## Healthcare and Pharmaceutical Label Printing

# Tools for 21 CFR Part 11 Compliance

This applies to versions 7.x or greater of LABELVIEW Gold



LABELVIEW<sup>™</sup> Gold label design software provides features to aid in the FDA's 21 CFR 11 compliance process. These software features can be configured to meet your internal requirements, as well as those of the FDA, to set up a compliant solution.

## **LABELVIEW Features:**

#### Secure Access for Label Design

#### System Security

The system security feature allows you to restrict users to certain features of the program. You can set up system security by assigning a user ID and password and then selecting the tasks the user may perform.

#### Label Security

The Label Setup > Password tab allows you to set up passwords to control access to specific labels, unlike the main system security password settings which control access to the program itself. Use of this feature is optional and is specific to each label. Whenever a password-protected label is called up, the user will be prompted to enter a password before the label is displayed.

#### Manage Variable Data

#### Pick List

The Pick List data source allows you to specify a list of valid choices, so that at print time you can enter a value by selecting it from a list. You can limit user input to only items in the pick list to ensure valid entries, or allow other entries besides those on the list.

#### Clear After Print

The Clear After Print option automatically clears variable values after a label prints. This feature eliminates the risk of retaining variable values between print jobs.

#### **Audit Trail Options**

#### Logging

When you enable logging, LABELVIEW generates reports that record the label formats being printed and the content of specific fields that you have set to be logged. With logging enabled, a report (lblview.rpt) is generated every time you print labels. Reports are stored as text files that can be viewed and/or imported into databases or other reporting applications.



# LABELVIEW Configuration Steps for 21 CFR Part 11 Compliance

Follow these three simple steps to configure LABELVIEW Gold to meet your compliance requirements:

Step I – Set up secured access for label design Step II – Configure security for variable data Step III – Save printed data to a logfile

#### Step I – Set up secured access for label design

Global Security

- 1. Choose Security from the Options menu.
- 2. Click the New button.

iystem Security	X
Users	
	New
	<u>E</u> dit
	Delete
	E <u>x</u> it

- 3. Add a username and password.
- 4. Check the appropriate boxes to enable each user's features.



Upon exiting LABELVIEW all users will be required to log in. Only users who have been set up can perform functions in LABELVIEW.



## Label Specific Security

- 1. Choose Label Setup from the Edit menu.
- 2. Click the **Password** tab.

Label Setup	
Label Setup   Options   Password   Label Description	on Job Modifier
Modify and Print Current Password Meteodox New Password Meteodox Confirmation Meteodox	Print only Current Password New Password Confirmation *********
	OK Cancel Help

3. Here you can enter a password to control who may edit and who may print the label. This level of security precedes global security.

## Step II - Configure security for variable data

#### Pick list Fields

1. Select **Pick list Setup** from the **Options** menu.





2. The Pick list Setup dialog box will open. Verify that the Pick list you wish to use is listed. If the Pick list is not listed, click **New**.

Picklist Setup	
Picklist Files:	
colors.pkl size.pkl	<u>N</u> ew
style, pkl	
	<u>E</u> dit
	<u>D</u> elete
	E <u>x</u> it

3. To add values to the new Pick list, click **New** and enter the values you wish to make available.

Picklist File: new file	×
New	
Edit	
<u>D</u> elete	
<u>A</u> s Default	T
Sort	
Enter value	
Default 500mg	-
String L OK Cancel	
	_

4. When you are finished entering values for the Pick list, click **OK**. Enter a filename for the Pick list you have created.



Picklist File: new file	X
New 500mg File Name	┓
dosage03122003.pkl	
Sort	
Default:       String Length:       10       ✓ Force data to come from list       ✓ Allow update at print time	

5. Click the Force Data to Come From List check box and click OK to exit the New Pick list dialog box.

Picklist File: new file	
New 500mg	M
Edit	
<u>D</u> elete	
<u>As Default</u>	
Sort	
Default:	
String Length: 10	ок
Force data to come from list	
Allow update at print time	<u>C</u> ancel

6. Click **Exit** to close the Pick list Setup dialog box.



P	icklist Setup	X
	Picklist Files:	
	colors.pkl dosage03122003.pkl	<u>N</u> ew
	size.pkl style.pkl	
		<u>E</u> dit
		<u>D</u> elete
		Exit
		<u></u>

7. Double-click an existing text field or create a new text field on a label. In the properties dialog box, select the **Pick list** data source option.

Text: TEXT6			×
Text Options Color			
Font	Scalable	•	
Font Height	0.25		
Font Width	0.14		
Rotation	Normal		
Data Source	Pick list		
Pick list	Fixed When printed		
Prompt	Linked dBase		
Justification	ODBC DB OLE DB		
	Date stamp Time stamp		
	Serial file CommWatch		
	Accumulator File Pick list	OK Cancel Help	1
	Shift Code Data Dictionary		_

8. Select the desired Pick list file in the **Pick list** drop-down list.

Text: TEXT6	
Text Options Color	1
Font	Scalable
Font Height	0.25
Font Width	0.14
Rotation	Normal
Data Source	Pick list
Pick list	dosage03122003 💌
Prompt	Select Weight
Justification	Left
	<u>K</u> <u>Help</u>



9. Enter the Prompt the user will see at print time

Text: TEXT6	×
Text Options Color	1
Font	Scalable
Font Height	0.25
Font Width	0.14
Rotation	Normal
Data Source	Pick list
Pick list	dosage03122003 💌
Prompt	Select Weight
Justification	Left
	<u> </u>

10. Click **OK** to exit the text field properties dialog box.

## Clear After Print

- 1. Double-click on each When Printed, Pick list, and Database key field.
- 2. Click the **Options** tab and set the **Clear After Print** option to **Yes**..

Text: TEXT1		×
Text Options Colo Increment Copies Field Name Reversed Leading Zeros Hidden Custom Spacing	r O Hequired No No TEXT1 Acm File No No No No No No No No No No	
	<u>QK</u> ancel <u>H</u> elp	



## Step III - Save printed data to a logfile

1. Choose **Configuration** from the **Options** menu.



2. Click the **Log** tab and then click the **Log** check box.

Configuration	
Label Select Print General Printing Op	Pad / Pocket LABELVIEW Click Print Display Network OLE DB Manager ptions Barcode Verifier Log DataWatch Command File CommWatch
🔽 Log	
Data Type	ASCII delimited
Extension	RPT V
Path	C:\DDCUMENTS AND SETTINGS\SALES DEMO\DESKTOP
🔽 Daily Based Filen	ame
	<u> </u>

- 3. Select the preferred data type.
- 4. Select the preferred log extension
- 5. Specify the location where the log files will be saved
- 6. Check the Daily Based Filename option to generate a log for each day of printing.



- 7. Open each label that requires logging.
- 8. Double-click each field that requires logging and set the **Log this Object** option to **Yes**.

Text: TEXT1			×
Text Options Cole Increment Copies	or ) 0 1	When Printed Opt Required Must Fill	ions:
Field Name Reversed Leading Zeros Hidden	TEXT1 No V No V	Acm File Log this Object	none
Custom Spacing	J	<u>K</u>	<u>Cancel</u> <u>H</u> elp

## Summary

TEKLYNX software assists companies and its investigators in complying with 21 CFR Part 11. Using proper design techniques and tools can make compliance easier. This document is intended to make it easier for you to comply with any future FDA regulations on discovery using LABELVIEW.

