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

This list of documents is used as the reference list for the following EMA procedures:
- Procedure for coordinating GCP inspections requested by the EMA/CHMP
- Procedure for preparing GCP inspections requested by the EMA/CHMP
- Procedure for conducting GCP inspections requested by the EMA/CHMP
- Procedure for reporting of GCP inspections requested by the EMA/CHMP.

The below list of documents is not an exhaustive list. The EMA website, section "Good clinical practice", should also be consulted for additional guidance documents.
The documents are to be taken into account where and if applicable.

- 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 (where applicable).

- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

- Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council.

- 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 (where applicable).

- 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, applicable version.

- EUDRALEX Volume 4 - Good Manufacturing Practice (GMP) guidelines.

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- EUDRALEX Volume 9 – Pharmacovigilance guidelines.
- EUDRALEX Volume 10 - Clinical trials guidelines.
- EUDRALEX – Advanced therapies guidelines.
- ICH E6 - Guideline for good clinical practice (EMA/CHMP/ICH/135/1995), applicable version.
- ICH Q2 - Validation of analytical procedures: text and methodology (CPMP/ICH/381/95).
- Guideline on Good Pharmacovigilance Practices.
- ICH E2A - Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), applicable version.
- ICH E2C - Note for Guidance on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (CPMP/ICH/288/95), applicable version.
- ICH guideline E2B (R3) on electronic transmission of individual case safety reports (ICSRs) – data elements and message specification - implementation guide, applicable version.
- ICH E3 - Structure and Contents of Clinical Study Reports (CPMP/ICH/137/95).
- ICH E8 – General Considerations for Clinical Trials (CPMP/ICH/291/95), applicable version.
- ICH E19 – Optimisation of Safety Data Collection (EMA/CHMP/ICH/173706/2019), applicable version.
- Declaration of Helsinki, applicable version.
- Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products (EMEA/CHMP/SWP/28367/07), applicable version.
- Risk proportionate approaches in clinical trials. Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use.