Understanding the Title 21 CFR Part 11 Regulation

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Understanding the requirements of 21 CFR Part 11 can be challenging. This white paper discusses the details of the regulation so that you can be more informed as you begin to implement 21 CFR Part 11 compliance as part of your workflow.

What is 21 CFR Part 11?

The U.S. FDA Title 21 CFR Part 11 regulation allows the use of computerized systems to enable automated generation and capturing of data, as well as the implementation of electronic signatures. The regulation also governs the use of electronic records and signatures. This has allowed companies to better collaborate on projects across locations.

History of the 21 CFR Part 11 regulation

- 1980s: Biotech and pharmaceutical companies request FDA acceptance of electronic records and signatures.
- February 1992: FDA publishes Advance Notice of Propose Rulemaking (ANPRM) soliciting comments
- August 1994: FDA publishes the proposed rule
- March 20, 1997: FDA publishes the final rule, effective August 20, 1997. The rule states - 11.1(d): "Electronic records that meet the requirements of this part may be used in lieu of paper records ..."

  Preamble, Federal Register, March 20, 1997, section 9: "The agency emphasizes that these regulations do not require, but rather permit, the use of electronic records and signatures

What is an electronic record?

Electronic records are any combination of text, graphics, data, audio, or pictorial information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer. It is also defined as a compilation of any symbol(s) executed to be the legally binding equivalent of an individual's handwritten signature. The FDA defines a handwritten signature as the *scripted name* or *legal mark* of an individual, handwritten by that individual and executed or adopted with the present intention to *authenticate* a writing in a *permanent* form.

Who does the 21 CFR Part 11 regulation apply to?

For the most part, companies that are in an FDA-regulated industry such as drug makers, medical device manufacturers, biotech companies, biologics developers, and contract research organizations when using electronic records and electronic signatures must implement the necessary checks to ensure they align with the regulation. These checks include access controls, system validation, and audit trails.

In addition, if you make submissions to the FDA in electronic format (such as a new drug application, 510(k), or clinical reports for example) you need to comply with the regulations of Part 11.

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How do software and automated systems help with 21 CFR Part 11 compliance?

Automated systems and software such as BD FACSuite™ Software, part of the BD clinical flow cytometry solution, include built-in functional controls that helps to achieve compliance with the functional aspects of 21 CFR Part 11. It should be noted that the functionality of a system or application can only provide the tools to comply with portions of the regulation.

Functional requirements of Part 11 can be satisfied through a software. However, there are action and procedural requirements that can only be satisfied through the company or persons performing the work. These comprise roughly one-third of the regulation.

What are the functional, procedural and action requirements of the 21 CFR Part 11 regulation?

The Part 11 regulation can be broken into three conceptual groups of requirements: functional, procedural and action items.

Functional requirements: capabilities that have to be built into the system, software or tool in order to comply with specific elements of the 21 CFR Part 11 regulation.

Procedural requirements: procedures that a company implements to comply with elements of the 21 CFR Part 11 regulation. These are elements that a software, application, or tool cannot provide the functionality to meet.

Action requirements: these are the elements where the person employing the system needs to do something in order to comply with the regulation. Similar to procedural requirements, a software, tool or application cannot provide the functionality to satisfy these aspects of the regulation.

Procedural Requirements: The company will need to have procedures in their quality management system to comply with these aspects of the regulation.

- Procedures for back-up and archive retrieval 11.10(c)
- Procedures for record retention 11.10 (c)
- Procedures for password control 11.10(d)
- Procedures that define developer and user training requirements 11.300(c)
- Procedures that hold individuals accountable for action performed under their log-on 11.10(j) and 11.200 (a)(2)
- Change control procedures for system documentation 11.10(k)
- Verification of individuals before assigning electronic signature authority 11.100(b)
- Security reporting procedures 11.100(d)

Action Requirements: These refer to steps that the company should also take to ensure compliance.

- Agency certification that electronic signatures are legally equivalent to handwritten signatures 11.100(c)
- Ensure electronic signatures is used only by genuine owner 11.200(a)(2)
- Collaboration of two or more individuals required to prevent use by someone other than the genuine owner 11.200(a)(3)
- Electronic signatures based on biometrics designed to ensure use only by owner 11.200(b)
- Testing of tokens or cards that bear or generate ID or password information 11.300(e)
- System validation 11.10(a)

Learn how the BD FACSuite Software helps meet the functional requirements of 21 CFR Part 11 compliance.

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