

What's New February 08

EMA/DG Enterprise Guidelines

Notice to Applicants - Vol 2

- Guideline on the Packaging information of medicinal products for human use authorized by the community ([Link](#))
- Volume 2B - Questions and Answers ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\01. EU\NtA (Rules Governing MPs in EU)\Volume 2 Notice to Applicants >

Notice to Applicants - Vol 4

- Revision of Part I Chapter 1 - Quality Management ([Link](#))

As an implementation measure related to the ICH Q9 guideline on quality risk management, the European Commission has reviewed the existing GMP provisions. With the revision of GMP Part I, Chapter 1 on Quality Management quality risk management becomes an integral part of a manufacturer's quality system. This concept will also be considered in a future revision of GMP Part II.

- GMP Annex 20 - Quality Risk Management ([Link](#))

The ICH Q9 guideline as such has been implemented with the new Annex 20. It should be noted that the new Annex is not intended, however, to create any new regulatory expectations; but rather provides an inventory of internationally acknowledged risk management methods and tools together with a list of potential applications at the discretion of manufacturers.

- Revision of GMP Annex 1 - Manufacture of sterile medicinal products ([Link](#))

The revision of the Annex was necessary in particular to align the classification table for environmental cleanliness of clean rooms with ISO standards. Two public consultations took place in preparation of this new revision. The revised Annex 1 provides supplementary guidance on the application of the principles and guidelines of GMP to sterile medicinal products. The guidance has been updated in four main areas:

- Classification table for environmental cleanliness of clean rooms, and associated text
- Guidance on media simulations
- Guidance on bioburden monitoring
- Guidance on capping of freeze-dried vials

The new annex should be implemented by 01 March 2009 except for the provisions on capping of freeze-dried vials, which should be implemented by 01 March 2010.

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\01. EU\NtA (Rules Governing MPs in EU)\Volume 4 Good Manufacturing Practices >

Notice to Applicants - Vol 10

- Ethical considerations for clinical trials on medicinal products conducted with the paediatric population ([Link](#))
- Draft Guidance on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the EMEA, in accordance with article 41 of Regulation No. (EC) 1901/2006 ([Link](#))
- Consultation on the Revised Annexes 1,2 and 3 on the Clinical Trial Application Form, the Substantial Amendment Form and the Declaration of the end of a Clinical Trial Form to the ' Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial' ([Link](#))

Annexes 1, 2 and 3 on the Clinical Trial Application Form, the Substantial Amendment Form and the Declaration of the end of a Clinical Trial Form to the ' Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial' have been revised in order to take into consideration needs stemming from Regulation (EC) No 1901/2006, of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, from the Guideline on Strategies to Identify and Mitigate Risks for First-in-Human Clinical Trials with Investigational Medicinal Products (Doc. Ref.EMEA/CHMP/SWP/28367/07, of 19 July 2007) and to clarify the submission of information on the results of clinical trials in view of its publication. These revised annexes will be required once the changes have been implemented in EudraCT version 7.0 on the EMEA website. It is anticipated that version 7.0 will be available towards the end of 2008.

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\01. EU\NtA (Rules Governing MPs in EU)\Volume 10 Clinical Trials >

Clinical

- Concept paper on development of Guideline on the treatment of attentional deficit hyperactivity disorder (ADHD) ([Link](#))
- Concept paper on revision of the Points to Consider on the clinical evaluation of new agents for invasive fungal infection ([Link](#))
- Concept paper on the development of a CHMP Guideline on the clinical investigations of medicinal products for the treatment of pulmonary hypertension ([Link](#))
- Concept paper on Haematological malignancies ([Link](#))
- Appendix to the Guideline on the evaluation of anticancer medicinal products in man - Methodological considerations for using progression-free survival (PFS) as primary endpoint in confirmatory trials for registration ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\01. EU\Guidelines\Non-clinical\Toxicology >

Non-clinical

- Guideline on Carcinogenicity evaluation of medicinal products for the treatment of HIV infection ([Link](#))
- Reflection paper on In vitro investigation of mitochondrial toxicity of anti-HIV nucleoside reverse transcriptase inhibitors ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\01. EU\Guidelines\Non-clinical\Toxicology >

Herbals

- Reflection paper on Markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\01. EU\Guidelines\Quality and Biologicals\Quality\Herbal Medicinal Products\Concept Papers >

RI Topics

Paediatrics

- Recommendation of the Paediatric Committee to the European Commission regarding the symbol ([Link](#))
- Re-examination procedure of paediatric investigation plan and/or waiver opinions by the Paediatric Committee (PDCO) ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\03. RI Topics\09. Paediatric (R) >

eCTD

- EMEA implementation of electronic-only submissions and eCTD submissions in the Centralised Procedure: Statement of Intent ([Link](#))
- EMEA implementation of electronic-only submissions and eCTD submissions in the Centralised Procedure: Questions and Answers ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\03. RI Topics\04. CTD and e-CTD (R)\e-CTD >

New Legislation

- Overview of Comments on guideline on Criteria for requiring one additional five-year renewal for centrally authorised medicinal products ([Link](#))

< The above documents can be found in S:\2.RI\RI - ISO 9001-2000\03. RI Topics\06. New Legislation\Adopted Guidance Documents >

Miscellaneous

Vaccines

- Report of EMEA expert meeting on the revision of the core SPC and Note for guidance for human normal immunoglobulin for intravenous use (IVIg) ([Link](#))

< The above documents can be found in S:\2.RI\Regulatory Intelligence\02. Miscellaneous Documents 2007\Vaccines >

Biotech

- BMWP/BWP Workshop on Immunogenicity assessment of therapeutic proteins
- EMEA Workshop on Viral/Vector shedding

< The above documents can be found in S:\2.RI\Regulatory Intelligence\02. Miscellaneous Documents 2007\Biotech\EMEA workshop on Immunogenicity of therapeutic proteins >

GMP

- Update on Q&A regarding Annexes 1, 8 and 13 ([Link](#))