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**Principal Documents taken into account for the preparation of procedures
for GCP inspections requested by the EMEA**

- 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.
- 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.
- [Directive 2003/94/EC](#) laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use
- Council Regulation (EC) No 1905/2005 of 14 November 2005 amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency.
- Rules for the implementation of Regulation (EC) No 297/95 as amended on fees payable to the European Medicines Agency and other measures (EMEA/MB/356866/2005)
- EUDRALEX Volume 4- Medicinal Products for Human and Veterinary Use : Good Manufacturing Practice
- EUDRALEX Volume 9- Pharmacovigilance
- EUDRALEX Volume 10- Clinical trials
- Note for guidance on Clinical Practice CPMP/ICH/135/95.
- CPMP/ICH/381/95 Validation of analytical procedures: definitions and terminology
- CPMP/ICH/281/95 Validation of analytical procedures: methodology
- CPMP/PhVWP/1618/01: "Position Paper on Compliance with Pharmacovigilance Regulatory Obligations", Adopted 5 December 2001.
- Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95).
- Note for Guidance on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (CPMP/ICH/288/95).
- Clinical Safety Data Management: Data elements for transmission of individual case safety reports (CPMP/ICH/287/95, modification).
- Structure and Contents of Clinical Study Reports (CPMP/ICH/137/95).
- Declaration of Helsinki