



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 CONDUCT OF GOOD
CLINICAL PRACTICE INSPECTIONS**

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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

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1 INTRODUCTION

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 procedures:

- '*Guidance for preparing for GCP inspections*' which describes the steps immediately before the conduct of an inspection and particularly the inspection plan.
- '*Procedure for reporting on GCP inspections*', which describes the contents of GCP inspection reports and the procedure for their approval.

During the preparation of the inspection an inspection plan is established. This plan will depend on the scope of the inspection. The lead inspector (LI) will conduct the inspection at the selected site.

Inspections will be conducted within the framework of this document and local procedures. The emphasis of the inspection may vary depending on whether or not the inspection is related to the assessment of a Marketing Authorization Application, to the routine surveillance of clinical trials performed in the Member States, or to another specific purpose.

2 OPENING MEETING

Before the start of the inspection an opening meeting must take place between the inspector(s) and the inspectee(s).

The purpose of an opening meeting is to:

- Introduce the inspector(s) to the inspectee(s).
- Explain the regulatory framework for the conduct of the inspection.
- Be informed of any national, departmental or other practices which affect the implementation of quality systems or Good Clinical Practice compliance by the inspectee(s).
- Identify the distribution of duties and functions for the conduct of the trial among the inspectee(s).
- Review the scope and the objectives of the inspection.
- Provide a short summary of the methods and procedures to be used for the conduct of the inspection.
- Confirm that the resources, documents and facilities needed by the inspector(s) are available.
- Confirm the time and date for the closing meeting and any interim meetings.
- Clarify the inspection plan, if necessary.

3 CONDUCT OF THE INSPECTION/COLLECTING INFORMATION

The inspection activities should be detailed on the inspection plan. Nevertheless during the inspection, the inspector(s) may adjust the plan to ensure the inspection objectives are achieved.

Sufficient information to fulfil the inspection objective(s) should be collected through examination of relevant documents with direct access, interviews and observation of activities, equipment and conditions in the inspected areas.

If access to records or copying of documents is refused for any reason or there is any withholding of documents or denial of access to areas to which the inspector has legal access, these refusals should be documented and included in the inspection observations.

For each type of site to be inspected as well as for the archiving, an annex identifies detailed items that may be checked during the inspection.

- Annex I: conduct of the inspection at investigator site.
- Annex II: conduct of the inspection at clinical laboratories.
- Annex III: conduct of the computer systems inspection.
- Annex IV: conduct of the inspection at sponsor site and/or Contract Research Organisations.
- Annex V: conduct of inspection of phase I units

For each item it should be checked, if applicable, how data was generated, collected, reported, analysed or modified.

4 INSPECTION OBSERVATIONS AND MINUTE OF THE INSPECTION

All inspection observations should be documented. If appropriate, copies should be made of records containing inconsistencies or illustrating non-compliance.

At the end of the inspection, the inspector(s) should review all observations to determine which are to be reported as non-compliance and/or quality system deficiencies. The inspector(s) should then ensure that these are documented in a clear, concise manner and are supported by objective evidence. All reported observations (findings) should be identified with reference to specific requirements of the standard(s) or other related documents against which the inspection has been conducted. The names and titles of persons interviewed or present during the inspection meetings and the details of the inspected organisation should be documented.

If required by local regulations, the inspection observations may be collected in a minute (or similar) to be written by the inspector(s) at the end of the inspection.

5 CLOSING MEETING WITH THE INSPECTEE (S)

At the end of the inspection, the inspector(s) should hold a closing meeting with the inspectee(s). The main purpose of this meeting is to present inspection findings to the inspectee(s) and appropriate management board, if necessary, to ensure that the results of the inspection are clearly understood and that there is no misunderstanding by either the inspector(s) or the inspectee(s).

Issues to be followed up by the inspectees should be addressed, including any additional documents that may need to be sent to the inspection team.

During this meeting the inspector(s) should give details on the circulation of inspection reports (i.e. deadline to reply) according to the '*Procedure for reporting on GCP inspections*', and national procedures, if applicable.

6 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