



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2012
EMA/INS/GMP/43493/2012
Compliance and Inspection

Work Plan for GMP/GDP Inspectors Working Group for 2012

Chairperson: David Cockburn

28 February – 01 March

29-31 May

03-05 September

27-29 November

A joint meeting with Quality Working Party (QWP) will take place during the September meeting (September 5).

A meeting with the Group's Interested Parties is planned to coincide with the November meeting (November 28).

A number of drafting group meetings will be organised to coincide with the main meetings but if needed a limited number of additional meetings will be organised.

A maximum of 4 x 1 day meetings of the Agency's Process Analytical Technology (PAT) team, which is also responsible to QWP and Biologics Working Party (BWP), will be organised.

1. Inspections under the Centralised system

Development and co-ordination of inspections relating to centrally authorised products, Plasma Master Files and Vaccine Antigen Master Files.

Ongoing activity.

Co-ordination of re-inspections of manufacturers in third countries.

To ensure that manufacturing sites listed on centralised marketing authorisations and located in third countries where no MRA is in place are re-inspected by, or on behalf of, the Supervisory Authority within the criteria agreed at Community level.



2. Mutual Recognition Agreements (MRAs)

MRA General

To continue to find ways to simplify operational aspects of all MRAs.

To continue to encourage the use of the EudraGMP database by MRA partners to replace the paper exchange of GMP certificates.

To review and utilise information exchanged in annual reports.

To include active substances in the operational phase of the current scope of MRAs where possible and to liaise with MRA partners on information exchange and collaboration on inspections performed outside of the respective territories.

MRA with Canada

To manage and follow up, as necessary, audits performed by Health Canada of new Member States and related pre-MRA audits.

MRA with Japan

To continue to work towards extension of the operational aspects under the current scope of the MRA.

3. Harmonisation Topics

Joint Audit Programme

Through the Compliance Group:

To ensure that the agreed audit programme for 2012 is carried out and to report to the Heads of Medicines Agencies on the 2011 programme.

To monitor the results of audits and follow up as necessary.

To improve the audit tools including the development of aspects related to the supervision of active substance manufacturers.

To exchange audits results with PIC/S and maintain mutual recognition between the Joint Audit Programme and the Joint Re-assessment Programme.

To review Annual Reports under the MRA maintenance programme with a view to provide input to the planning of the Joint Audit Programme.

Compilation of Community Procedures on Inspections and Exchange of Information

To continue to identify GMP and GDP related topics for development as Community procedures.

This is expected to include a number of issues arising from the implementation of the Falsified Medicines legislation. Potentially these include:

- Revision of the procedure for Coordination of Third Country inspections
- Revision of the procedure for API inspection triggers
- Revision of the procedure on Conduct of inspections
- Revision of the procedure for dealing with non-compliance
- Revision of inspection report formats

- Revision of format for GMP certificates
- Formats for API registrations
- Formats for Wholesale Distribution Authorisations and GDP Certificates/non-compliance statements
- Triggers for inspection of brokers
- Triggers for manufacturers and importers of excipients.

Work started in 2011 on a common interpretation of the Community format for manufacturing authorisations will continue, which may lead to minor changes to the format itself.

4. GMP and GDP topics

GMP Guide: Chapters 1 and 2 (Quality Management and Personnel)

To finalise these chapters as part of the EU implementation of ICH Q10.

GMP Guide: Chapters 3 and 5 (Premises and Equipment and Production)

To undergo a public consultation on the changes to be made relating to the topic of "Dedicated Facilities" once toxicological input has been developed by the Safety Working Party.

To undergo a public consultation and finalise the amendments to Chapter 5 of the GMP Guide relating to the qualification of suppliers and supply chain traceability for starting materials, and, to clarify analytical testing expectations of medicinal product manufacturers with respect to raw materials.

GMP Guide: Chapter 6 (Quality Control)

To undergo a public consultation on the revision aimed at identifying minimal requirements for the transfer of analytical methods.

GMP Guide: Chapter 8 (Complaints and Product Recall)

To undergo a public consultation on changes to this chapter arising from discussions at a meeting of Quality Defect contact points held at EMA on 7-8 October 2009 on product shortage notifications and to introduce specific Quality Risk Management concepts within the context of this chapter. Minor amendments may also be needed to reflect new obligations arising from the Falsified Medicines legislation.

GMP Guide: Annex 15 (Validation)

To initiate a review and revision of the Annex as necessary in order to maintain consistency with the new CHMP guideline on process validation and in the light of ICH Q8, Q9 and Q10.

GMP Guide: Annex 16 (Certification by a QP and Batch Release)

To undergo a public consultation on a revision in the light of recent changes to the GMP Guide, developments such as Real Time Release Testing, globalisation, and to clarify a number of outstanding issues.

GMP Guide: Annex 17 (Parametric Release)

To initiate a review and revise the Annex as necessary in view of the revision of the CHMP guideline on Parametric Release/Real Time Release Testing.

Good Distribution Practice (GDP)

To review and evaluate public comments on the draft revision of the GDP guideline on behalf of the European Commission.

Work will also be initiated on GMP guidance on storage during transport which will also consider any impact on other scientific guidelines in consultation with the Quality Working Party and Biologics Working Party.

EudraGMP database

To continue to fulfil the role of Telematics Implementation Group (TIG) for EudraGMP and to act upon the recommendations of the EudraGMP IT subgroup formed to advise the TIG.

Depending on budget availability to develop to develop an inspection planning module for third country inspections and to develop new modules to meet new requirements arising from the Falsified Medicines legislation:

- Third Country inspection planning
- Database for API manufacturers, importers and distributors registration
- Database for Wholesale Distributor Authorisations and GDP Certificates
- Database for GDP Certificates for APIs

5. Collaboration with European Commission

EU enlargement

To develop contacts and collaboration in the field of GMP Inspections with EU candidate and accession countries identified by the European Commission. These countries are invited to observe meetings of GMP/GDP IWG.

Contribution to the Implementation of the Falsified Medicines Legislation

In addition to the specific items already mentioned in Sections 3, 4 and above, the following topics will be addressed:

- To assist the European Commission in developing the implementing act defining the standards and process for assessment of Third Country API regulatory framework and verification measures.
- To assist the European Commission in developing the delegated act establishing Principles and Guidelines of GMP for APIs.
- Develop a draft guideline on principles of Good Distribution Practice for APIs on behalf of the European Commission for public consultation.
- Develop, agree and publish in consultation with the European Commission, templates for Third Country authority statements for export of APIs to EU and for notification of non-compliance.
- To develop a risk assessment guideline to establish appropriate GMP for excipients on behalf of the European Commission for public consultation.

Good Practices for Blood and Tissue Establishments

To contribute when requested to the good practice guidelines under development according to Directive 2005/62/EC and 2004/23/EC.

6. Liaison with other groups

To maintain dialogue and monitor developments involving external groups in areas of common interest order to communicate the work of the Group and to assess the impact of other groups' activities on GMP and GDP guidance, Compilation of Community Procedures and inspection related activities:

- Biologics Working Party
- GCP Inspectors Working Group
- Safety Working Party
- Industry associations and relevant professional associations (Interested Parties)
- European Directorate for the Quality of Medicines and Healthcare
- Heads of Medicines Agencies, in particular the Working Group of Enforcement Officers and Product Testing Working Group
- International regulator partners
- Joint CHMP/CVMP Quality Working Party
- Process Analytical Technology team
- Pharmacovigilance Inspectors Working Group
- Pharmaceutical Inspection Cooperation Scheme (PIC/S)
- World Health Organisation

Particular attention will be paid to supporting collaborative activities such as API inspections, joint inspections of medicinal product manufacturers with US FDA in the EU and USA and contributing to capacity building for countries developing their regulatory systems through existing international platforms, for example the WHO project with the State Food and Drug Administration (SFDA) of the People's Republic of China.

Steps will be taken to implement reliance upon information provided by US FDA on sites in USA in lieu of performing EU inspections.

7. Other

The Group will undertake any other issues arising and referred to it by the European Commission, Heads of Medicines Agencies or the Scientific Committees of the European Medicines Agency.