



WORK PLAN FOR GMP/GDP INSPECTORS WORKING GROUP FOR 2008

CHAIRPERSON: Emer Cooke

STATUS: January 2008

1. MEETINGS SCHEDULED FOR 2008

- 05-07 February 2008
- 20-22 May 2008
- 01-03 October 2008
- 25-27 November 2008

A joint meeting with Biologics Working Party has been proposed to coincide with the May meeting (21 May).

A joint meeting with Quality Working Party will take place during the October meeting (October 3).

A meeting with interested parties is planned to coincide with the November meeting (November 26).

A number of drafting group meetings will be organised to coincide with the main meetings but if needed a limited number of additional meetings (maximum 3) will be organised.

A maximum of 4 x 1 day meetings of the PAT team, which is a joint responsibility with QWP and BWP, will be organised where possible coinciding with meetings of either QWP, BWP or GMP/GDP Inspectors Working Group.

2. INSPECTIONS UNDER THE CENTRALISED SYSTEM

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

This is an ongoing activity.

Co-ordination of re-inspections of manufacturers in 3rd 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.

Maintenance of existing EMEA GMP database for Centrally Authorised Products / list of manufacturers in third country sites.

To maintain the existing EMEA corporate database and to develop a new database. See also EudraGMP project in section 4.

3. MUTUAL RECOGNITION AGREEMENTS (MRAs) FOR GMP INSPECTIONS

Harmonisation of Maintenance Programmes under all MRAs

This is an ongoing activity.

MRA General

To develop the MRAs in the context of active substances and to liaise with MRA partners on the introduction of Quality Risk Management and its impact on the MRAs

To develop practical arrangements for access to EudraGMP by MRA partners.

MRA with Japan

To work towards extension of the scope of the MRA.

MRA with Canada

To continue to assist new member states prepare for evaluation by Health Canada. To contribute to a re-evaluation of the equivalency of Health Canada in view of recent EU legislative changes.

4. HARMONISATION TOPICS

Joint Audit Programme

To carry out the agreed programme for 2008.

Compilation of Procedures on Inspections and exchange of information

To continue to identify topics for development as Community procedures and in particular to complete work already started in relation to the implementation of Quality Risk Management principles.

5. GMP and GDP TOPICS

Revision of chapter 4 of the GMP Guide (Documentation)

To agree on a text for public consultation to update guidance in relation to electronic documentation. This revision will be performed in parallel with an update to Annex 11 of the GMP Guide (Computerised systems).

Comment: Texts for public consultation expected in early 2008.

Amendment to Chapters 3 and 5 of GMP Guide (“Dedicated Facilities”)

To agree on a text for public consultation on the need for dedicated self-contained facilities. To consult the Safety Working Party as appropriate. In the meantime to publish a report on progress with this topic.

Comment: Text for public consultation expected late 2008.

Amendment to Chapter 5 of the GMP Guide (“Qualification of Suppliers”)

To finalise a proposed amendment to Chapter 5 of the GMP Guide in order to reflect, in guidance, the new obligations of manufacturing authorisation holders to only use active substances that have been manufactured in accordance with GMP.

Comment: Text for public consultation expected early 2008.

Amendment to Chapter 5 of the GMP Guide (“Testing of Starting Materials”)

To finalise the common approach on what is expected from manufacturing authorisation holders with respect to the assurance of the quality of raw materials used and to include a new text within the GMP Guide.

Comment: Text for public consultation expected early 2008.

Annex 2 of the GMP Guide (Biological Medicinal Products)

Once public comments have been evaluated to finalise the text of the annex in order to update it, to integrate proposals for advanced medicinal products and to clarify the GMP requirements for biological substances in view of the restructuring of the GMP Guide.

Comment: Public consultation ends March 2008.

Annex 6 of the GMP Guide (Medicinal Gases)

To finalise the amendment of the annex, initiated in view of the restructuring of the GMP Guide and to update the annex.

Comment: Final text expected mid 2008.

Annex 13 of the GMP Guide (Investigational Medicinal Products)

To agree on a text for public consultation to address reference and retention samples. Minor editorial changes to the Annex will also be included.

Comment: Public consultation expected by mid 2008.

Annex 14 of the GMP Guide (Medicinal Products Derived from Human Blood or Plasma)

To finalise the amendment of the annex initiated in view of Directive 2002/98/EC.

Comment: Text for public consultation expected by mid 2008

GMP issues specific to Investigational Medicinal Products (IMPs).

To publish Questions and Answers on issues discussed with GCP Inspectors Working Group and developed by the GCP/GMP subgroup (representation from both GCP and GMP/GDP IWGs) to assist in the interpretation of GMP in a number of specific circumstances as identified in the work plan of the subgroup. To consider issues referred by the relevant CTFG working group. To consider the public comments on the proposal to develop a harmonised format for the batch release certification referred to in Art. 13 of Directive 2001/20/EC.

Comment: Initial Q&As to be published in early 2008.

Homoeopathic Medicinal Products

To monitor developments relating to homoeopathic medicinal products and consider whether there is any implication for GMP.

Good Distribution Practice (GDP)

To review existing Community GDP guidance and consider whether any improvements are necessary. To liaise with PIC/S and WGEO on work in the area of GDP.

6. COLLABORATION WITH EUROPEAN COMMISSION

EudraGMP database

To fulfill 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.

Comment: Public access to database expected by mid 2008.

Directive on GMP for certain excipients

To assist in the identification of the list of excipients to which GMP requirements apply and the conditions of application.

EU enlargement

To develop contacts and collaboration with Croatia and Turkey in the field of GMP Inspections. These countries are invited to observe meetings of GMP/GDP IWG.

Good Practices for Blood Establishments

To contribute to the guidelines to be developed according to Directive 2005/62/EC.

Good Manufacturing Practice for Active Substances

To establish a drafting group to develop an action plan in response to the Community survey on the implementation of the new obligations for manufacturing authorisation holders.

Proposed Regulation on Advanced Therapies

To review the need for further specific GMP guidance (Annex 2 of the GMP Guide) for medicinal products covered by the new regulation.

Parallel Trade and Counterfeit Trade

To contribute to these projects with respect to GMP/GDP related aspects.

Variations Regulation

To contribute as necessary to the development of proposals for improving the regulation of post-authorisation changes in particular where an impact on GMP inspection resources is foreseen.

7. LIAISON WITH OTHER GROUPS

ICH Topics: ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System), ICH Quality Implementation Group

To monitor the development of these topics, contributing as necessary and assessing the impact on GMP, GDP and inspection related activities.

GCP Inspectors Working Group

To maintain a dialogue with GCP Inspectors, in particular through the GCP/GMP subgroup, on areas of common interest at the interface between GMP for investigational medicinal products and GCP.

Joint CHMP/CVMP Quality Working Party

To identify areas of common interest and maintain a dialogue with QWP on these areas. To support the work of the EMEA PAT team.

Biologics Working Party

To identify areas of common interest and maintain a dialogue with BWP on these areas. To support the work of the EMEA PAT team.

Pharmacovigilance Inspectors

To identify areas of common interest and maintain a dialogue with pharmacovigilance inspectors on these areas.

Heads of Medicines Agencies

When requested to collaborate on HMA initiatives in GMP-related areas. In particular the joint audit programme and the meaning of compliance with the requirements of the marketing authorisation in the context of the duties of the Qualified Person.

To contribute to the development of the benchmarking scheme (BEMA) regarding interactions with GMP/GDP processes.

To identify areas of common interest and maintain a dialogue with the Working Group of Enforcement Officers on these areas.

PIC/S

Ongoing collaboration on areas of mutual interest to ensure harmonisation or equivalence in inspection processes and related matters, and an efficient use of Community inspection related resources. In particular to work jointly on enhanced training in the area of Quality Risk Management.

EDQM

To continue co-operation in areas of common interest, in particular inspections in relation to CEP scheme and sampling and testing of products in the pre-and post-authorisation phases of the centralised procedure.

Industry and Related Stakeholders

To communicate outcomes of discussions to stakeholders through appropriate mechanisms and to maintain dialogue, including at least one meeting with interested parties.

International

To co-operate with wider international partners on the sharing of inspection information.