Attachment 1: International orders and guidelines with respect to GCP inspections

Order/Guideline	Short description	Content with respect to GCP inspections	Comment	Source/Link
EC No. 726/2004	Aim: Definition of common procedures for the approval, supervision and pharmacovigilance of pharmaceutical drugs in humans and animals.	Article 57: (…) The agency, acting particularly through its agencies, shall undertake the following tasks: … i) coordinating the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice and the verification of compliance with pharmacovigilance obligations.	Replaces order 2309/93 aiming at improving clarity. Only very general information on inspections.	EUDRALEX Volume 1, chapter 'regulations', in all EU languages: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm
Guideline 2001/20/EC	„Clinical Trials Directive" Guideline 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.	Article 15 deals with inspections, which can be conducted at the trial site or sites, the manufacturing site of the investigational medicinal product, any laboratory used for analyses in the clinical trial and/or the sponsor's premises. The inspections shall be conducted by the competent authority of the Member State concerned, which shall inform the Agency; they shall be carried out on behalf of the Community and the results shall be recognised by all the other Member States. These inspections shall be coordinated by the Agency. Reference to „detailed guidelines on the documentation relating to the clinical trial", which are the qualification of the inspectors and description of the procedures → see guideline 2005/28/EC.	Guideline 2001/20/EC was implemented in Germany into national law in 2004 within the 12th Amendment of the German Drug Law (Arzneimittelgesetz [AMG]) and the GCP order.	EUDRALEX Volume 1, chapter 'directives', in all EU languages: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm
Guideline 2005/28/EC	„GCP Directive" Guideline 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 products.	In chapter 5 requirements for inspectors are described; chapter 6 details on the inspection procedures. Article 23 (1) of chapter 6 lists following occasions for GCP inspections: (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.	Article 29 points to more detailed documents for the description of inspections, further on the necessity of harmonization between member states. → Implementation in EUDRALEX Volume 10, Chapter IV.	EUDRALEX Volume 1, chapter 'directives', in all EU languages: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm

Attachment 1 (continued): International orders and guidelines with respect to GCP inspections

Order/Guideline	Short description	Content with respect to GCP inspections	Comment	Source/Link
EUDRALEX Volume 10 – Clinical trials 2006 Chapter IV: Recommendation on Inspections	EUDRALEX Volume 10 contains guidance documents applying to clinical trials. Chapter IV contains details for: Qualification and Training of GCP-inspectors, and conduction of GCP inspection.	Part 1: Detailed description on the prerequisites for inspectors Part 2: Overview of the administrative framework; Appendix on topics for the guidance documents requested in 2005/28/EC: Selection of the trials/sites to be inspected: ▪ Coordination/co-operation with other organisations involved in assessing GCP requirements ▪ Assessing GCP requirements ▪ Preparation of GCP inspections ▪ Conduct of GCP inspections ▪ Preparation of GCP inspection reports ▪ Record keeping and archiving of documents obtained or resulting from the GCP inspection ▪ Actions taken after completion of GCP inspection ▪ Communication on Good Clinical Practice inspections and findings	Article 15 of the directive 2001/20/EC requires detailed guidance for the "qualification of inspectors". This requirement is fulfilled with chapter 5 of the guideline 2005/28/EC as well as with chapter IV of volume 10.	EUDRALEX Volume 10, Chapter IV: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev10.htm
Procedural requirements EMEA GCP Inspectors Working Group on GCP Inspections	Description of procedures for the coordination, preparation, conduct and reporting of GCP inspections carried out in the context of the Centralised Procedure.	Details regarding the content and scope of inspections at investigational sites, laboratories, sponsors, CROs, phase I units as well as requirements for IT systems, file structure and archiving.	→ see also national procedural requirements of the ZLG laid down in Table 2.	http://www.emea.europa.eu/Inspections/GCPproc.html