

OpenText Compliance Brief - FDA 21 CFR Part 11

Overview of FDA 21 CFR Part 11

21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations (CFR) that establishes the US Food and Drug Administration (FDA) regulations on electronic records and electronic signatures. Part 11, to which it is commonly referred, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and essentially equivalent to paper records.

Part 11 requires subject organizations to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data.

Part 11 requires both procedural (e.g. training, SOPs) and administrative controls to be put in place by the organization in addition to the technical controls within software.

Requirements of Part 11 for Life Sciences companies can be summarized as follows:

- Ensure the authenticity, integrity, and confidentiality of electronic records
- Generate accurate and complete copies of records for the FDA to inspect and review
- Ensure the security and easy retrieval of electronic records
- Ensure that only authorized individuals can access, manipulate, and electronically sign records
- Maintain a log of all changes made to electronic records throughout their lifecycle
- Record and store electronic signatures with the electronic records to which they have been applied
- Ensure that record processing steps are performed in the proper order
- Ensure that persons who develop, maintain or use the electronic record/electronic signing system are properly trained
- Ensure that individuals are accountable for actions initiated under their electronic signatures
- Maintain control over system documentation
- Establish and maintain SOPs regarding all of the above and other requirements

INDUSTRY

Life Sciences

WHO IS SUBJECT

Pharmaceutical companies, medical device manufacturers, biotech companies, biologics developers, contract research organizations, and other FDA-regulated industries, with some specific exceptions

THE OPENTEXT SOLUTION

OPENTEXT REGULATED DOCUMENTS

OpenText Regulated Documents helps Life Sciences companies manage electronic records and signatures in compliance with 21 CFR Part 11 through:

- *The capabilities of OpenText Content Server, OpenText Electronic Signatures, and OpenText XML Workflow Extensions*
- *Consulting services that help Life Sciences organizations develop the policies, procedures, and best practices to ensure that OpenText software products are used in a 21 CFR Part 11-compliant manner.*

OpenText Content Server has the required technical elements of a CFR 21 Part 11 compliant system.

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