



Heads of Medicines Agencies
European Medicines Agency – Inspections
GMP Inspection Services Group



Joint Audit Programme for EEA GMP Inspectorates

London, 19 September 2006
Doc. Ref. EMEA/INS/GMP/313474/2006

**JOINT AUDIT PROGRAMME FOR EEA GMP
INSPECTORATES**

Programme

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Joint Audit Programme for EEA GMP Inspectorates

1. Scope

The scope of the Joint Audit Programme (JAP) is to verify the implementation of relevant provisions of European Directives into national laws, authorisation / licensing system for manufacturers, GMP compliance certification, administration of inspections, inspectorate, resources, complaints, rapid alerts including laboratory support, enforcement and internal quality assurance. The Joint Audit Programme covers all EEA GMP inspectorates in the field of human and veterinary medicinal products.

The audit programme forms an essential part of the quality system adopted by GMP inspectorates as part of the Compilation of Community Procedures on Inspections and Exchange of Information. It ensures harmonised inspections standards and a harmonised approach to practical interpretation of GMP on the basis of European Community legislative requirements to support mutual recognition of inspection outcomes.

Additionally, and in order to satisfy requirements laid down in mutual recognition agreements (MRAs) between the European Community and some third countries, all member states have agreed to carry out an harmonisation of inspection practices and compliance procedures. This is particularly important in order to preserve confidence in the GMP compliance systems among MRA partners as agreed in the MRA maintenance programmes.

In order to rise up to these challenges and to preserve the confidence achieved both within the European Community and at MRA level, the Heads of Agencies group in the field of inspection decided in October 2000 to set up a joint audit programme with a view to evaluate their inspection systems, with the mission, wherever necessary, to implement corrective actions likely to guarantee the quality equivalency of these systems.

2. Responsibilities

2.1 Compliance Group

The Joint Audit Programme is managed by the Compliance Group. Its role is to oversee the audit programme, plan the visits, review the outcome and coordinate follow-up of any corrective measures. The GMP inspection services group at the EMEA adopted the mandate for the Compliance Group and nominates its members. In detail the JAP related responsibilities of the Compliance Group include:

- to plan and co-ordinate visits as lined out in this programme
- to monitor the visits
- to review the outcome of the visits
- to coordinate follow up of any corrective measures
- to discuss and resolve where possible any major problems that occur and to present to the GMP Inspection Services Group any issues which cannot be resolved
- to ensure that documentation of the programme is relevant and up to date
- to report at the meetings of the GMP inspection services Group
- to provide annual reports to the Heads of Medicines Agencies
- to define and monitor training courses for auditors
- to discuss and exchange information with PIC/S compliance group on Joint Re-assessment programme (JRP) with respect to mutual recognition of the audit results
- to exchange information with other regulatory bodies (e.g. WHO) involved in audits concerning GMP inspectorates

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2.2 GMP Inspection Services Group

The main tasks of the GMP inspection services group with respect to the JAP are:

- endorse audit plans
- adoption of final audit report and actions taken
- provide audit reports to the group of Heads of Medicines Agencies when deemed necessary
- release annual reports to HMA
- nomination of the members of the compliance group
- adoption/implementation of the documentation prepared by the compliance group
- discussion/resolution of possible major problems received by the compliance group
- responsibility for follow up if corrective actions are not implemented within the agreed time frame

2.3 EMEA

The EMEA provides coordinating support for the programme. EMEA will:

- provide secretariat for the Compliance Group
- maintain the Joint Audit Programme documents
- maintain and update the list of auditors and audit training records
- maintain and update the list of audits carried out in the EEA
- keep inventory of audit reports and follow-up measures
- sent out audit notifications
- draft annual report to the HMA

2.4 Heads of Medicines Agencies

The group of the HMA continuously evaluates the programme on the basis of the annual reports. The Heads of Medicines Agencies are asked to support the EEA Joint Audit Programme by providing the necessary resources. The group could be asked to evaluate how to further proceed in case of uncorrected serious deficiencies. This includes the option to formally refer the issue to the Commission for consideration of infraction proceedings.

3. General Principles

3.1 Audit Schedule

Audits should be performed every 5-6 years for every member state's GMP inspectorate. With 42 GMP inspectorates in the EEA (excluding regional or federal ones) this results in 7 – 8 audits to be carried out per year. Additional audits may be considered as a result from previous evaluations. Any additional audits should be based on specific requests from the European Commission or should be taken into account if a Member States applies for it.

The Compliance Group sets up an audit schedule annually, using the information held at the EMEA. The audit schedule includes the EEA GMP inspectorates to be audited, auditors, date, rapporteur, particular scope and rationale. For planning purposes the Compliance Group liaises with PIC/S and MRA partners. The audit schedule is discussed and agreed by the GMP inspection services group.

Based on the audit schedule the EMEA officially announces the audits to the authority. The EMEA also requests Member States to nominate auditors for specific audits.

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3.2 Qualification and training of auditors

Auditors should be experienced inspectors nominated by the competent authorities and trained in this programme, in particular in the scope, audit techniques, procedures.

3.3 Audit Procedure

A description of the necessary steps from initiating the audit to reporting on the audit and follow up is given in a separate document titled audit procedure.

3.4 Coverage of the audit

The audit at the GMP inspectorate and any relating units or institutions should cover the following aspects:

- Quality system, including implementation of Compilation of Community Procedures
- Implementation of Legislation related to the GMP supervision system
- Authorisation/ licensing system for manufacturer
- 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)

3.5 Audit report

It is the responsibility of the team leader to create the final audit report including (if any) corrective actions and comments by the audited authority and to send it to the audited authority and the Compliance Group Secretariat at EMEA within 8 weeks after the visit. The Compliance Group should use the information received for monitoring the progress after the audit and ensure that critical observations are brought to the attention of the GMP inspection services group and the Heads of Medicines Agencies group, if deemed necessary. The final audit report and, if any, corrective actions (including time frame) should be adopted by the GMP inspection services group. In case of uncorrected serious deficiencies, the Heads of Medicines Agencies group would refer the issue formally to the Commission for consideration of infraction proceedings.

The EMEA will prepare an annual report on all audits performed. This report will be reviewed by the Compliance Group, agreed by the GMP inspection services group and sent to the group of the Heads of Agencies and .Heads of Veterinary Agencies.

4. Audit Programme Cooperation

In order to avoid duplication of work, the Compliance Group should through EMEA cooperate with PIC/S, the MRA partners and if possible the WHO for any evaluation programmes. Results from the JAP should be acknowledged by PIC/S for the assessment/ reassessment scheme without further duplication of activities and vice-versa.

Results of the JAP must not be shared with non-EEA partners unless specifically requested by the concerned member state.

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5. Supporting documents

The Joint Audit Programme for EEA GMP inspectorates is described in a number of supporting documents listed below.

In addition the Compliance Group Secretariat holds the CVs of the auditors, training documents, annual audit schedules, annual reports to the Heads of Medicines Agencies and the individual audit reports.

List of JAP documents

JAP Programme

JAP Procedure

JAP Audit plan

JAP Audit notification

JAP Audit checklist

JAP Audit report

JAP Confidentiality agreement for audits

JAP CV template for auditors

JAP Procedure for observing inspections

JAP Observed inspection checklist