

FDA 21 CFR Part 11

FDA 21 CFR Part 11 defines requirements for managing electronic records and signatures to ensure integrity, authenticity, and traceability.



What it is

At a glance

PUBLISHER U.S. Food and Drug Administration (FDA)	TYPE Regulation	VERSION 21 CFR Part 11
EFFECTIVE August 20, 2003	DOMAIN Quality & Safety	FAMILY Other
REGION United States	INDUSTRY Healthcare & Life Sciences	ADOPTION MODEL Regulatory Compliance
IMPLEMENTATION COMPLEXITY High		

Source: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

Why it matters

- **Strengthen data integrity controls** Ensure authenticity, accuracy, and reliability of electronic records through robust validation and audit trail requirements.
- **Enhance regulatory alignment** Support compliance with FDA expectations for electronic systems, reducing regulatory risk during inspections and submissions.
- **Support secure electronic signatures** Enable use of electronic signatures that are legally equivalent to handwritten signatures, streamlining digital approvals and documentation.
- **Increase audit readiness** Maintain comprehensive audit logs and documentation that simplify regulatory audits and improve traceability of critical actions.

How SmartSuite supports 21 CFR Part 11

Validation Plan and Evidence Tracking

Track validation plans, test scripts, results, approvals, and change impact evidence.

Electronic Records and Audit Trail Evidence

Manage record integrity requirements and store audit trail proof where applicable.

eSignature Governance Workflow

Document eSignature procedures, approvals, training, and controls for signature use.

SOPs, Training, and Attestations

Centralize SOPs, training completion, and policy acknowledgements with traceability.

Change Control and Release Discipline

Run change control workflows to maintain validated state with review and approval history.

Inspection Readiness Reporting

Report validation status, open issues, and evidence coverage for audit preparedness.

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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application)

FDA Electronic Records and Signatures Rule Summary

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

[fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application)

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](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-guidance-manual-cpgm)

FDA Regulatory Information Manual

Describes regulatory information about FDA-specific electronic record standards.

[fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application)

Frequently asked questions

What is FDA 21 CFR Part 11 used for?

FDA 21 CFR Part 11 governs the creation, modification, storage, and use of electronic records and electronic signatures in regulated environments overseen by the FDA. It ensures that digital records and signatures are trustworthy, reliable, and equivalent in integrity to paper records and handwritten signatures used in pharmaceutical, biotechnology, and medical device industries.

Is FDA 21 CFR Part 11 mandatory for all organizations?

FDA 21 CFR Part 11 is mandatory for organizations subject to FDA regulations, such as those complying with GxP (Good Practice) requirements in the life sciences sector. If electronic records or signatures are used in regulated processes, companies must meet Part 11 compliance for those systems and workflows.

What organizations does FDA 21 CFR Part 11 apply to?

Part 11 applies to organizations governed by FDA requirements that use or maintain electronic records or electronic signatures connected to FDA-regulated processes. This primarily includes pharmaceutical manufacturers, biotech firms, contract research organizations, and medical device companies.

What are the key compliance requirements under FDA 21 CFR Part 11?

Compliance with FDA 21 CFR Part 11 requires validated systems, secure user authentication and access controls, robust audit trails, electronic signature attribution, and complete procedural documentation. Organizations must also implement change controls, regular training, and periodic compliance assessments.

How does system validation work under FDA 21 CFR Part 11?

System validation under Part 11 involves documented testing and verification to ensure software applications and digital record systems function consistently and accurately. Organizations must maintain validation protocols, test scripts, results, and evidence that systems meet requirements for accuracy, integrity, and reliability.

How does FDA 21 CFR Part 11 relate to other regulatory frameworks?

Part 11 is often integrated with broader compliance programs, such as GxP (Good Laboratory, Clinical, and Manufacturing Practices) and ISO standards. While it specifically addresses electronic records and signatures, its controls are typically mapped to overall quality management and cybersecurity frameworks to ensure comprehensive risk management.

What ongoing activities are required to maintain FDA 21 CFR Part 11 compliance?

Maintaining compliance requires continuous risk assessments, routine system audits, access reviews, regular training, change management, and documented evidence of procedural adherence. Organizations should also monitor audit trails and address any compliance gaps promptly through corrective action processes.

How would SmartSuite support FDA 21 CFR Part 11?

SmartSuite enables organizations to manage FDA 21 CFR Part 11 compliance by tracking risks, managing control libraries mapped to regulated systems, collecting and storing validation evidence, and facilitating audit readiness. Its dashboards, compliance workflows, and reporting features support the ongoing monitoring, documentation, and remediation required for sustained Part 11 compliance.

License included / downloadable: Yes FDA 21 CFR Part 11 is a U.S. federal regulation and is publicly available through official FDA and U.S. government publications.

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