19 February 2019

EMA/170408/2018 – Rev. 1

Committees and Inspections

Joint Audit Programme for EEA GMP inspectorates

JAP Observed inspection checklist

Observed inspection checklist /report

Auditee: <name of audited GMP inspectorate>

Inspector(s): <name and role of inspector(s)>

Inspected company: <name and address of company>

Type of inspection: <inspection type>

Date: <date(s) of inspection>

Auditor(s): <name, NCA and role of auditor(s) and observer(s)>

| **OBSERVED INSPECTION FORM** |
| --- |
| **Number** | **Criterion**  | **Comment/Observation** |
| **A. Pre-inspection** |
| 1 | Requirements as detailed in the procedure for pre-inspection preparation are met [indicator 36] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 2 | An inspection plan is developed prior to commencement of the inspection [indicator 36] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 3 | The inspection plan is based on the company’s GMP compliance history, critical activities and type(s) of dosage forms or products manufactured [indicator 37] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 4 | Criteria for notification of inspections are met [indicator 36] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| **B. Inspection** |
| 5 | The inspection methodology as described in the inspection procedure is followed [indicator 43] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 6 | The different stages as described in the inspection procedure are followed [indicator 43] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 7 | GMP inspection covers the company’s manufacturing operations as described in the manufacturing authorisation [indicator 44] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 8 | Critical stages and parameters of manufacturing processes are assessed [indicator 44] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 9 | Qualification and validation are assessed [indicator 45] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 10 | The inspection plan is adjusted, where warranted, based on inspection findings [indicator 46] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 11 | The depth of the inspection is in line with the inspection findings [indicator 47] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 12 | Observations are based on GMP requirements [indicator 39] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 13 | Observations are factual [indicator 39] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 14 | Observations are classified/categorised according to risk [indicator 40] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 15 | Assessment of the company's overall compliance rating is in line with the inspection findings [indicator 41] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| **C. Inspection report** |
| 16 | Inspection reports are completed in the required reporting format [indicator 42] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| **D. Post-inspection** |
| 17 | Post inspection activities, as described in procedure, are adequate: this can be checked with a retrospective study based on a previous inspection [indicator 48] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 18 | Inspection findings and conclusions are subject to an internal review [indicator 49] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 19 | An up-to-date manual or electronic database of inspections is maintained [indicator 51] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 20 | The integrity and confidentiality of inspection data is controlled [indicator 51] | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| **E. Inspector(s)** |
| 21 | Inspector’s skills match with required skills (especially general inspection’s methodology and knowledge of manufacturing operations of the site to be inspected) | <comment/observation>Conclusion: Criterion - <Not><Partially> met |
| 22 | The auditee inspector is consistent in his approach | <comment/observation>Conclusion: Criterion - <Not><Partially> met |

Auditor: <name of auditor responsible for observed inspection report>

Date: <date of observed inspection report>