compliance Group.

<Based on the information gathered during the <on-site audit> <Desktop audit> <distant assessment> and after review of the documented evidence supporting the implementation of all CAPAs for observations raised, the audit team concluded that all indicators from the JAP Audit checklist can be considered as fulfilled and that <abbreviation auditee> – <member state> operates in compliance with the EU legislation, with GMP regulations, with the Compilation of Union Procedures on Inspections and exchange of information and with the JAP requirements.>

<Based on the information gathered during the <on-site audit> <Desktop audit> <distant assessment>, after review of the documented evidence supporting the implementation of CAPAs for observations raised and agreeing with the proposed plan for the remaining CAPAs for indicators <#>, the audit team concluded that following the successful implementation of these CAPAs within the agreed timelines, all indicators from the JAP Audit checklist will be considered as fulfilled and that <auditee abbreviation> – <member state> will be considered in compliance with the EU legislation, with GMP regulations, with the Compilation of Union Procedures on Inspections and exchange of information and with the JAP requirements.>

**Signature on behalf of the audit team**

|  |  |
| --- | --- |
| Name lead auditor | <name> |
| **Organisation** | <NCA> - <country> |
| **Signature** |  |

**Distribution of the audit report**:

* <name contact person auditee> (<abbreviation auditee>)
* <name and NCA co-auditors>
* Compliance Group secretariat (EMA) jap@ema.europa.eu