



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 January 2011
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Compliance and Inspection

Work Plan for GMP/GDP Inspectors Working Group for 2011

Chairperson: David Cockburn

1. Meetings scheduled for 2011

22-24 February
24-26 May
07-09 September
22-24 November¹

A joint meeting with Quality Working Party (QWP) will take place during the September meeting (September 7).

A meeting with the Group's Interested Parties is planned to coincide with the November meeting (November 23).

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.

2. 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.

¹ Corrected November meeting dates



3. Mutual Recognition Agreements (MRAs)

MRA General

To harmonise operational aspects of all MRAs.

To continue to encourage the use of the EudraGMP database 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.

ACAA with Israel

To assist the Commission in the practical implementation of the agreement with Israel with respect to GMP and related activities once the agreement is in force.

4. Harmonisation Topics

Joint Audit Programme

Through the Compliance Group:

To ensure that the agreed audit programme for 2011 is carried out and to report to the Heads of Medicines Agencies on the 2010 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 continue to define and monitor training courses for auditors of GMP inspectorates.

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

To exchange information with other regulatory bodies (e.g. WHO) involved in audits concerning GMP inspectorates.

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 Community format for Wholesale Distribution Authorisations, GDP certificates and GDP non-compliance statements depending on the final requirements of the anti-falsification legislation.

To develop a common approach for dealing with information on GMP non-compliance received from non-EEA non-MRA partner sources.

5. 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 share proposals and consult US FDA prior to initiating a public consultation on proposals for the revision of guidance on the circumstances where certain products should be produced in dedicated and self-contained facilities.

To finalise the amendments to Chapter 5 of the GMP Guide in order to reflect, in guidance, the obligations of manufacturing authorisation holders to only use active substances that have been manufactured in accordance with GMP, to clarify analytical testing expectations of medicinal product manufacturers with respect to raw materials and to strengthen the guidance on qualification of the supply chain and traceability of starting 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 7 (Contract Manufacture and Analysis/Outsourced Activities)

To finalise the revision on broadening of scope as part of the EU implementation of ICH Q10.

GMP Guide: Chapter 8 (Complaints and Product Recall)

To initiate a revision in the light of 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.

GMP Guide: Annex 2 (Biological substances and Medicinal Products)

To finalise revision of the Annex following the public consultation conducted in 2010.

GMP Guide: Annex 15 (Validation)

To revise the Annex in order to maintain consistency with the new CHMP guideline on process validation and in the light of ICH Q8, Q9 and Q10. The impact of the ongoing revision of chapters 3 and 5 ("Dedicated Facilities") will also be taken into account.

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

To initiate a revision in the light of recent changes to the GMP Guide, developments such as PAT and Real Time Release Testing, globalisation, anti-falsification legislation and to clarify issues such as control reports for batches moving between Member States, sampling and testing of batches produced in 3rd countries and dealing with minor deviations from marketing authorisations.

GMP Guide: Annex 17 (Parametric Release)

To revise the Annex in view of the revision of the CHMP guideline on Parametric Release/Real Time Release Testing.

Good Distribution Practice (GDP)

To finalise a draft revision of the Community GDP guideline and forward to the European Commission to release for public consultation. A further consultation may be necessary if significant changes are required as part of the implementation of the anti-falsification legislation.

Work will also be initiated on complementary 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.

6. Collaboration with European Commission

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.

To finalise public access.

To finalise the user specification for the inspection planning module for third country inspections and to initiate discussion on a specification to meet new requirements arising from the anti-falsification legislation.

EU enlargement

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

Implementation of the anti-falsification legislation

To develop a work plan and initiate new work needed for the practical implementation of the legislative proposals once finalised.

Good Practices for Blood and Tissue Establishments

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

Part III of the EU GMP Guide

To request the publication of Part III of the GMP Guide along with a revised introduction. The initial publication is expected to include:

- Explanatory notes and content for a Site Master File
- ICH Q9 (transferred from Annex 20 of the GMP Guide)
- ICH Q10
- International harmonised batch certificate content

7. 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
- 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
- ICH Quality Implementation 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 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.

8. 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.