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STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

21 CFR Part 11

Electronic Records; Electronic Signatures

DOCUMENT	QES-WP-110, Rev B	DATE	November 7, 2026
ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
EDITION	Current as published in the eCFR (in force since 1997), read with FDA's 2003 scope and application guidance	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices, Pharmaceutical, Laboratories & Calibration	ONLINE	qesisbest.com/standard-21-cfr-11.html

IN FORCE FDA's 2003 guidance narrowed how it enforces some provisions; the rule itself is unchanged.

What It Covers

The conditions under which FDA treats electronic records and electronic signatures as trustworthy and equivalent to paper and handwritten signatures.

Who It Applies To

Anyone keeping records required by FDA regulations in electronic form, or submitting them electronically — device, drug, and laboratory organizations alike.

Key Requirements

- Validated systems, with accurate and complete copies of records available for inspection (§11.10(a)–(b)).
- Secure, computer-generated, time-stamped audit trails of record changes (§11.10(e)).
- Access limited to authorized people, with authority and device checks (§11.10(d), (g), (h)).
- Signatures that show name, date, time and meaning, and are linked to their records (§11.50, §11.70), with controls on IDs and passwords (§11.300).

What an Auditor Asks to See

- The inventory of computerized systems holding regulated records, and their validation status.
- Audit trail configuration and evidence that audit trails are reviewed.
- User access lists and how they are maintained when people leave.

Where Systems Fall Short

- Spreadsheets used as regulated records with no controls at all.
- Audit trails switched on but never reviewed.
- Shared logins on laboratory instruments.

How QES helps. An inventory of regulated systems sorted by risk, so validation effort goes where the records matter. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. eCFR — 21 CFR Part 11 — www.ecfr.gov/current/title-21/part-11.

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