



European Medicines Agency
Inspections

London, 13 August 2007
Doc. Ref.: EMEA/INS/GMP/470302/2006 corr

MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE GMP/GDP INSPECTORS WORKING GROUP (GMDP IWG)

I. GENERAL CONSIDERATIONS

In 1981 the European Commission established the Working Party on Control of Medicinal Products and Inspections. This working party established the groundwork for harmonisation of Good Manufacturing Practice (GMP) inspections in the European Community and practical implementation of Mutual Recognition Agreements (MRAs) with certain 3rd countries. The working party was also responsible for developing the first European Community GMP Guidance.

In 1996 the Ad Hoc GMP Inspection Services group was set up with the aim of developing specific aspects in relation to the centralised procedure and both groups worked in a parallel and complementary manner. Responsibility for MRAs was transferred to EMEA in 1997 and in 1998 the Commission's working party was dissolved leaving the EMEA group as the only forum for discussion of GMP-related topics at Community level. Given the need for such a forum and the tasks given to EMEA in Regulation (EEC) No. 2309/93 subsequently replaced by Regulation (EC) No. 726/2004, to, inter alia, co-ordinate the verification of compliance with the principles of Good Manufacturing Practice, the tasks of the Commission's Working Party were assumed by the Ad Hoc GMP Inspections Services group. It also serves as the Telematics Implementation Group (TIG) for the EudraGMP database.

The Ad Hoc group has met regularly since 1996, its 45th meeting taking place at the end of 2006 so therefore the term "Ad Hoc" is no longer appropriate.

The Principles and Guidelines of GMP apply systematically across the entire range of medicinal products whether for human or veterinary use and regardless as to whether the active substance used is chemical, biological or herbal in nature and therefore developments at Community level affect a wide range of different stakeholders.

II. MANDATE AND OBJECTIVE

According to Directives 2001/83(2)/EC conclusions reached following a GMP inspection are valid throughout the Community. The GMP/GDP Inspectors Working Group provides input and recommendations on all matters relating directly or indirectly to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) irrespective of the marketing authorisation procedure through different reporting lines as indicated below.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 70 51

E-mail: mail@emea.europa.eu <http://www.emea.europa.eu>

©EMEA 2007 Reproduction and/or distribution of this document is authorised for non commercial purposes only provided the EMEA is acknowledged

Co-operation with the European Commission

- Development and agreement by consensus of GMP/GDP related guidelines for submission to the European Commission for adoption.
- Development, agreement by consensus and maintenance of high-level procedures for the conduct of GMP and GDP inspections, dealing with suspected quality defects, taking regulatory action against manufacturers/distributors and exchange of information. Agreed procedures will be submitted for adoption by the European Commission and published in the Compilation of Community Procedures for Inspections and Exchange of Information.
- Discussion on practical implementation of GMP and GDP guidelines, common interpretation of guidelines and harmonisation of GMP/GDP inspection approaches in the EEA covering national, mutual recognition, decentralised and centralised procedures.
- Development, implementation and monitoring of plans for implementation/operation of MRAs (GMP sectoral Annex) and other similar Community arrangements.
- Formulating advice and comment on GMP/GDP related issues including draft legislation to the European Commission.
- Development and agreement by consensus of other documents within the framework of pharmaceutical guidelines and related documents in connection with GMP/GDP such as Reflection Papers and Questions and Answers to be published on the EMEA website.

Co-operation with EMEA

- Advising on procedures for the coordination of inspections requested by the Scientific Committees.
- Advising on the coordination of sampling and testing of medicinal products authorised by way of the centralised procedure.
- Formulating advice and comment on GMP/GDP related issues to the scientific committees and their working parties.
- Liaison with Good Clinical Practice (GCP) Inspection Services, Quality Working Party (QWP), Biologics Working Party (BWP) and Immunological Working Party (IWP) on matters of mutual interest.
- Facilitating the introduction of new approaches to manufacturing and control methodologies through the EMEA Process Analytical Technology (PAT) team.

Co-operation with Heads of Medicines Agencies (HMA)

- When requested, formulating advice and comment on GMP/GDP related issues to HMA and its working groups.
- Overseeing the Joint Audit Programme and providing annual reports to HMA.
- To contribute to the development of the Benchmarking of European Medicines Agencies with respect to those elements related to GMP/GDP inspections and related processes.
- Liaison and co-operation with the Working Group of Enforcement Officers (WG EO).

Relationship with Coordination groups

- When requested, formulating advice and comment on GMP/GDP related issues to the Coordination Groups for Mutual Recognition and De-centralised Procedures (CMD (h&v)).

Co-operation with other bodies

- Liaison and cooperation on matters of mutual interest with international bodies. In particular: The Pharmaceutical Inspection Cooperation Scheme (PIC/S), European Directorate for the Quality of Medicines and HealthCare (EDQM), World Health Organisation (WHO), and International Conference on Harmonisation (ICH) as well as MRA partners and key regulatory authorities.

- Liaison with interested parties (EFPIA, IFAH, AESGP, APIC, and other specific interested groups).

Communication with the public and external bodies

GMP/GDP Inspectors Working Group will regularly communicate details of its work to external organisations and the general public using appropriate vehicles including in particular the EMEA and HMA websites.

III. COMPOSITION AND RULES OF PARTICIPATION

Chairmanship

Meetings will be chaired by a representative of EMEA, normally the Head of EMEA Inspections Sector or delegate. Members may request, for specific topics coming under the heading of cooperation with HMA that a co-chair is appointed from within the members. Appointment of the co-chair will be by consensus of the members or, if necessary, using the voting rules described in section VI.4.

Membership

Membership is composed of experts nominated by their relevant authority with senior responsibility for and broad experience in the area of GMP/GDP inspections. A replacement, to participate in those exceptional cases where the nominated member is unable to attend a meeting, may also be nominated.

Meeting documentation will be distributed by EMEA to members and any nominated replacements.

There will be one member from each of the EEA Member States with one additional member from each Member State where there is a separate GMP inspectorate for veterinary medicinal products. Members from EU Member States will be reimbursed for attendance at meetings. Additional staff of the authorities may attend with the chairman's agreement, in particular where their participation is needed for a specific topic. The European Commission – DG Enterprise and Industry will also be invited to send a representative to meetings.

The Executive Director of the Agency and members of EMEA secretariat may attend all meetings.

Observers

Observers may include representatives of:

EDQM

EU Liaison Officer for PIC/S.

EU accession countries

MRA partners (Operational)

Specific confidentiality rules will apply to observers. Observers attend at the discretion of the chairman, in line with EMEA policy on observers, and may not be involved when particular items of concern to EEA Member States are discussed, product specific matters or other confidential matters.

Observers are encouraged to participate freely in discussions but shall not take part in any decision-making process.

Other observers may participate with the agreement of the chairperson in consultation with the group where possible.

IV. MEETING FREQUENCY

GMP/GDP Inspectors Working Group shall meet at least 4 times per year. The dates of the meetings shall be included in the work plan. Drafting groups will conduct the majority of their business by correspondence and teleconference but upon reasoned request meetings will be organized by EMEA usually in the margins of the plenary meeting of GMP/GDP Inspectors Working Group.

V. DURATION OF ACTIVITY

Not applicable.

VI. RULES OF PROCEDURE

1. Responsibilities of Chairperson

The Chairperson is responsible for the efficient conduct of the business of GMP/GDP Inspectors Working Group and shall in particular:

- Plan the work of GMP/GDP Inspectors Working Group;
- Monitor, that the rules of procedure are respected;
- Ensure that at the beginning of each meeting that any potential conflict of interest is declared regarding any particular item to be discussed;
- Aim to achieve consensus on issues discussed;
- Decide in exceptional cases, when a vote is necessary;
- Ensure, the regulatory and scientific consistency of recommendations;
- Co-ordinate the work of GMP/GDP Inspection Services with that of the Agency's Scientific Committees, Working Parties and other relevant groups of EMEA, Heads of Medicines Agency or European Commission;
- Report on the activities of GMP/GDP Inspectors Working Group to the Agency's Scientific Committees, Working Parties and other relevant groups of EMEA, Heads of Medicines Agency or European Commission as appropriate

2. Responsibilities of EMEA Secretariat

The EMEA Secretariat shall provide technical, scientific legal, regulatory and administrative support to GMP/GDP Inspectors Working Group. This includes the following:

- Prepare for and co-ordinate the work of GMP/GDP Inspectors Working Group;
- Organize meetings and ensure timely circulation of meeting documents;
- Facilitate the necessary contacts between GMP/GDP Inspectors Working Group and other bodies;
- Ensure adequate co-ordination of the work carried out by GMP/GDP Inspectors Working Group and other concerned groups;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of GMP/GDP Inspectors Working Group;
- Prepare the agenda, table of actions and summary records of meetings;
- Communicate, in a pro-active manner, any output of GMP/GDP Inspectors Working Group to interested parties

- Transmit any recommendations of GMP/GDP Inspectors Working Group to the relevant body for adoption and/or publication as appropriate.

3. Responsibilities of Members

Membership implies a commitment to participate actively in the work of GMP/GDP Inspectors Working Group and to attend meetings regularly

- Members shall ensure that they communicate the views of the Member State, which they represent when contributing to discussions and agreements.
- Members shall ensure that all agreements are communicated within their Member State and should ensure that necessary steps are taken to act upon those agreements as appropriate.
- Members may identify and propose topics for consideration by GMP/GDP Inspectors Working Group. Any proposal should be supported by a problem statement or other adequate justification
- Members tabling documents for discussion at meetings of the GMP/GDP Inspectors Working Group shall respect any guidelines prepared by the group for this purpose or relevant Community guidelines.
- Members shall observe deadlines for submission of documents to EMEA in order that documents can be distributed to the other members in time to enable them to establish the position of the Member State that they represent.

4. Organisation of meetings

- The meetings will be held and minuted in English.
- The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMEA Secretariat, in consultation with the chairperson, at least 14 calendar days before the meeting.
- When a Member of GMP/GDP Inspectors Working Group is unable to participate in a meeting or part of a meeting, or discussion topic due to a conflict of interest, he/she must inform the Secretariat in advance in writing.
- GMP/GDP Inspectors Working Group shall prepare and agree an annual work plan. The work plan shall be regularly reviewed and updated as necessary.
- A quorum is required for all internal decisions or recommendations of GMP/GDP Inspectors Working Group. This shall be reached when two thirds of the total members of the GMP/GDP Inspectors Working Group is present.
- Whenever possible, internal decisions or recommendations of the group shall be achieved by consensus. If such a consensus cannot be reached the chair or any member may propose a vote. Each Member State shall have 2 votes, 1 on behalf of the veterinary medicinal products sector and 1 on behalf of the human medicinal products sector unless the subject of the vote affects only one of these sectors, in which case only one vote per member state shall be permitted. An absolute majority (i.e. favourable votes by at least half of the total number of members eligible to vote plus one) shall be required. Divergent positions shall be mentioned in the summary record of the meeting.
- Prior to any vote the group will agree, depending on the nature of the topic, whether any members should not participate in the vote.

5. Drafting Groups

When further consideration is required in order to prepare proposals on specific topics drafting groups may be convened constituted of members of GMP/GDP Inspectors Working Group or other experts, as appropriate. The drafting group will report to GMP/GDP Inspectors Working Group. Rules of procedure for drafting groups will be developed.

6. Guarantees of independence

The members of GMP/GDP Inspectors Working Group and experts referred to above shall not have any direct interests in the pharmaceutical industry that could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the Agency, which is accessible to the public, on request at the Agency's office.

Members and experts attending meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (EMEA/H/31653) are applicable to members of GMP/GDP Inspectors Working Group and experts participating in the activities of GMP/GDP Inspectors Working Group.

7. Code of conduct

Members of GMP/GDP Inspectors Working Group and experts participating in EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

8. Contacts with Interested Parties

- Where relevant, GMP/GDP Inspectors Working Group will establish contacts, on an advisory basis, with parties concerned with the manufacture and control of medicinal products.
- The pharmaceutical industry, health care professionals, patients/consumers or other interested parties have the opportunity to comment in writing on draft guidelines and general regulatory developments during the public consultation of the documents.
- When considered appropriate by GMP/GDP Inspectors Working Group, oral or written presentations by interested parties can be made during meetings at earlier stages of development of guidelines. GMP/GDP Inspectors Working Group may also meet with interested parties to discuss general matters or specific issues.
- In any case, GMP/GDP Inspectors Working Group shall neither conduct any deliberations nor reach any formal Agreements in the presence of members of interested parties.
- Before any consultation session, interested party representatives and GMP/GDP Inspectors Working Group members will communicate to the EMEA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Chairperson and circulation by the EMEA secretariat.

9. General Provisions

Members of GMP/GDP Inspectors Working Group as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy. When participating in international or other fora on behalf of GMP/GDP Inspectors Working Group, members shall ensure that the views expressed are those of GMP/GDP Inspectors Working Group. When participating in international or other fora not specifically on behalf of GMP/GDP Inspectors Working Group, members shall make clear that the views expressed are their own views, or those of the National Competent Authority, and not those of GMP/GDP Inspectors Working Group.