SmartSuite

Framework / Quality & Safety / Other

FDA 21 CFR Part 11

FDA 21 CFR Part 11 sets the controls that make electronic records and electronic signatures trustworthy and equivalent to paper for FDA-regulated firms, in force since August 20, 1997.



What it is

FDA 21 CFR Part 11 is the U.S. Food and Drug Administration regulation that sets the criteria under which electronic records, electronic signatures and handwritten signatures executed to electronic records are considered trustworthy, reliable and generally equivalent to paper records and handwritten signatures (11.1(a)). It applies to any person who creates, modifies, maintains, archives, retrieves or transmits records in electronic form under an FDA records requirement, or submits electronic records to the agency under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act (11.1(b)), and it has been in force since August 20, 1997.

At a glance

PUBLISHER
U.S. Food and Drug Administration (FDA)

TYPE
Regulation

VERSION
21 CFR Part 11, final rule 62 FR 13430 (March 20, 1997), as amended through 88 FR 13018 (March 2, 2023)

EFFECTIVE
August 20, 1997

DOMAIN
Quality & Safety

FAMILY
Other

REGION
United States

INDUSTRY
Healthcare & Life Sciences

ADOPTION MODEL
Regulatory Compliance

IMPLEMENTATION COMPLEXITY
High

Source: ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

Why it matters

- **Records that hold up in an inspection** Validation, accurate and complete copies, and protection of records through the retention period (11.10(a) to (c)) make electronic records usable as evidence.
- **Signatures with legal weight** Electronic signatures that meet Subpart C are the legal equivalent of handwritten signatures, initials and other signings required by FDA regulations (11.1(c)).
- **Traceable changes** Secure, computer-generated, time-stamped audit trails record who created, changed or deleted a record and when, without obscuring earlier entries (11.10(e)).
- **Accountability for signers** Written policies hold individuals accountable for actions taken under their electronic signatures, to deter falsification (11.10(j)).

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How SmartSuite supports 21 CFR Part 11

Regulated Systems Inventory

List every system that creates or keeps predicate-rule records, flag it as closed or open (11.3(b)(4) and (9)), and record its validation status and owner.

Validation Evidence by System

Link validation plans, test results and approvals to each system to evidence 11.10(a), with change control to keep the validated state.

Audit Trail and Record Controls Register

Record how each system meets 11.10(b) to (e): copies, retention, access limits and secure, time-stamped audit trails.

Electronic Signature Governance

Track signature policies, identity verification, the 11.100(c) certification to the FDA, and training records for signers (11.10(i) and (j)).

Risk-Based Scope Decisions

Document the 2003 guidance risk assessments that decide where validation and audit trails apply, with approver and review date.

Inspection Readiness Reporting

Report open gaps, overdue reviews and evidence coverage across all Part 11 controls to quality and IT owners.

Common framework mappings

GAMP 5 | ISO 27001:2022 | NIST CSF 2.0 | NIST 800-53 Rev.5 | SOC 2

Official resources

FDA 21 CFR Part 11 Guidance for Industry

Provides clarity on scope and application of electronic records and signatures regulation.

fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application

21 CFR Part 11 (eCFR, current text)

Outlines the requirements for electronic records and signatures used in FDA-regulated industries.

ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

FDA Compliance Programs Guidance Manual

Defines compliance guidelines for industries under FDA electronic record regulations.

fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-guidance-manual-cpgm

Electronic Records; Electronic Signatures final rule (Federal Register, March 1997)

Describes regulatory information about FDA-specific electronic record standards.

federalregister.gov/documents/1997/03/20/97-6833/electronic-records-electronic-signatures

Frequently asked questions

Does 21 CFR Part 11 require electronic records?

No. Part 11 sets the criteria that apply when a person chooses to keep records electronically or to sign them electronically instead of on paper (11.2). It applies to records created, modified, maintained, archived, retrieved or transmitted under FDA records requirements and to electronic submissions to the agency (11.1(b)), but not to paper records that are simply sent by electronic means.

What are the 11.10 controls for closed systems?

Section 11.10 lists eleven controls: validation; accurate and complete copies; protection of records through retention; limiting access to authorized individuals; secure, computer-generated, time-stamped audit trails; operational system checks; authority checks; device checks; qualified personnel; written accountability policies for signatures; and controls over system documentation and its revision history. Open systems add encryption and digital signature standards (11.30).

What must an electronic signature show and how is it controlled?

A signed record must display the signer's printed name, the date and time of signing and the meaning of the signature (11.50), and the signature must be linked to the record (11.70). Each signature belongs to one verified individual (11.100(a) and (b)); non-biometric signatures use at least two components such as an identification code and password (11.200), with the password controls in 11.300. The organization also certifies to the FDA that its electronic signatures are legally binding (11.100(c)).

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What did the FDA's 2003 scope-and-application guidance change?

The guidance, Part 11, Electronic Records; Electronic Signatures - Scope and Application, said the FDA would interpret Part 11 narrowly and would exercise enforcement discretion for the validation, audit trail, record retention and record copying requirements, and for legacy systems in operation before August 20, 1997 that met predicate rules. The regulation itself remains in force, and the predicate rules that require the records are enforced in full.

Is there newer FDA guidance on Part 11?

Yes. In October 2024 the FDA finalized Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers, which replaced the 2007 guidance on computerized systems used in clinical investigations. It applies Part 11 to sponsors, investigators, institutional review boards and contract research organizations running clinical investigations of foods, medical products, tobacco products and new animal drugs.

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Full framework page and mappings: smartsuite.com/frameworks/fda-21-cfr-part-11-electronic-records-and-electronic-signatures