Does Your QMS Comply with 21 CFR Part 11

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A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. So, it is beneficiary for an organization to implement a documented quality management system, because meeting the customer's requirements helps to instill confidence in the organization which leads to more customers, thus more sales. Also, meeting the organization's requirements ensures compliance with regulations and provision of products and services in the most cost and resource-efficient manner, creating room for expansion, growth, and profit. In addition, these benefits offer more advantages including reducing waste, preventing mistakes, lowering costs, facilitating, and identifying training opportunities, engaging staff and boosting loyalty, communicating a readiness to produce consistent results, and more …

QMS generally are designed based on the organization's needs, however there are some elements common to all systems that include the organization's quality policy and quality objectives, quality manual, procedures, instructions, and records, data management, internal processes, customer satisfaction from product quality, improvement opportunities and quality analysis.

The process of implementing a QMS requires four steps: (a)design, (b)deployment, (c)control and management and (d)review and improvement. The first two steps are generally based on the organization's needs and the other two steps are crucial for the system's continuity and efficiency.

To understand the importance of QMS, try to have a look at what not having a formalized quality management system means. First it will prevent a company from obtaining contracts or doing business with top-tier organizations. And a Lack of document control will prevent a business from improving, because it has no formal starting point. Without well archived documents and data, the workforce is unorganized and lacks accountability. Also, employees who leave the company take irreplaceable information with them, leaving others to figure it out and endanger the quality of the business.

Therefore, in order to attain the entire potential of the organization, it is important to have a QMS with no flaws which complies with 21 CFR part 11.

What is 21 CFR Part 11 Compliance?

21: Short for "Title 21," is the section of the CFR that applies to food and drugs. The CFR contains 50 "titles."

CFR: Short for "Code of Federal Regulations," which is a coded (numbers and letters) set of laws published by the federal government of the United States.

Part 11: Scope is specific to electronic records and electronic signatures, which includes electronic submissions to the FDA.

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So it's Part 11 of Title 21 of the Code of Federal Regulations, that sets out how a company operating in the US can use electronic quality records and digital signatures instead of paper based documentation and 'wet signatures' in such a way that complies with FDA regulations. Each title of the CFR addresses a different regulated area; 21 CFR relates to Pharmaceuticals and Medical Devices and Part 11 being applicable to electronic records and electronic signatures. This part ensures that companies and organizations implement good business practices by defining the criteria under which electronic records and signatures are accurate, authentic, trustworthy, reliable, confidential, and equivalent to paper records and handwritten signatures on paper. Part 11 essentially allows any paper records to be replaced by an electronic record and allows any handwritten signature to be replaced by an electronic one as well.

Part 11 includes:

SUBPART A – GENERAL PROVISIONS

- 11.1 – Scope
- 11.2 – Implementation
- 11.3 – Definitions

SUBPART B – ELECTRONIC RECORDS

- 11.10 – Controls for closed systems
- 11.30 – Controls for open systems
- 11.50 – Signature manifestations
- 11.70 – Signature/record linking

SUBPART C – ELECTRONIC SIGNATURES

- 11.100 – General requirements
- 11.200 – Electronic signature components and controls
- 11.300 – Controls for identification codes/passwords

Why Does 21 CFR Part 11 exist?

We all agree that a paper-based system is not practical for any company specially one that is aiming to grow, and a reliable electronic system is necessary to make data access easy for all employees.

21 CFR Part 11 validation exists for:

1. System validation:
As said before part 11 is important for the validation of the electronic systems to maintain accuracy, consistency, and reliability of data.

2. Record generation:
All data archived in the system will be easily accessible because Part 11 requires that all records have an index and search facility with results showing the entire access history along with digital signatures.

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3. Security:
Although records are easily accessible audit trails are secure and all processes are well-documented and have an audit history for audit trials to be successful.

4. Operational checks:
Constant operational system checks are provided, followed by a workflow for all operations and all documents are reviewed before they are approved and entered.

5. Security Checks through electronic signatures:
Access to the system is provided through IDs and passwords, and digital signatures. The system specifies who can have access and to what. This information must be tracked until the final version is locked in. The electronic signatures that are included in part 11 are computed based on the authentication of the originator, determined by a certain set of rules. This ensures verification of the identity and integrity of the data and helps prevent fraud.

6. Training:
Part 11 requires that all users of the system are well trained on their tasks. And all training procedures must be documented.

Who Does 21 CFR part 11 Apply to?

Part 11 mainly applies to drug makers, medical device manufacturers, biotech companies, biologics developers, CROs, and other FDA-regulated industries. But actually, if you have uploaded your documents into a computer system of any kind the regulations could apply to you.

Implementing Part 11 will introduce you to a smooth way to get a compliant and paperless QMS. This can include different types of information such as text, images, videos, and audios.

What are the Requirements?

In general, systems are subject to 21 CFR Part 11 if the documents are submitted to the FDA or relevant for an FDA inspection. It has to be noted that old systems that were in operation before 20 August 1997 and systems that generate paper printouts are not part 11 compliant.

So 21 CFR Part 11 is only applicable on electronic records, but some systems can produce a paper printout yet rely on electronic recordings to generate it, in that case one should justify the decision not to apply Part 11.

Regulatory requirements

For Closed Systems

21 CFR Part 11.10 defines the requirements for closed systems in order to ensure that the people who work with the system are authentic, have integrity and, respect confidentiality of the data. Therefore, the below requirements are mandatory:

1. System validation
2. Generation of human readable records
3. Protecting records
4. Limit system access to authorized users only and regular authority checks
5. Use of computer-generated, time-stamped audit trails

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6. Operational system checks
7. Peripherals check to ensure that the inputs and outputs are correct.
8. Provide training on the system for users
9. Prevent falsification
10. System documentation

For Open Systems

Part 11 places additional requirements for open systems which include measures such as document encryption and the use of digital signature standards to ensure the authenticity, integrity and confidentiality of records.

Digital Signature Requirements

First about the content, a digital signature must contain the name of the person, the date and time of the signature and the purpose of it (approval, review, written by …)

1. It should be protected against falsification.
2. It must be linked to the document in a way that it can't be used on another one.
3. It should be unique to every person.

The identification must be based on two components, for example identification code and password. When using identification codes and passwords, Part 11 requires the following:

1. Four- eyes principle: any attempt to misuse a signature calls for the collaboration of two or more individuals.
2. Unique combinations so that duplication is impossible
3. Codes and passwords should regularly be checked and updated for more security
4. Establish a "deauthorization" system if password or code is lost
5. Have security measures to protect against and detect unauthorized access attempts.
6. Input and output devices should always be checked to ensure they are working correctly.

How Can One Meet 21 CFR Part 11 Compliance?

Below are 7 tips you can use to make sure you are compliant to 21 CFR part 11:

1. Determine Whether 21 CFR PART 11 Applies to Your Company

People who rely on paper records mostly think that their documents are protected and there is no need to be subject of 21 CFR PART 11. They also think that the paper is their master record, and it doesn't matter what happens to it afterwards (being uploaded or scanned) but in fact the moment a document is updated to a system a company is subject to compliance with 21 CFR Part 11.

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Section 11.3 of the FDA defines “electronic record” to be “any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.” So clearly most companies are affected.
Therefore, even if the company has a paper-based record it also probably has some updated files that needs to be validated.

2. Follow 21 CFR PART 11 Data Security and Password Protection Practices

Security is a huge part of concern when it comes to 21 CFR PART 11, because it is very important to make sure the right people have access to the right documents or data. This is applicable whether you have a quality system solution or a simple folder tree, what differs is that if you opt for the folder tree you will have to apply a complicated process to check folders security. According to experts on 21 CFR PART 11 here are few tips to secure passwords:

1. The access to records should be by a unique login with a username and password, and any user that remains inactive for more than 10 to 20 min should be automatically logged out.
2. After 3 to 5 failed passwords, experts advise that the system should lock out users
3. If users remain inactive for 30 days they should be locked out

3. Have Clear Audit Trails for traceability

A complete history of your record-keeping system is essential so that FDA can view these records upon inspection. Audit trails should clearly show which user performed which action at what time. And if you want to have a smooth inspection you better have easy access to these records.

4. Follow 21 CFR PART 11 Guidelines on Electronic Signatures

As said previously 21 CFR Part 11 guidelines assure security on signatures and help avoid falsification on digital records of course. On the other hand, with paper there is a loophole because anyone can make changes on any paper without leaving a trace. You should note that if you intend to use electronic signatures you need to notify the FDA by sending a letter.

5. Do Not Outsource Your Responsibility

Some software platforms claim that they can take care of your 21 CFR PART 11 compliance, it will not be as efficient as you doing it yourself.

6. Validate for IQ, OQ, and PQ

You need to validate for Installation Qualification to make sure your software is installed correctly, for Operational Qualification to know if the software is capable of meeting the regulatory requirements, and for Performance Qualification to know if the software is in its best performance.

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7. Consider 21 CFR PART 11 When Choosing QMS Solution

Take your time and investigate various QMS solutions considering the needs of your company when it comes to validating for 21 CFR Part 11. Because a bad choice of QMS will cost you additional money and time.

In conclusion, every company is recommended to consider complying with 21 CFR PART 11 and should not look at this task as a punishment but as a way to make data well organized, secured, easily accessible with a low risk of mistakes. And having some time and resources for this task will pay off eventually in terms of quality and productivity.

It is also important to create a Part 11 compliance culture in the company making sure that everyone understands 21 CFR PART 11 and the benefits that it can bring to the company. Implementing 21 CFR PART 11 does not have to be difficult or quick. There is always a large fund of knowledgeable people and established methods for achieving Part 11 compliance. And Software technology tools and templates are also abundant.

If you'd like to learn more about Intellect QMS No-Code Compliance Platform, simply click on the Demo Request button below.

Demo Request