

Master Plan

21 CFR Part 11 Compliance

1. Introduction

In 1997 the United States Food and Drug Administration (FDA) issued a regulation that provides criteria for acceptance by the FDA of electronic records, electronic signatures and handwritten signatures. This was done in response to requests from the industry. With this regulation, titled Rule 21 CFR Part 11, electronic records can be equivalent to paper records and handwritten signatures.

Such a regulation is important because electronic data handling offers noteworthy benefits in the manufacturing area and also for the huge amount of data generated in analytical laboratories. The use of fully electronic data acquisition, evaluation, management and archiving promises major improvements in the workflow. Also the FDA approval process is expected to be shorter and access to documentation will be faster and more productive.

The rule applies to all industry segments regulated by the FDA that includes Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and current Good Manufacturing Practice (cGMP). The rule has an impact on all FDA regulated industries that use computers for regulated activities.

Implementing the rule in a company should follow a documented process and should be well planned. This document should serve as a framework to implement Part 11 projects within a company.

2. Scope, Vision, Strategies, Objectives

2.1 Scope

Software and computer systems used in FDA regulated environments.

2.2 Vision

Our company intends to fully comply with 21 CFR Part 11 within three years. Within this time frame we will convert paper records and handwritten signatures to electronic records and electronic or digital signatures to an extent technically feasible.

2.3 Three Year Objectives

- All computer systems comply with 21 CFR Part 11.

- 80% of all signatures within our company are based on electronic signatures.
- 80% of all our regulatory documents are archived in electronic form.
- No deviations related to electronic records and signatures from internal audits.

2.4 Strategies to Achieve the Objectives

- Management initiates and supports the project and nominates a sponsor and a project leader.
- Nominate Part 11 project team.
- Develop and communicate vision, objectives and strategies.
- Communicate advantages of e-records/signatures and Part 11 compliance and train staff on Part 11.
- Develop Part 11 interpretation guidelines for your company; for example, define scope and requirements for computer systems.
- Prioritize systems for implementation based on risk assessment, e.g., impact on product quality and patient safety.
- Make a gap analysis between requirements and actual system functionality and procedures for each system.
- Implement Part 11 functionality and procedures for each system.
- Share progress with employees and management and celebrate success.

3. Related Documents

21 CFR Part 11 does not stand on its own. It always refers to the predicated rules (GLP, GMP, GCP, Food and others) and requirements for Part 11 include many activities already going on within an organization. Examples are validation programs, risk management, security policies and procedures for data archiving. Therefore it is important to have a good link to such activities and their related documents.

3.1 FDA Regulations and Guidelines

Regulations are important to understand requirements. Most important are the FDA's 21 CFR Part 11 and predicate rules.

3.3.2 Network Qualification Plan

A network qualification plan describes a company's approach for qualifying IT infrastructure and networks. It is used as a source for project specific individual qualification project plans.

3.3.3 Risk Management Master Plan

A risk management master plan describes a company's approach for risk assessment and risk management, for example, to comply with 21 CFR Part 820 and the FDA's Part 11 Guidance: Scope and Applications. It is used as a source for project specific individual risk management project plans.

3.3.4 Security Master Plan

A security master plan describes a company's approach to ensure security and limited and authorized access to buildings, critical areas within buildings, e.g., data centers and to computers and data.

3.4 Written Procedures

(All procedures are included in the Part 11 compliance package from Labcompliance: www.labcompliance.com/books/part11)

Routine activities in regulated environments should follow written procedures. These are typically defined as standard operating procedures. Examples are:

- 3.4.1 Training for GxP, 21 CFR Part 11 and Computer Validation.
- 3.4.2 Risk Assessment used in GxP Environments.
- 3.4.3 Part 11 Scope and Controls.
- 3.4.4 Testing File Integrity of E-Mail Attachments.
- 3.4.5 Validation of Commercial Computer Systems.
- 3.4.6 Risk-Based Validation of Computer Systems.
- 3.4.7 Auditing Computer Systems.
- 3.4.8 Retention and Archiving of Electronic Records.
- 3.4.9 Change Control of Computer Systems.
- 3.4.10 Scanning of Paper Documents for FDA Compliant Archiving.
- 3.4.11 Assessment of Suppliers of Software and Computer Systems.

3.5 Checklists, Forms, Templates, Examples

(All are included in the Part 11 compliance package from Labcompliance: www.labcompliance.com/books/part11).

Checklists, forms, templates and examples help implement individual projects effectively and consistently. Examples are:

- Develops and maintains security procedures.
- Administrates user IDs and encrypted passwords for authorized access to systems.
- Develops and delivers training related to security procedures and other IT related issues.
- Forms and leads the department's Part 11 project sub-team.

4.4 Quality Assurance

- Reviews procedures and other documents for compliance with internal standards and regulations.
- Develops training material and delivers training about regulations and internal standards.
- Audits computer systems for compliance with procedures.

4.5 Regulatory Affairs

- Communicates with regulatory agencies to get the most accurate information on regulations, guidelines and their interpretations.
- Updates the project team on regulations, guidelines and their interpretations.

4.6 Quality Control

- Ensures that all software and computer systems in the department are listed in the Part 11 system inventory list.
- Actively participates in the definition of Part 11 requirements for all software and computer systems in the department.
- Ensures that all systems are brought into Part 11 compliance according to the project schedules.
- Ensures that QA and IT are notified before purchase of new systems.
- Forms and leads the department's Part 11 project sub-team.

4.7 Manufacturing/Laboratories

- Ensures that all software and computer systems in the department are listed in the Part 11 system inventory list.
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