

Overview of the main differences between 21 CFR Part 11 and EU GMP Annex 11

ASPECT	21 CFR PART 11	EU GMP ANNEX 11
Purpose	Provides criteria for electronic records, electronic signatures, and handwritten signatures, which are captured for an electronic record.	Provides guidance to the EMA GMP's industry criteria for effective implementation, validation, use, control, and maintenance of computerized systems.
Scope	Applies to electronic records, electronic signatures, and handwritten signatures executed to electronic records that are created, modified, maintained, archived, retrieved, or transmitted, under FDA regulations.	Applies to all forms of computerized systems used as part of a GMP regulated activities within the EU. Does not apply to medical device software. It may be applicable to software used in the production of a device and software used in implementation of the device manufacturer's Quality system.
Applicability	Applies to drug, biotechnology, and medical equipment manufacturers in FDA-regulated industries, including electronic submissions to the FDA.	Intended to ensure product Quality, process control, or QA when a computerized system replaces manual operations.
Legal	Legal requirement issued by the FDA. Applicable to FDA-regulated industries.	Not a legal requirement; it is a guideline in the context of the EMA GMPs. However, it is mandatory on each national level in the EU and therefore essential for compliance with related EU regulations.
Overarching Structure	Subpart A: General Provisions 11.1 Scope 11.2 Implementation 11.3 Definitions Subpart B - Electronic Records 11.10 Controls for closed systems 11.30 Controls for open systems 11.50 Signature manifestations 11.70 Signature/record linking Subpart C - Electronic Signatures 11.100 General requirements 11.200 Electronic signature components and controls 11.300 Controls for identification codes/passwords	Consists of four sections: - General guidance - Project phase - Operational phase - Glossary
Key Terminology	- Electronic record - Electronic signature - Digital signature - Handwritten signature - Closed system - Open system	- Electronic signature - Computerized system - Accuracy checks - Audit trail - Data storage - Printouts - Change Management - Periodic evaluation

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KJ Lindholm-Leary



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