



# 21 CFR Part 11

## Frequently Asked Questions (FAQs)



The United States Food and Drug Administration (FDA) defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records in Title 21 CFR Part 11.

Training records have always been part of an inspection of the quality system by regulatory authorities, and when an organization is using electronic training records, those need to be compliant with Title 21 CFR Part 11.

However, as with many government regulations, those who must adhere to these rules often have many questions.

### Which organizations does Part 11 apply to?

Part 11 applies to drug manufacturers, biotech companies, medical device manufacturers, contract research organizations, and several other FDA-regulated industries (such as food and beverage manufacturing). Additionally, some organizations that are not FDA-regulated may choose to use Part 11 as a guide to assure that they are utilizing good processes for managing their electronic training records and other documents.

### What is an Electronic Signature?

According to the FDA, “Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature.”

Certain signatures are required, and if they are executed electronically, then compliance is required.

### If you have Electronic Signatures, do you have to comply with Electronic Record Requirements?

Use of Electronic Signatures implies that a system is an Electronic Record system, and must be in compliance with all provisions of 21 CFR Part 11.

## What are the main business ramifications of 21 CFR Part 11 on my system?

The ramifications include a number of areas:

1

Evaluation of the regulatory impact and the scope of the system. Is it an electronic record, electronic signature, etc.? The rule includes all records that are generated, stored or reported, such as attendance records, test scores and many others.

2

Certification to the FDA that a company considers Electronic Signature to be the legally binding equivalent of traditional handwritten signatures

3

Various SOPs to document establishment of user identity, user accountability, procedures, etc.

4

Audit trail monitoring

5

Validation of commercial and custom software

6

Qualification of personnel developing, administering, maintaining or using the system

7

Archiving and retrieval

8

Costs and staffing for all items mentioned above



## Does the FDA require validation of commercial software such as the Learning Management System (LMS)?

In many cases, the FDA does require the validation of commercial software for its intended use. The FDA has stated, “The agency believes that commercial availability is no guarantee that software has undergone “thorough validation” and is unaware of any regulatory entity that has jurisdiction over general purpose software producers.

The agency notes that, in general, commercial software packages are accompanied not by statements of suitability or compliance with established standards, but rather by disclaimers as to their fitness for use. The agency is aware of the complex and sometimes controversial issues in validating commercial software. However, the need to validate such software is not diminished by the fact that it was not written by those who will use the software.”<sup>1</sup>

The FDA requests that your Learning Management System is validated for intended use.

Compliance with GxP predicate rules (e.g. 21 CFR 210 or 21 CFR 820) in combination with electronic records as per 21 CFR Part 11 or EU GMP Annex 11 for computerized systems is mandatory in regulated environments.

## What is the difference between a closed and open system?

The agency agrees that the most important factor in classifying a system as closed or open is whether the persons who are responsible for the content of the electronic records control the access to the system containing those records.

A closed system refers to an environment in which system access is controlled by those persons who are responsible for the content of electronic records that are in the system. An open system denotes an environment in which system access is not controlled by those persons who are responsible for the content of electronic records that are in the system. If those persons do not control such access, then the system is open because the records may be read, modified, or compromised by others to the possible detriment of the persons responsible for record content. Hence, those responsible for the records would need to take appropriate additional measures in an open system to protect those records from being read, modified, destroyed, or otherwise compromised by unauthorized and potentially unknown parties.

<sup>1</sup>Part 11, Department of Health and Human Services, Food and Drug Administration, “21 CFR Part 11, Electronic Records and Electronic Signatures; Final Rule”



### Can I purchase a compliant application or solution?

No solution by itself is compliant. Both the hardware and the software must be validated. Validation needs to be done across an entire solution, from end-to-end. This includes the data center, the server and related appliances, and the administration of these components. This validation is necessary regardless of whether an organization is using the hardware and software on premise or if it is hosted via SaaS.

### What must a vendor do to claim that their hardware and software are 'compliant' with 21 CFR Part 11?

No vendor can claim that his or her software products are certified Part 11 compliant. A vendor, instead, can say that he has all of the Technical Controls for 21 CFR Part 11 compliance built into his product. But remember, it is the responsibility of the user to implement the Procedural and Administrative Controls (both correctly and consistently) along with using products with the correct Technical Controls for overall Part 11 compliance.

NetDimensions' award-winning talent management solutions for life sciences can help your organization manage learning and development in compliance with 21 CFR Part 11 of the Code of Federal Regulations. [Contact us today.](#)

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**The Role of the LMS in 21 CFR Part 11 Compliance**

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Reference: <http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm>

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