



Stakeholders' Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22

Revision of Good Manufacturing Practice (GMP) Guidelines Chapter 4 (Documentation), Annex 11 (Computerised Systems) and New Annex 22 (Artificial Intelligence)

Target audience

Public health stakeholders involved in GMP activities

The organisations representing stakeholders involved in GMP activities are encouraged to take part in the consultation and to receive all the comments of this consultation from their members, to compile and send the comments via the EU Survey tool.

Why we are consulting

In light of the rapid advancement of digital technologies and the implementation of AI systems in pharmaceutical manufacturing, the update of Good Manufacturing Practice (GMP) guidelines is essential to ensure that they continue to provide clear, practical and relevant guidance for manufacturers and national competent authorities.

The revision of GMP Annex 11 and Chapter 4, along with the introduction of a dedicated Annex 22 on Artificial Intelligence aim at supporting innovation in the manufacturing of medicines and ensuring regulatory harmonisation.

To maintain the global alignment of standards, achieving at the same time assurance for the highest quality, these 3 documents have been drafted by the EMA GMDP-Inspectors Working Group in cooperation with the PIC/S.

Revision of Chapter 4 - Documentation

The revised Chapter 4 incorporates changes which highlight the importance of documentation in GMP compliance and support the use of new technologies, hybrid solutions, and new services in the management of documentation. Risk-management principles are now central and integrated within the data governance system to ensure the accuracy, integrity, availability, and legibility of documents across all formats—paper, digital, or hybrid. All documentation, whether in text, image, video, or audio form, must remain complete and readable throughout its lifecycle. The guideline also clarifies the

requirements for the management of electronic records, signatures, and data integrity while ensuring consistency with the concurrent revision of Annex 11.

- [Draft guidelines: Revised Chapter 4 - Documentation](#)

Revision of Annex 11 – Computerised Systems

The revised Annex 11 establishes enhanced requirements for the lifecycle management of computerised systems, mandating that Quality Risk Management principles be comprehensively applied during all steps. The updated provisions reinforce obligations concerning the definition and ongoing maintenance of system requirements and the oversight of suppliers and external service providers. Furthermore, the Annex strengthens controls related to the assurance of data integrity, audit trails, electronic signatures, and system security.

- [Draft guidelines: Revised Annex 11 – Computerised Systems](#)

New Annex 22 - Artificial Intelligence

The new annex on Artificial Intelligence establishes requirements for the use of AI and machine learning in the manufacturing of active substances and medicinal products. It sets up requirements for the selection, training, and validation of AI models. Emphasis is made on the definition of the intended use of the model, the establishment of performance metrics, the quality of model training data, and the management and processing of test data. Annex 22 foresees a continuous oversight of AI systems, including change control, model performance monitoring and procedures for human review when necessary.

These 3 documents taken together aim at providing a comprehensive and robust framework that supports the implementation of IT technologies in pharma manufacturing while safeguarding product quality and patient safety.

- [Draft guidelines: New annex 22 – Artificial intelligence](#)