21 CFR Compliance

TEKLYNX® International

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WHITE PAPER

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 designed correctly, properly approved, and is unique in choice to the operator is critical. How do today's label printing products provide for security, traceability and version control to meet the needs of 21 CFR compliance and other mandates that require electronic records and electronic signatures?

21 CFR Part 11 – Overview

The Food and Drug Administration (FDA) 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.

Current State of Labeling Software

Today a number of the companies in the label design and printing software business have recognized the need for change control and closed loop software systems not only for FDA based customers but also for efficiency, traceability and cost control within their larger customer base. These software packages are available on the market today and should be considered for any company needing to comply with FDA regulations. 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

ELECTRONIC RECORDS - From the end-user standpoint 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 and 2) A software package that keeps the right records for your business. The procedures are easily created with a software system that provides centralized storage of all data, ideally in a server environment. With this centralized client-server based approach, IT backup procedures can then ensure that the data is secure and restorable should a problem occur.

The label design software should then provide all of the features outlined below to ensure that the right records are kept to generate accurate and complete copies of the data required. This data should be made available in both electronic and in 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. A few of the label design and printing software packages will provide answers to the questions of who, what, where & when as they relate to the design and printing of labels. Who designed the label? What workstation did they design it on and when? What data was printed, by whom, when? To have a complete audit trail the software needs complete traceability on both aspects of the software; label design 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 and the audit trail of a print job based on version 4 of the label is required, the software should automatically 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. This requires all of the variable fields of the label to be

stored on the database. The audit trail should also include information on who printed the labels and 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 who, and the software can then track what, where, and when.

Figure 1 – Flow Diagram

LIMITED ACCESS - Look for a label design and printing software that can ensure unique identification of individuals and easily add them to "user groups". Four good user groups to start with would include:

Administrator – High level access for installation, one time setup and adding/removing users & user groups.

Manager – Access to audit information as well the creation of approval workflows.

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.

PrintUser – Access to label printing functions of the software only.

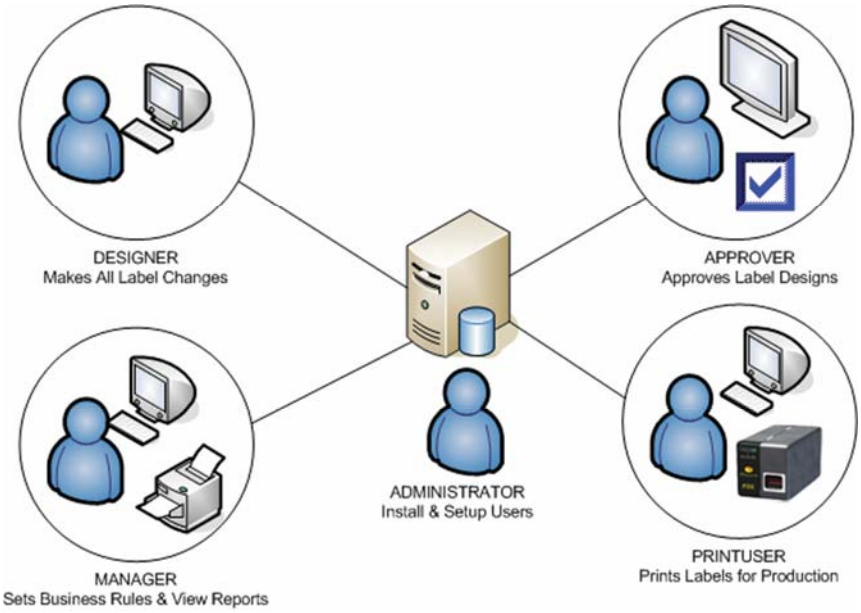

Figure 2 - Users interacting with the system

Additionally at the point of critical approvals the software should allow (prompt) 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 some of the software vendors that incorporate 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. A good label design package will provide this and even email the right users when the design has been submitted into the approval workflow by the designer.

How this applies to other standards

Increasingly change control, security and traceability are becoming more important even in none 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. In recent years more and more offerings for traceability of data and change control features are making their way into software systems designed to handle critical tasks. In the label design and printing software space we are starting to see more of the horizontal software packages incorporate these features with 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.

Future problems/needs of labeling software

There are a number of choices for labeling software packages that incorporate these features. Look for a reputable company with the features needed that can meet your needs today and grow with your business. While you may be printing at a workstation today you may be planning a new ERP system for next year and want to have your "PrintUser" be an ERP system like SAP or Microsoft Dynamics. Make sure whatever software you choose to ensure your labeling compliance is able to grow with and support your business locally and globally.

Benefits

The benefits of a labeling solution designed to meet 21 CFR Part 11 are many.

Feature	Function	Benefit
Archiving/Version Control	Complete and automatic label version control.	Instant access to old versions, exact reprint capabilities & complete traceability to who designed what 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	Limits access to the label design and printing process. For standard users groups are setup; Administrator, Manager, Designer & PrintUser.	Locks down and secures the label design and printing process. Only authorized users can access the system and depending on the user access is limited. PrintUsers can only "Check-Out" and print 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 an enterprise level database support for storage of the label designs and history data. A database like SQL or Oracle 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.

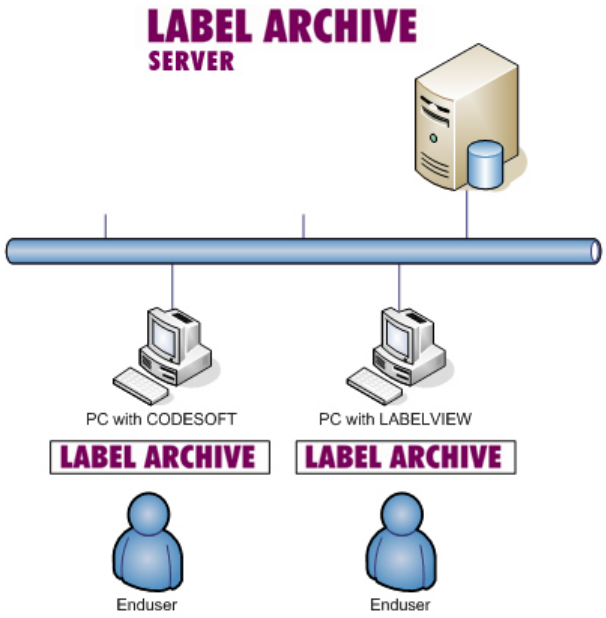

Figure 3 - Architecture diagram

The ideal solution will also be flexible enough to support you company specific business rules with respect to the approval of changes to label forms. Rules should be creatable from the manager within each responsible group and provide for all logical scenarios. For example the manufacturing group may require different approvals than the packaging group 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 who. The system should track user as well as 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 new versions that might add additional variable fields, storing all the data for all versions of the labels together makes this scenario almost impossible to manage.

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 in the example. The history will also capture the who, where, and when of the printing. 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 and approved version and making subsequent change to that same label design can occur simultaneously.

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

A checklist of features to look for in a 21 CFR Part 11 compatible labeling system:

- Centralized security
- Centralized database approval
- Centralized administration
- Enterprise database support (SQL, Oracle, etc)
- 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, where and why
- Watermark (reprints and test labels)
- Printer support (how many printers and what manufacturers)
- Automated printing support

For More Information

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