Report

Ensuring FDA compliance: the essential guide to FDA 21 CFR Part 11

Loftware™

www.loftware.com

Ensuring FDA compliance:
the essential guide to FDA 21 CFR part 11

What is FDA 21 CFR part 11?

FDA 21 CFR Part 11 allows medical device and life science organizations to use electronic records and signatures in place of paper. This helps organizations reduce the cost of managing and documenting their entire labeling lifecycle, from routing and approval workflow, version control and comparison, to audit trails and reports.

The regulation applies to all aspects of the research, clinical study, maintenance, manufacturing, and distribution of medical products, and covers:

- Required records that are maintained in electronic format in place of paper format
- Required records that are maintained in electronic format in addition to paper format, and that are relied on to perform regulated activities
- Records submitted to FDA in electronic format
- Electronic signatures that are intended to be the equivalent of handwritten signatures.

Compliance is not as easy as it seems

The premise may seem straight-forward, but implementing these regulations, adhering to them, and being able to document that your organization is compliant is another matter altogether. Many companies fall short of meeting these requirements because they are:

- Using software that is non-compliant to 21 CFR Part 11;
- Using software that is non-compliant to quality systems regulation 21 CFR Part 820;
- Not documenting labeling SOPs (Standard Operating Procedures);
- Not ensuring traceability in the event of a product recall; or
- Using a labeling system that does not meet the needs of the FDA and GMP, and/or it cannot be made to meet these requirements.

In order to meet these regulations, companies turn to software and other solutions to help bridge the gap. But a piece of software by itself cannot be compliant. Any critical software must be supported by a properly conceived and performed validation project, normally following GMP guidelines:

- The software was written and tested using a documented and recognized lifecycle-based QA procedure
- The software automatically generates complete and accurate records of every critical action performed within the system
- Records are stored in a way to ensure accurate and speedy retrieval
- Records are protected against unauthorized input, deletion or modification of data
- The software installation is executed by following a pre-approved installation validation plan (IQ/OQ/PQ) supported by reports.

The nine phases of FDA 21 CFR Part 11 compliance

Of course the use of electronic records is voluntary. There is no FDA requirement that an electronic record or signature be used, but it certainly makes sense from a cost and process perspective. When a validated and secure FDA 21 CFR Part 11 compliant solution is deployed, electronic records and signatures are as valid as paper records and handwritten signatures. And electronic records are much easier to gather, filter, and present for internal use or FDA audits. So what does a FDA 21 CFR Part 11 compliant labeling environment look like?

Throughout the entire labeling lifecycle there are steps that need to be taken and processes to manage and enforce. From the moment a label designer releases a label to be reviewed by a quality control, marketing, or regulatory group, information regarding who released the label, the version number of that label, and when it was released for approval must be captured. Loftware has established an eight-pronged approach to helping organizations meet internal business requirements and operational processes while ensuring FDA compliance.

Phase one: planning

As with any system rollout, defining and documenting the processes and procedures is vital. All procedures, including detailed functional specifications are recommended to be based on GMP guidelines.

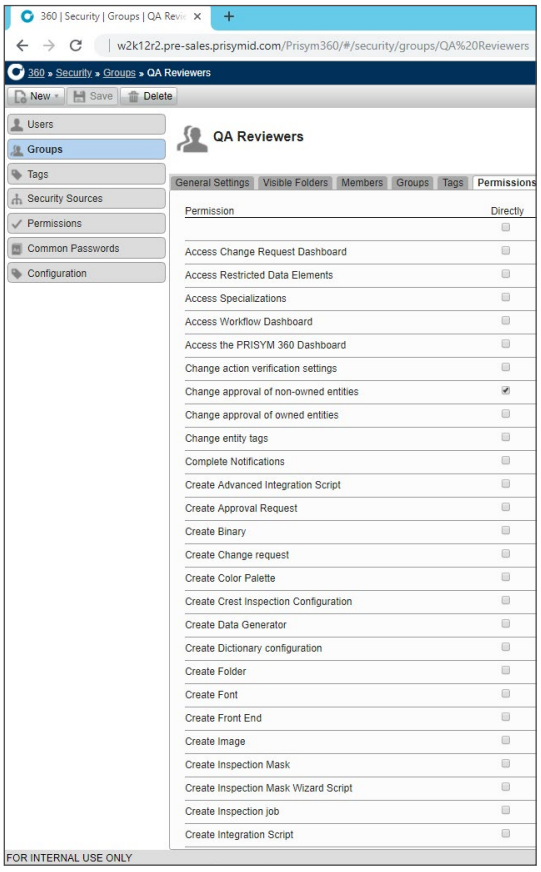
Phase two: security

FDA 21 CFR Part 11 compliance begins with ensuring security controls throughout labeling operations.

Granting each user specific authorized permissions, a unique user name, and requiring the user to approve completed activities with their credentials is the first step towards creating, documenting, and time-stamping an audit trail by capturing relevant information such as:

- Who accessed the labeling system
- What jobs or actions were performed
- If a label was modified, approved, rejected or printed
- If a report was created or exported.

Supporting the entire labeling operation with a validated closed-loop solution helps define and enforce business policies across labeling operations and limits access to the labeling system to authorized individuals.

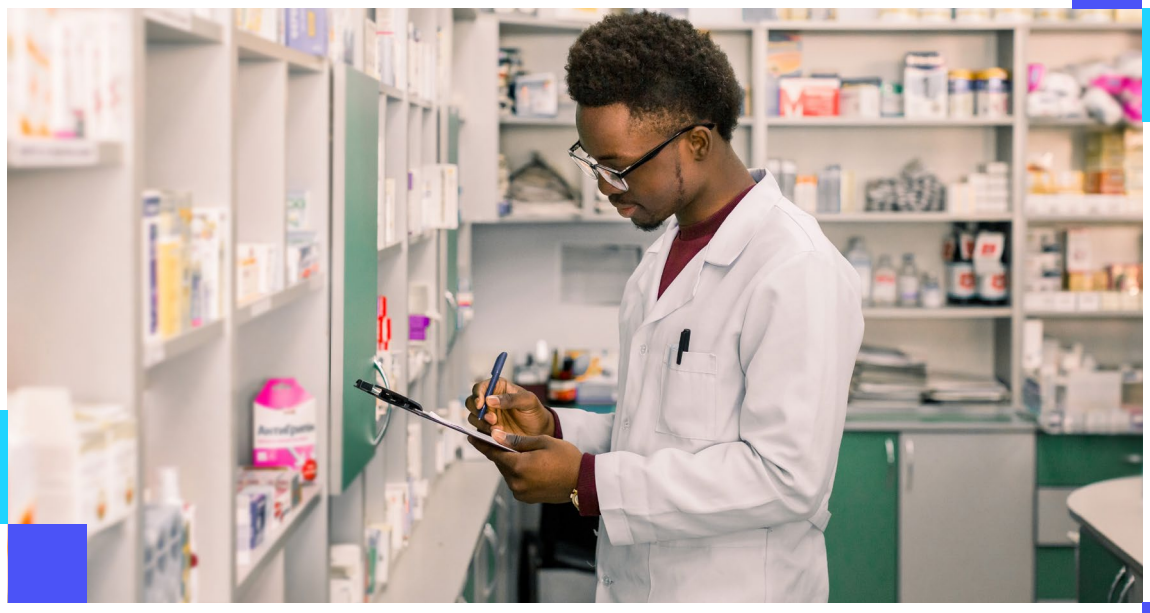


Phase three: design

With user names and passwords in place to meet electronic signature requirements, incorporating FDA 21 CFR Part 11 compliance into the label design process enables users to:

- Control who has permission to create a new label
- Designate who has the ability to make changes to a label or create a new version of that label
- Capture the release information of that label into the review and approval cycle, such as who designed the label, who released it for review and when, and the name and version number of the label
- Ensure that the correct version of the correct label is available for printing.

To be FDA 21 CFR Part 11 compliant, users must be able to accurately log, track and report on all versions of the labels which have either been released for approval or approved for production. Implementing a label management system is recommended to automatically track and enforce this level of version control and revision control for label designs. This will help ensure that every version of every label ever designed within the system is not only available to authorized users, but can be used to satisfy regulatory audit requirements.



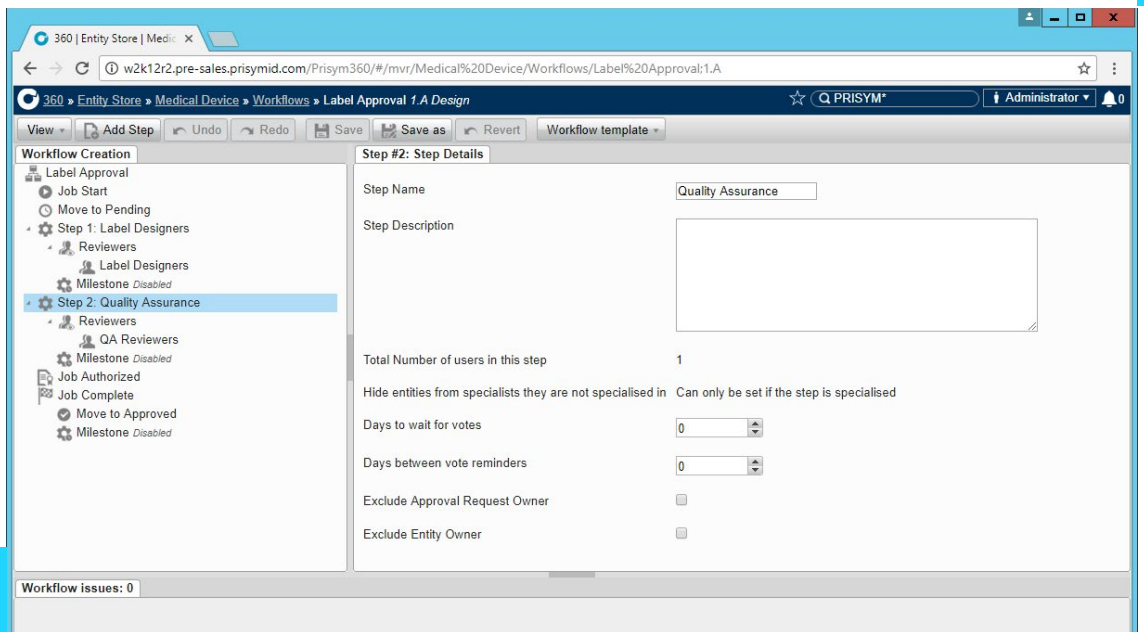
Phase four: approval

The approval phase consists of capturing all of the necessary electronic signatures and records. An electronic record is defined as “any combination of items such as text, graphics, data, pictorial, or other information in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.”

The benefits of moving away from the traditional paper-based workflow process in achieving FDA 21 CFR Part 11 compliance are numerous:

- Reduced cycle times to move a label through the review process
- Increased visibility into the status of a label in the review cycle
- Flexibility in managing complex routing paths through individuals or reviewer groups
- The ability to control which labels are released for print on the manufacturing floor or in distribution centers.

As in the design phase, by implementing security controls into the label lifecycle, it is easy to manage who has permission to review, approve or reject a label; determine which labels a reviewer can approve; log and report which version of the label was routed for approval; enforce and track the defined sequence of steps for a label through the approval cycle; and ensure that unauthorized changes to the labels cannot be made. The security controls in place also enforce the use of electronic signature comments when a reviewer approves or rejects a label. All of these actions are user, date, and time stamped for tracking and reporting capabilities and a full audit trail of all review and approval activities is maintained within the secure audit log. As with the security step, a validated label lifecycle management system must be used in order to ensure FDA 21 CFR Part 11 compliance.



Phase five: data

Managing all the product data, symbols, graphics, and languages can be an enormous challenge.

Incorporating FDA 21 CFR Part 11 compliance into the SOPs for managing product data provides:

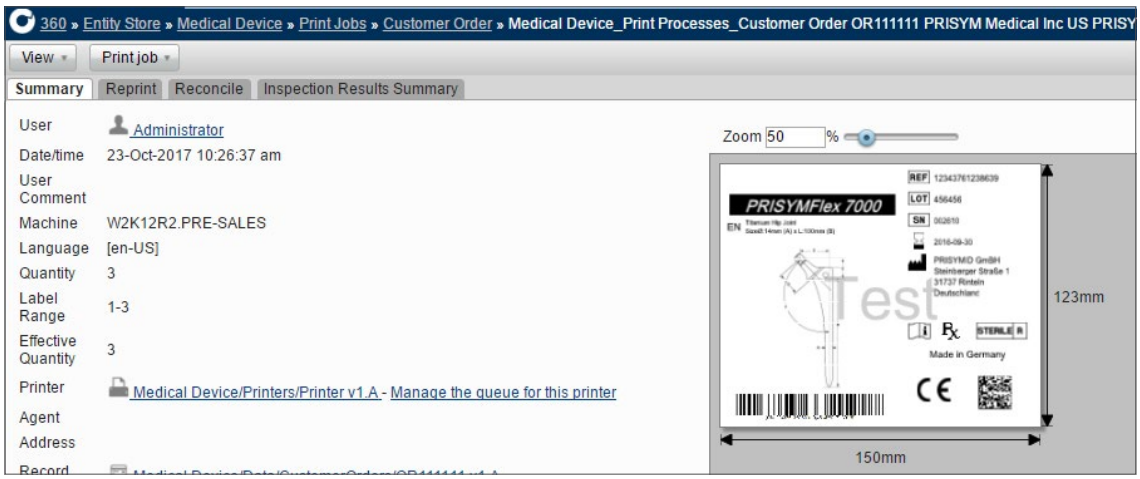
- Control over who can add or change data in the data tables
- Control over who can approve these additions or changes
- Ability to capture and log by who and when these changes were executed
- A historical, reportable audit log of all additions, version changes, and activities.

Choosing a solution that will help manage the editing and creation of records in a database table ensures that by the time the label is printed, the label design and the data have been audited, tracked and stored in a secure audit log. This requires a closed system that will automatically track and enforce this level of version control and revision control for data records.

Phase six: print

If the FDA performs an audit, they may want proof of exactly what was printed at a particular time. Being compliant makes it much easier to produce this information. With the right security controls in place to manage label printing operators and operations, an organization can control who can print, what they can print, and then capture that data in an audit trail.

To further comply with FDA 21 CFR Part 11, organizations must be able to produce the necessary electronic documentation regarding exactly what was printed. Further, it is critical to be able to not only capture all of this information, but be able to prove that the information is authentic. It is vital to use a validated, lifecycle management labeling system with a secure audit log that will capture all labeling lifecycle activities, including label printing. In addition to the who and when of label printing, elements that will need to be captured are the label format and version, as well as data, manufacturing date, expiration date, and images.



Phase seven: re-print

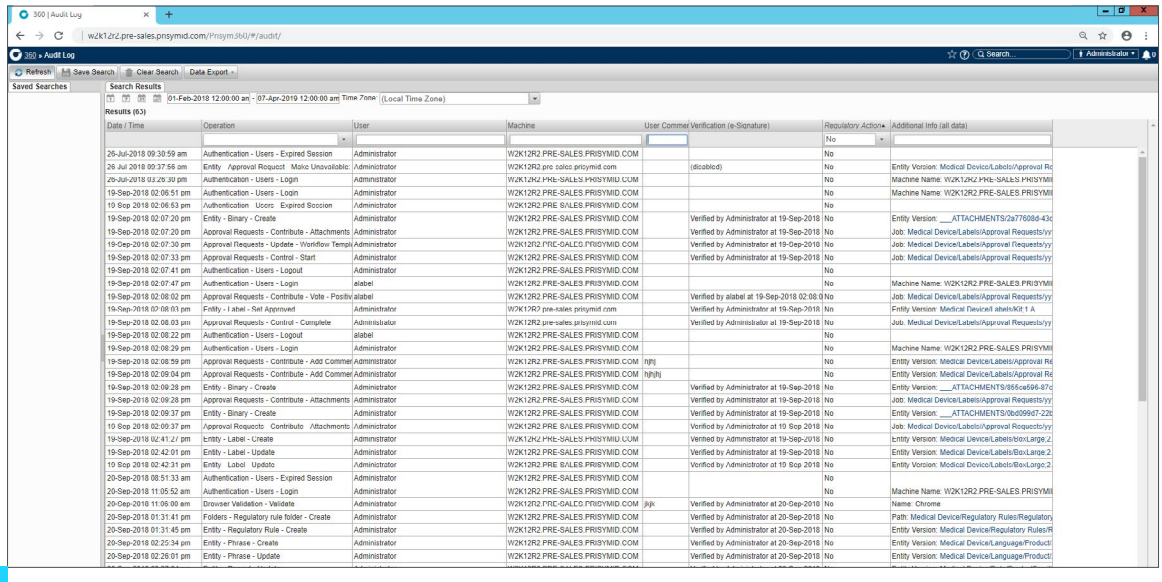
There are many times it will be necessary to re-print a carbon-copy of a printed label, such as a label that has been damaged or requires re-pack, or in response to an FDA audit. FDA 21 CFR Part 11 compliance enables organizations to capture and report on who printed what, whether during an original production print or re-print, and provides proof of what was printed to the FDA. This requires a labeling system that, whenever a label is printed, stores all design information, version information and any variables that were used.

Phase eight: reconcile

Reconciliation is the act of accounting for all the labels that were printed, whether in the original or subsequent print jobs. This activity is important as it ensures that no labels have been removed from the production area. Normally reconciliation is conducted using an automated vision inspection system which can automatically check and make decisions on printed labels or by a user with specific permissions. The reconcile action is a normal part of labeling operating procedures and provides an additional verification about the labels produced. Reconciling creates an additional entry within the audit trail of any print and re-print activities and allows operators to account for any lost, damaged or destroyed labels.

Phase nine: audit

The previous steps have involved capturing information that is required by the FDA to be 21 CFR Part 11 compliant. It is also important to have an audit log as the central repository for every action that occurs within the system, allowing users to filter, sort, drill down, retrieve, export, and present any information related to product labeling. FDA 21 CFR Part 11 compliance includes having an audit log that contains a complete and accurate history of the system and can produce appropriate reports for regulatory purposes, perform re-prints and reconcile print jobs without having to revert to paper processes.



Summary

For organizations in FDA-governed industries, FDA 21 CFR Part 11 plays an important role in reducing the cost and burden of a paper-based process. But with that comes the challenge of not only remaining compliant, but documenting your adherence to these regulations. While no software in itself can be FDA compliant, choosing labeling software that was designed with these regulations in mind can go a long way towards eliminating many of the challenges associated with compliance.

Top things to remember

Is the software written “fit for purpose” for life sciences labeling requirements, specifically 21 CFR Part 11?

In the event of a product recall or FDA audit, is there an audit log going back 5 years?

Does the software have full lifecycle documentation?

Was the software installed as part of a full validation exercise?

About Loftware

Loftware (who acquired PRISYM ID) is the world's largest cloud-based Enterprise Labeling and Artwork Management provider, offering an end-to-end labeling solution platform for companies of all sizes. Maintaining a global presence with offices in the US, UK, Germany, Slovenia, China, and Singapore, Loftware boasts over 35 years of expertise in solving labeling challenges. We help companies improve accuracy, traceability and compliance while improving the quality, speed, and efficiency of their labeling. As the leading global provider of Enterprise Labeling and Artwork Management, along with Clinical Trials Labeling and Regulated Content Management, Loftware enables supply chain agility, supports evolving regulations, and optimizes business operations for a wide range of industries. These include automotive, chemicals, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail and apparel.

For more information on Loftware's clinical trial offerings, please go to
www.loftware.com

Loftware™