21 CFR Compliance:
How LABEL ARCHIVE Can Help
Secure Your System

TEKLYNX

Introduction

21 CFR Part 11 as it relates to Label Design and Printing

Label design and label printing is an important part of the manufacturing process. The label contains information about the product, its use, and your company. Ensuring that the label has been correctly designed, properly approved, and is unique in choice to the print user is critical. Label printing software must provide security, traceability and version control to meet the needs of 21 CFR compliance and other mandates that require electronic records and electronic signatures.

TEKLYNX' LABEL ARCHIVE software meets these needs by providing a traceability layer for the label design and printing process, complete with archiving, approval, print history, and security for label design and production environments. Designed to work with CODESOFT label design and printing software, LABEL ARCHIVE addresses the label control standards required of a 21 CFR Part 11 solution.

21 CFR Part 11 – Overview

The Food and Drug Administration (FDA) first issued 21 CFR Part 11 in 1997 to provide acceptance of electronic records, electronic signatures and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures on paper. If you are complying with agency regulations and doing so by using electronic records, 21 CFR Part 11 applies. If you are designing and printing labels with critical information on the label then you should consider a label design and printing software that has been designed with 21 CFR Part 11 in mind.

Requirements of the Labeling Software

The labeling software used as part of a 21 CFR Part 11 solution should address the need for change control and a closed loop system, not only for FDA-based customers but also for efficiency, traceability, and cost control within a larger customer base.

Specifically, the labeling software should be able to retain electronic records, provide complete audit trails, require electronic signatures for access and approvals, and limit access by individuals.

Specific Needs

1. Electronic Records and Retention
2. Audit Trails
3. Electronic Signatures
4. Limited Access
5. Validated Computer Systems

LABEL ARCHIVE security and traceability software meets these needs with its unique and flexible feature set:

21 CFR Requirement	LABEL ARCHIVE Feature
Electronic Records and Retention	Centralized server-side encrypted activity log
Audit Trails	Tracks who, what, where, and when for each print job – including specific variable data for each job
Electronic Signatures	User ID and password sign-in required to design, print or approve labels
Limited Access	User privileges are controlled with customizable user groups
Validated Computer Systems	LABEL ARCHIVE can be part of a Validated Computer System when installed and configured in accordance with FDA guidelines

ELECTRONIC RECORDS - Retention of electronic records as related to label design and printing software is about having:

1) Procedures in place to ensure that the records are available when needed
2) A software package that keeps the right records for your business

The procedures are easily created with a software system such as LABEL ARCHIVE that provides centralized storage of all data in a server environment. With this centralized client-server approach, IT backup procedures can ensure that the data is secure and restorable should a problem occur.

The label design software should provide all of the features outlined below to ensure that the right records are maintained in order to generate accurate and complete copies of the required data. This data should be made available in both electronic and human readable form. Should an audit be performed, the agency would need to be able to inspect, view and copy any necessary data.

AUDIT TRAILS - The software needs to be able to provide an audit trail. LABEL ARCHIVE makes detailed audit trails easily accessible, and provides answers to the questions of who, what, where, and when as they relate to the design, approval, and printing of labels. Who designed the label? What workstation did they design it on and when? Who approved the template? What data was printed, by whom, and when?

LABEL ARCHIVE provides a complete audit trail by allowing for total traceability on all aspects of the label; label template design, label template approval, and label printing. On the label design side, one of the most important and sometimes overlooked requirements is associating the data with the correct version of the label design. If your company is currently on version 6 of a particular label design but the audit trail of a print job based on version 4 of the label is required, the software should associate the data with the right version. Ideally it will store the data based on the version.

On the label printing side the audit trail should provide all of the data needed to reproduce the label even if that data is no longer available from the source. This requires all of the variable fields of the label to be stored in the database. The audit trail should also include information on who printed the labels and on what workstation the print job was initiated.

ELECTRONIC SIGNATURES - Electronic signatures are based on unique IDs and passwords to associate a digital pattern to a unique individual. Companies need to ensure that computer based security procedures are taught and maintained throughout the organization. Once this is in place, electronic signatures can be used to identify the user, and the software can track what, where, and when. LABEL ARCHIVE tracks all of a user's label design and printing activities and associates them to a log – including users' unique IDs.
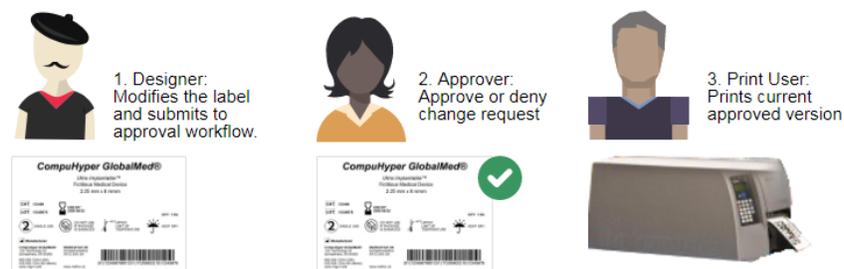

1. Designer: Modifies the label and submits to approval workflow.

2. Approver: Approve or deny change request

3. Print User: Prints current approved version

Figure 1 – Flow Diagram

LIMITED ACCESS - The label design and printing software should ensure unique identification of individuals and easily add them to "user groups." The four default user groups in LABEL ARCHIVE are:

1. *Administrator* – High level access for installation, one time setup, and adding/removing users & user groups.
2. *Manager* – Access to audit information as well the creation of approval workflows.
3. *Designer* – Access to the design functions of the label design software. These individuals will create label designs and also be responsible for implementing changes to the label.
4. *Print User* – Access only to label printing functions of the software.

The role of Approver is commonly used, but is not set up as a default user group, because the permissions assigned to the Approver are unique to each company.
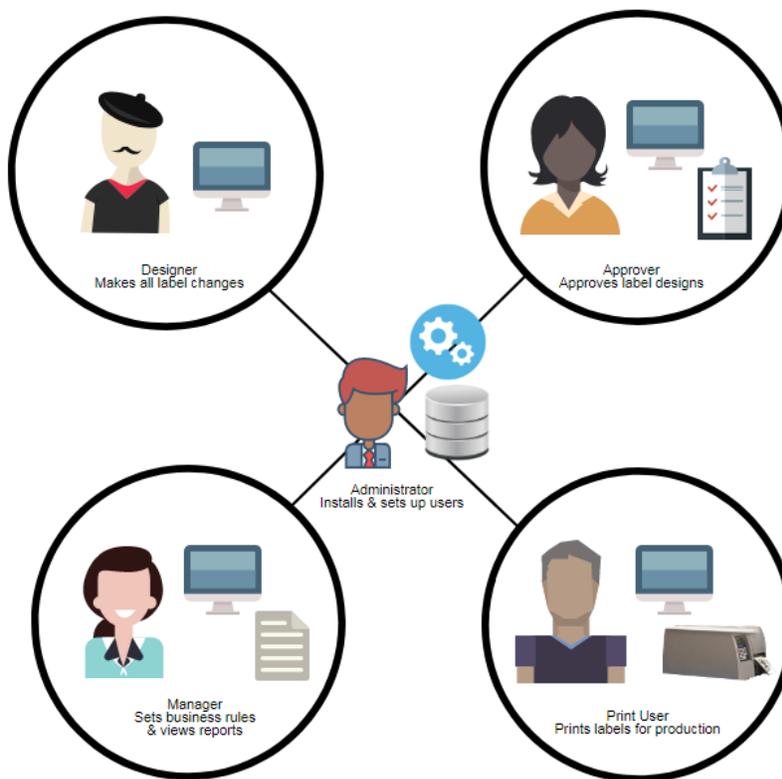
Figure 2 - Users interacting with the system

At the point of critical approvals, LABEL ARCHIVE prompts for the user's password again to ensure that the individual did not walk away from their workstation only to have another person take over. These critical approvals are aided by the use of approval workflows in the software.

Approval workflows are logical rules that dictate who needs to approve the design before it can be used for printing. LABEL ARCHIVE provides this capability and even emails the right users when the design has been submitted into the approval workflow by the designer.

VALIDATED COMPUTER SYSTEMS - By definition, a validated computer system is one that has been tested to establish objective evidence that the processes in use on the computer system consistently produce results or products that meet predetermined specifications. LABEL ARCHIVE is a very configurable solution that can be set up to achieve compliance with the CFR regulation. When LABEL ARCHIVE is configured properly, it becomes part of the Validated Computer System. Validation is typically done by a the organization implementing the solution, or a third party service provider. Validation is a multiple step process that is outlined by the FDA. Here is a link to a presentation from the FDA that outlines the validation process.

https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM466496.pdf

How this applies to other standards

Increasingly, change control, security, and traceability are becoming more important even in non-critical industries and functions. Companies competing in the global economy today simply cannot afford to leave anything to chance and are looking for these types of solutions. Many companies today are looking for software systems that allow for the traceability of data and offer flexible change control features that are designed to handle critical tasks. Ideally, the label design and printing software should incorporate these features while also providing the ability to turn on and off specific items to meet the needs of a larger group of customers. For example, a company wanting to comply with ISO may only need to track users and print jobs and not all of the specific data for each job. LABEL ARCHIVE's customizable controls make it flexible enough to meet these diverse needs.

Benefits

LABEL ARCHIVE offers a wide range of benefits designed to comply with 21 CFR Part 11.

Feature	Function	Benefit
Archiving/Version Control	Automatic label version control.	Instant access to old versions, exact reprint capabilities & complete traceability to who modified which label and when.
Approval	Mandatory rules for labels to reach production. Each person in the workflow is notified and must approve the label.	Ensures that business processes are followed and only APPROVED labels enter production.
History	Complete logging of variable label data (by label version) as well as complete event logging (print events, design modifications, label check-out, etc).	Reprint any print job and access all of the variable data that was printed to prove compliance or data integrity for audits or quality checks.
Security	Restricts access to the label design and printing process. User groups can include; Administrator, Manager, Designer, Approver, and Print User.	Locks down and secures the label design and printing process. Only authorized users can access the system and depending on the user group, access is limited. Print Users can only check-out and print approved labels.

What to look for in an ideal solution

The ideal solution will be server-based with centralized security, database, and administration. Ideally the solution will offer enterprise-level database support for storage of the label designs and history data. A robust database will have the power to support a true enterprise system and be flexible and scalable to meet the needs of a small to large corporation.
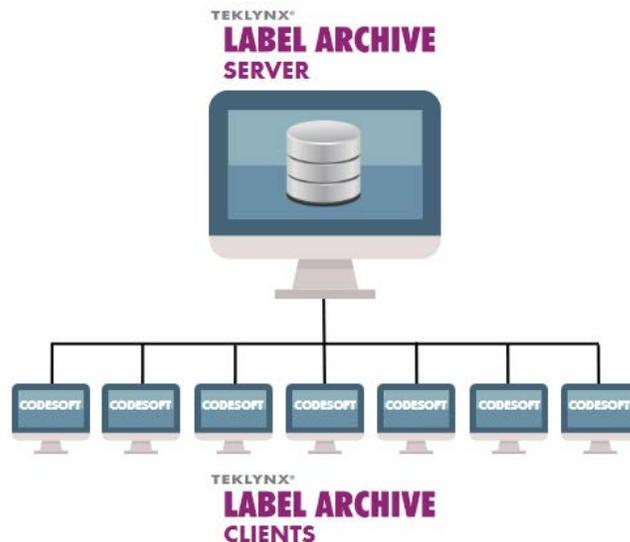

Figure 3 - Architecture diagram

The ideal solution will also be flexible enough to support your company-specific business rules with respect to the approval of changes to label forms. Rules should be creatable by the manager within each responsible department and provided for all logical scenarios. For example, the manufacturing department may require different approvals than the packaging department where RFID labels are added before being shipped to customers. In this last example the customer may want to be part of the approval process as well. An ideal solution will provide a method for Internet-based approval and email messaging to alert users when their approval is needed.

The ideal solution will track all printed label data and store the history of what labels were printed by whom. The system should track the user as well as the workstation. Within the database this history should be associated to the version of the label on which it was printed. This version-based association allows for storing new versions that might add additional variable fields without adding those fields to previous versions.

Variable data will need to be duplicated and stored for future retrieval. This means that if the data for the label is originating from SAP for example, the data will need to be stored locally with the print job while at the same time being printed to the printer. After printing, should a reprint or audit of the system be required, a simple call to the software will allow the exact label to be reprinted **without** a call to SAP. The history will also capture who printed the label, where did the printing occur, and when.

The ideal system will manage version control automatically. When you make an edit to the label (assuming you have the rights to do so) the version number will change automatically. The system should not allow any changes to an approved label, instead that approved label needs to be versioned one number ahead and editing can be performed from there. This is a required detail to ensure printing an approved version and making subsequent changes to that same label design can occur simultaneously.

Last but not least, the ideal system should prevent duplicate labels from entering production. This is done by allowing for a watermark on any reprints or test prints. The watermark differentiates production approval labels from others and ensures the integrity of a tightly controlled system.

Securing your system with a LABEL ARCHIVE solution

LABEL ARCHIVE features/functionality that contribute to a 21 CFR Part 11 compatible labeling system include:

- ✔ Centralized security
- ✔ Centralized database approval
- ✔ Centralized administration
- ✔ Enterprise database support
- ✔ Supports customizable logical approval rules
- ✔ Supports Internet-based approval
- ✔ Automatic version control
- ✔ Forced versioning for approved design
- ✔ Retention of previous version
- ✔ History tracking – variable data plus who, what, when, and where
- ✔ Watermarks on reprints and test labels
- ✔ Native printer support
- ✔ Automated printing support

LABEL ARCHIVE's unique feature set allows you to retain electronic records, provide complete audit trails, require electronic signatures for access and approvals, and limit access by individuals. It provides security, traceability and version control to meet the needs of 21 CFR compliance and other mandates that require electronic records and electronic signatures.

For More Information

For more information on LABEL ARCHIVE and its functionality, visit the TEKLYNX website at http://www.teklynx.com/labelarchive.