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Compliance and Inspection

# Workplan for GCP Inspectors Working Group for 2012

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## 1. Introduction

The GCP Inspectors Working Group (GCP IWG) was established by the EMA 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:

- To continue with the progress of the CHMP[1] Work programme 2011-2013 related to GCP inspections to cover the following main topics:
  - Triggering inspections
  - Guidance for assessors on how to integrate GCP findings in the overall risk/benefit assessment
  - Follow up of inspections findings
- To work closely with the FDA on the possibility for implementing a similar pilot FDA[2]-EMA GCP initiative in the field of generics
- To implement actions arising from the "Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EU Regulatory Authority" and contribute to establishment of a network for international cooperation on GCP inspections
- To provide expert support to the European Commission on GCP related matters and inspections in relation to its revision of the Clinical Trials legislation

## 2. Meetings scheduled for 2012

- 28 Feb-29 Feb 2012
- 21-23 May 2012

[1] Committee for Medicinal Products for Human Use
[2] Food and Drug Administration

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- 12-13 September 2012
- 10-12 December 2012

The following joint meetings will take place:

- Joint meeting with interested parties on 21 May 2012
- Joint meeting with CHMP clinical assessors on 10 December 2012

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-CMD(h)[3] subgroup
- Quality risk management in clinical trials subgroup
- GCP IWG–CHMP clinical assessors
- GCP-CTFG[4] subgroup

# 3. Inspections conducted in support of the centralised procedure

- To ensure the allocation of GCP inspection resources for the conduct of routine and triggered GCP inspections in the context of the centralized procedure
- To ensure entry of information on GCP inspections in the EudraCT database

# 4. Harmonisation topics

## *4.1. Procedures and Guidance documents*

- 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 documents in relation to the implementation the CHMP Work programme 2011-2013 related to GCP inspections:
  - Points to consider document for assessors and inspectors on the interpretation of inspection findings and their impact on risk benefit evaluation and the development of the CHMP opinion on an application
  - Policy for follow-up of inspection findings, including those findings to be followed up as part of the opinion forming process and those to be followed up outside of that process for the future quality of the inspected entity
  - Points to consider document for assessors and inspectors on the identification of triggers for inspection, their investigation and scope
  - Revised policy on the selection of routine inspections and their scope

[3] The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
[4] Clinical Trials Facilitation Group

### *4.2. Inspection cooperation in the EU*

- To finalise the procedure on the coordination of GCP inspections of EU interest, outside the context of the marketing authorization procedure, and to be performed under national programmes
- To perform joint inspections

### *4.3. Training and development*

- To conduct the 10th GCP IWG Workshop
- To develop opportunities for inspectors from countries outside Europe:
  - to invite them to participate in the above mentioned GCP IWG workshops
  - to join EU inspections taking place in their countries as observers
  - Other related training opportunities. To liaise with WHO in this context

## 5. Topics of interest

- To finalise the following reflection papers with the comments form the public consultation and progress its publication:
  - Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EU Regulatory Authority
  - Reflection Paper on the laboratories that perform the analysis or evaluation of clinical trials samples
  - Reflection paper on quality risk management in clinical trials with the comments from the public consultation (end of consultation 15/02/2012)
  - Reflection paper on the Use of Interactive Response Technologies (Interactive Voice/Web Response Systems) in Clinical Trials (end of consultation 15/02/2012)
- To prepare a reflection paper on the inspector's expectations on TMF
- To prepare Q&A documents, as required, to clarify the inspectors' expectations with respect to certain processes and procedures

## 6. Collaboration with European Commission

- To provide expert support on GCP related matters and inspections and in particular in its revision of the Clinical Trials legislation
- 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), in development of their GCP Inspection roles
  - To invite these countries to observe meetings of the GCP IWG
  - To contribute to workshops in candidate countries on GCP matters

- ATIMPs[5] in clinical trials of Regulation on Advanced Therapies:
  - To monitor the implementation of GCP guidelines on advanced therapies in collaboration with CTFG and CAT[6]
- Paediatric Regulation and orphan drugs:
  - To develop procedures for inspections arising from issues raised by PDCO[7] or COMP[8]

# 7. Liaison with other EU groups

## 7.1. GMDP[9] IWG

- To maintain a dialogue with the GMDP group on areas of common interest

## 7.2. PHV[10] IWG

- To maintain a dialogue with the PhV IWG on areas of common interest and in particular concerning pharmacovigilance in relation to clinical trials

## 7.3. CTFG

- Collaboration on areas of mutual concern in the area of supervision of clinical trials conducted in the Community and in particular to finalize and implement the following procedure:
  - Procedure for the coordination and conduct of GCP inspections of EEA interest outside the context of a Marketing Authorization procedure

## 7.4. 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
- To prepare the 2012 programme 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 and to prepare

## 7.5. PIC/S[11]

- To maintain the existing links with the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

## 7.6. 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 EU and in relation to inspections in countries outside EU

[5] Advanced Therapy IMPs
[6] Committee for Advanced Therapies
[7] Paediatric Committee
[8] The Committee for Orphan Medicinal Products
[9] Good Manufacturing and Distribution Practice Inspectors Working Group
[10] Pharmacovigilance Inspectors Working Group
[11] Pharmaceutical Inspection Co-operation Scheme

### *7.7. Other bodies*

- Develop contact with Ethics Committees, including the preparation for? a possible joint meeting

## 8. Liaison with international partners

- To continue with the operational phase of the European Medicines Agency-FDA GCP initiative and to work closely with the FDA on the possibility to implement a similar pilot programme for generics
- To develop principles, processes and opportunities for joint inspections with 3rd countries
- To establish a network for international cooperation on GCP matters and inspections