EUROPEAN COMMISSION
ENTERPRISE and INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

GUIDANCE DOCUMENTS CONTAINING THE COMMON PROVISIONS ON THE CONDUCT OF GCP INSPECTIONS BY COMPETENT AUTHORITIES OF THE DIFFERENT MEMBER STATES

GUIDANCE FOR THE COMMUNICATION ON GOOD CLINICAL PRACTICE INSPECTIONS AND FINDINGS

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This document forms part of the guidance documents containing the common provisions on the conduct of GCP inspections . Please check for updates in the Volume 10 of the Rules Governing Medicinal Products in the European Union.
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm

1 INTRODUCTION

The scope of this document is to provide guidance for communication of GCP inspection reports and findings following a GCP inspection carried out by competent authorities of the different Member States, which may take place on any of the following occasions:

(a) before, during or after the conduct of clinical trials;
(b) as part of the verification of applications for marketing authorisation;
(c) as a follow-up to the granting of authorisation.

The scope of this guidance is to provide unified standards on the conduct of GCP inspections that are applicable for any site to be inspected. This guidance takes into account the following procedure:

- *"Guidance for Preparation of Good Clinical Practice inspection reports"*, which describes the contents of GCP inspection reports and the procedure for their approval.

2 REPORTING

Following the conduct of the GCP inspection a report will be written in accordance with the *"Guidance for Preparation of Good Clinical Practice inspection reports"*.

The circulation of inspection reports (deadline to reply) will be set according to the *"Guidance for Preparation of Good Clinical Practice inspection reports"*, and national procedures, if applicable.

An inspection report will be defined as complete when the inspector(s) has/have assessed the responses from the inspectee(s) on the findings described in the original inspection report.

3 REPORTING IN EUDRACT

It is the responsibility of the Lead Inspector to ensure that the GCP inspection is documented in the EUDRACT database for inspections in accordance with the Commission Directive 2005/28/EC. This database entry should be performed as soon as possible following the actual conduct of the GCP inspection.

4 COMMUNICATION WITHIN A MEMBER STATE

The GCP inspection report will be distributed and circulated within a Member State in accordance with the local regulations (see also *Guidance for Preparation of Good Clinical Practice Inspection Reports, Section 2.3, Forwarding the IR*). Furthermore, it is the responsibility of the Lead Inspector to ensure that relevant staff in the Member State receives adequate information about the GCP inspection and its findings, where this information may be of value for the receiving staff in future decision or evaluations.

5 COMMUNICATION WITHIN A MEMBER STATE SHOULD TEXT FROM GUIDANCE

Essential information about the inspection and its findings is entered in the EUDRACT database; therefore, the GCP inspection report will normally not be circulated to other Member States Competent authorities. Under specific circumstances it might, however, be necessary to share the information obtained during an inspection and such request will be in accordance with the "*Guidance for exchange of GCP Inspection Reports according to Directive 2001/20/EC Article 15 (2)"*. In order to ensure that relevant findings are communicated within the European Community it is the responsibility of the Lead Inspector to inform other Member States about these findings. This can be

performed as a communication during the GCP Inspectors Working Group meetings at the EMEA under agenda items "GCP Inspection and compliance issues of community interest". If a finding has direct bearing on the quality of the study or patient safety and/integrity in other participating Member States in the study, it is the responsibility of the Lead Inspector to contact the relevant GCP Inspector in those countries.

5 REFERENCES

- Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such product.
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, as amended.
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- EUDRALEX Volume 10 - Clinical trials, of the Rules Governing Medicinal Products in the European Union: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm