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STANDARDS & GUIDANCE BRIEF · EUROPEAN UNION · EU GMP ANNEX

EU GMP Annex 11

Computerised Systems

DOCUMENT	QES-WP-122, Rev B	DATE	November 7, 2026
ISSUED BY	European Commission (with PIC/S)	PREPARED BY	Conner Davidson
EDITION	2011 version (applied from June 30, 2011); revision in consultation since July 7, 2025	STATUS CHECKED	October 24, 2026
INDUSTRIES	Pharmaceutical, Laboratories & Calibration	ONLINE	qesisbest.com/standard-eu-gmp-annex-11.html

REVISION IN PROGRESS The 2011 text remains in force. A full revision, with a new Annex 22 on artificial intelligence and a revised Chapter 4, was published for consultation on July 7, 2025 (closed October 7, 2025); as of September 2026 the final texts had not been published. **Next:** Final texts expected late 2026 to 2027, with an application date set in them.

What It Covers

The use of computerized systems as part of GMP-regulated activities: risk management, validation, data integrity, audit trails, security, change and incident management, and business continuity.

Who It Applies To

Manufacturers, importers and laboratories working to EU GMP, and PIC/S inspectorates.

Key Requirements

- Risk management applied across the life cycle of each system.
- Validation documented, with supplier assessment where suppliers are used.
- Audit trails for GMP-relevant changes and deletions, and their review.
- Security, change control, periodic evaluation, incident management, and business continuity.

What an Auditor Asks to See

- The inventory of GMP computerized systems and their validation status.
- Audit trail review procedures and records.
- Supplier assessments for systems and cloud services.

Where Systems Fall Short

- Spreadsheets and instrument software outside the system inventory.
- Audit trail review defined but never performed.

How QES helps. A system inventory and validation approach sized to risk, ready for the revised annex when it lands. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. European Commission — EudraLex Volume 4, EU GMP guidelines — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en; GuideGxP — Annex 11 revision status (September 2026) — www.guidegxp.com/blogs/data-integrity-csv/eu-gmp-annex-11-revision-2026.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.