Follow-up on CAPA implementation from JAP audit <member state> (<agency>)

By <Audit team><Compliance Group>
Status <date>

|  |  |  |  |
| --- | --- | --- | --- |
| Indicator and finding | Proposed corrective actions | Objective evidence | Conclusion of the <Audit team><Compliance Group> |
| *<#>. <indicator title> – Indicator <partially><not> fulfilled:*<finding from audit report>  | <corrective action proposed by agency including deadline for implementation> | <description of documented evidence supporting the implementation of the CAPA> | <indicator considered fulfilled> |

**Conclusion after review of objective evidence by <Audit team><Compliance Group sponsor>:**

<After receipt and review of the documented evidence on the outstanding CAPAs, the <Audit team><Compliance Group sponsor> concluded that following the successful implementation of the CAPAs, indicators <number> can now be considered as fulfilled.>

<As all indicators are now fulfilled, the <Audit team><Compliance Group sponsor> recommend to the Compliance Group that <agency> is now considered in compliance with the EC legislation, with GMP regulations, with the Compilation of Union Procedures on Inspections and exchange of information and with the JAP requirements.>

Name: <name auditor/Compliance Group sponsor> Date: <date>

**Conclusion after discussion at Compliance Group:**

< Taking into account the documented evidence on the outstanding CAPAs and the recommendation from the <Audit team><Compliance Group sponsor>, the Compliance Group concluded at its <date> meeting that <following the successful implementation of these corrective actions> <the corrective actions are considered satisfactory> <with the provision that the CAPA plan is completed satisfactorily> all indicators can be considered as fulfilled and that <agency> – <member state> is in compliance with the EC legislation, with GMP regulations, with the Compilation of Union Procedures on Inspections and exchange of information and with the JAP requirements. The follow-up to the CAPAs and the audit are now formally closed.>

Name: <name>, on behalf of the Compliance Group Date: <date>