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Compliance and Inspection

Workplan for GCP Inspectors Working Group for 2010

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1. INTRODUCTION

The GCP Inspectors Working Group (GCP IWG) was established by the EMEA in 1997, within the scope of article 57(1)(i) of Regulation (EC) No. 726/2004.

This group focuses on harmonisation and co-ordination of GCP related activities at Community level. The group activities for this year are outlined in this document and the priorities of the group will be:

- Provide guidance in relation to quality risk management in clinical trials
- Develop processes in relation to GCP and inspections of clinical trials conducted in third countries
- Publication of anonymised GCP inspections findings

2. MEETINGS SCHEDULED FOR 2010

- 24 – 25 February 2010
- 09 – 10 June 2010
- 08 – 09 September 2010
- 01 – 02 December 2010

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The following joint meetings will take place:

- Joint meeting with CHMP[1] assessors
- Joint meeting with the CTFG[2]
- Joint meeting with interested parties

A number of subgroup meetings to discuss specific topics and draft documents will be organised to coincide with the main meetings when possible but if needed a limited number of additional meetings or teleconferences will be scheduled (see section 7):

- GCP-GMDP[3] subgroup
- GCP-CMD(h)[4] subgroup
- Computer systems subgroup
- Quality risk management in clinical trials subgroup
- GCP IWG-CTFG

Delegates from this group are also involved in the Agency's multidisciplinary Working Group on 3rd country clinical trials.

3. INSPECTIONS CONDUCTED IN SUPPORT OF THE CENTRALISED PROCEDURE

Development and co-ordination of GCP inspections relating to Centrally Authorised Products.

- This is an ongoing activity and includes coordination of re-inspections when needed.

Maintenance of the information on GCP inspections for Centrally Authorised Products.

- To enter the information on GCP inspections in the EudraCT database.
- To develop the GCP module of the Corporate GxP database for the coordination of GCP inspections for Centrally Authorised Products.

4. HARMONISATION TOPICS

Procedures and Guidance documents

[1] Committee for Medicinal Products for Human Use
[2] Clinical Trials Facilitation Group
[3] Good Manufacturing Distribution Practice
[4] The Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

- To update, as needed, the existing GCP Inspection procedures and guidance for GCP inspections conducted in the context of the Centralised Procedure.
- To prepare the following guidance on GCP Inspection in accordance with article 29 of Directive 2005/28/EC, and to publish it in Chapter IV, Volume 10 of the Rules Governing Medicinal Products in the European Union:
- Actions taken after completion of Good Clinical Practice inspection.

Inspection cooperation in the community

a) Cooperation between MS

- To continue with joint inspections of sites involving inspectorates from more than one Member State.

b) Cooperation with 3rd countries

- To develop principles, processes and opportunities for joint inspections with 3rd countries.

Training and development

- Develop peer review of case studies.
- Sharing and discussion of inspection reports, including grading of anonymised findings.
- Develop and monitor opportunities for joint inspections.
- Provision of on the job training and a process for ensuring that all members gain experience through this.
- Development of training tools for GCP inspections.
- Develop opportunities for lectures/workshops at the time of GCP IWG meetings, on special topics, by members of the group and by invited guests.
- Conduct the 8th GCP IWG Training Workshop to be co-hosted by a National Competent Authority and the Agency.
- Conduct the 1st basic GCP IWG Training Course to be co-hosted by a National Competent Authority and the Agency.
- To develop opportunities for inspectors from developing countries authorities to participate in GCP IWG training basic course and/or workshop mentioned above, to join EU inspections taking place in their countries as observers, or other related opportunities. To liaise with WHO in this context.

5. TOPICS OF INTEREST

- To continue support for the routine GCP inspection programme supporting the centralised procedure.

- To further develop processes related to GCP and inspections of clinical trials conducted in third countries (ethical and quality considerations) and to support the conduct of inspections in those countries.
- To finalize the following reflection papers:
    - Reflection paper on expectations for electronic source documents used in clinical trials.
    - Reflection paper on quality risk management in clinical trials.
    - Reflection paper on guidance for good clinical practice laboratories
- To revise the training document on triggers for GCP inspection
- To discuss and prepare a document with specific triggers for assessors in the context of the assessment of acceptability of clinical trials from 3rd countries.

6. COLLABORATION WITH EUROPEAN COMMISSION

Expert support on GCP related matters, in particular inspection

Implementation of Directive 2001/20/EC and of Directive 2005/28/EC and related guidance documents

- Develop guidance, additional documents related to this, or provide input and advice on guidance or other texts being prepared by the Commission - as requested by the Commission and in conjunction with other parties as appropriate.

EudraCT Database

- To advise the EudraCT TIG, when needed, on inspection issues related to further development of the database.
- To work on standards report queries for the EudraCT data warehouse to support the inspection processes.

EU enlargement

- To assist the candidate countries Croatia, Former Yugoslav Republic of Macedonia and Turkey and the potential candidate countries Albania, Bosnia and Herzegovina, Montenegro, Serbia and Kosovo (under UNSC Resolution 1244/99), to develop their GCP Inspection roles.
- To further develop contacts and collaboration with these countries in the field of GCP Inspections.
- To invite these countries to observe meetings of the GCP Inspectors Working Group.
- To contribute to workshops in candidate counties on GCP matters

Regulation on Advanced Therapies

- To monitor the implementation of GCP guidelines on ATIMPs in clinical trials of advanced therapies.

Paediatric Regulation

- To establish good working contacts with the Paediatric network

Variations Regulation

- To monitor the implementation of the variation regulation in particular when any impact on GCP inspection processes is foreseen.

7. LIAISON WITH OTHER GROUPS

GMDP[5] IWG

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

PhV IWG[6]

- To maintain a dialogue with the Pharmacovigilance Inspectors Working Group on areas of common interest and in particular concerning pharmacovigilance in relation to clinical trials.

CTFG[7]

- Collaboration on areas of mutual concern in the area of supervision of clinical trials conducted in the Community and in particular to prepare, through the GCP IWG-CTFG subgroup, a pilot programme of inspections focused on particular priorities such as central laboratories, CROs, sponsor/legal representatives which may have an impact on many clinical trials.

CMD(h)

- To maintain a dialogue with CMD(h), in particular through the GCP/CMD subgroup, on areas of common interest and in particular concerning Bioequivalence/Bioavailability studies.
- The implementation of a pilot process for the preparation of an annual risk based programme of routine GCP inspections of the contract research organisations most often used in the conduct of the bioequivalence trials included in marketing authorisation applications for generic products in the mutual recognition and decentralised procedure has been finalised. The pilot will be run for 12 months to gain experience.

[5] Good Manufacturing and Distribution Practice Inspectors Working Group
[6] Pharmacovigilance Inspectors Working Group
[7] Clinical Trials Facilitation Group

- To finalize the document for assessors on triggers for selection of applications and sites to be inspected in the context of generic applications.

Heads of Medicines Agencies

- When requested to collaborate on HMA initiatives in GCP-related areas, in particular in the area of supervision of clinical trials conducted in the Community and in relation to inspections in 3rd countries.
- To contribute to the development of the benchmarking scheme (BEMA) regarding interactions with GCP processes.

PIC/S[8]

- 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.

Other Regulatory Agencies

- To operate the pilot programme of the European Medicines Agency-FDA GCP initiative
- Development of contacts between EU and 3rd country agencies, on GCP matters.
- To develop inspection processes and contacts in the context of clinical trials conducted in developing countries through liaison with WHO and developing country inspectorates. To co-operate with wider international partners on the sharing of inspection information.
- To develop contacts with the paediatric network.

Other Bodies

- Develop contact with Ethics Committees, including the preparation of a possible joint meeting.

[8] Pharmaceutical Inspection Co-operation Scheme