

## Healthcare and Pharmaceutical Label Printing

### Tools for 21 CFR Part 11 Compliance

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*This applies to versions 7.x or greater of CODESOFT Enterprise*



CODESOFT Enterprise 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.

### CODESOFT Features:

#### Secure Access for Label Design

CODESOFT uses NT security. The network administrator will need to set up the users as needed per the requirements of 21 CFR Part 11.

##### *User Manager*

User Manager is a tool for managing access rights to CODESOFT functionality. It allows an administrator to set up user groups and assign access to functionality based on the users assigned to that group. User Manager also allows an administrator to create and delete user accounts.

##### *Profiles*

A profile is the association of a user group with a specific set of access rights. A user is typically assigned to a user group that provides access to all the CODESOFT functionality the user needs to do his or her job.

##### *Profile Management*

With profile management, the computer on which CODESOFT and User Manager are installed is the one that manages user profiles. User Manager administers the user profiles declared on the network.

When the user launches CODESOFT, User Manager verifies that the user is registered in one of the user groups. If not, the user is automatically assigned to the Guest user group. As such, the user has access only to the functionality associated with that group. NOTE: If the workstation on which CODESOFT is installed is connected to an NT network, the administrator will have direct access to the names of all users on the network. This reduces the risk of creating users with incorrect names.

#### Manage Variable Data

##### *Variable Properties*

CODESOFT allows a user to define the properties of a Form variable. Form variables are populated by data that a user inputs at the time of printing. The form can be defined to prompt the user for a specific entry, to provide lists of predefined entries from which the user can select, or to allow free-form entries every time you print. Removing all information from previous print jobs ensures that the information remains current and accurate.

### *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.

## **Audit Trail Options**

### *Printing LogFile*

CODESOFT can log the label variables associated with the label at print time with the use of the Printing LogFile. A printing logfile is a file that provides a record of the labels you have printed. You define the content and file format of the logfile, as well as whether to include variables, and the date and time of printing. Content for the logfile is generated automatically when printing starts. Reports are stored as text files that can be viewed and/or imported into databases or other reporting applications.

## **Label Revision Control**

### *Summary*

The Summary allows a user to add a description of changes or edits to a specific label to facilitate revision control.

### *Export to File*

The Export to File feature allows you to save the Summary label description information to a text file.

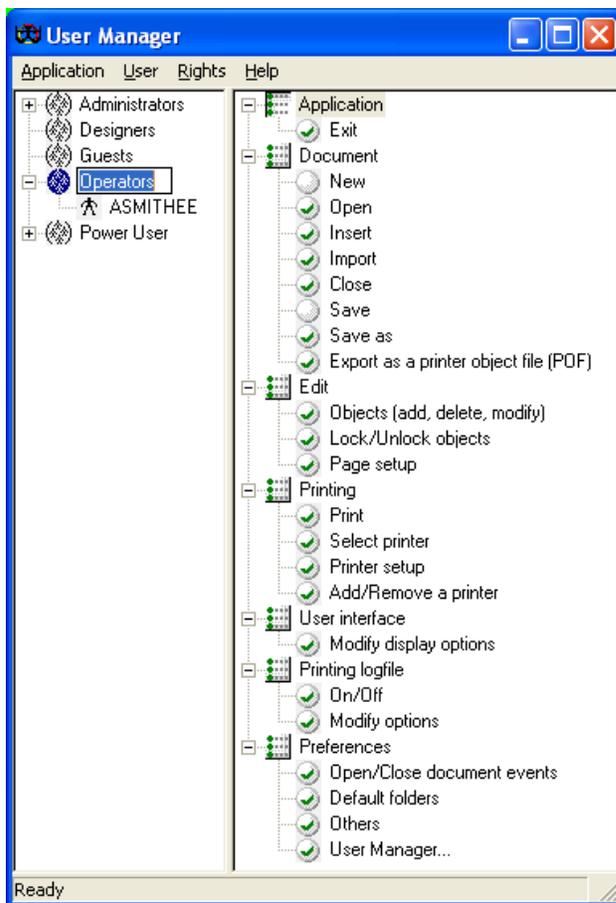
## CODESOFT Configuration Steps for 21 CFR Part 11 Compliance

Follow these four simple steps to configure CODESOFT Enterprise to meet your compliance requirements:

- Step I – Set up secured access for label design
- Step II – Print entered and/or retrieved data only
- Step III – Save printed data to a logfile
- Step IV – Set up revision control

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

1. Open the **User Manager** by selecting **Start > Programs > CODESOFT 7 > User Manager**.
2. Once in the User Manager you can set up new groups or add new users.

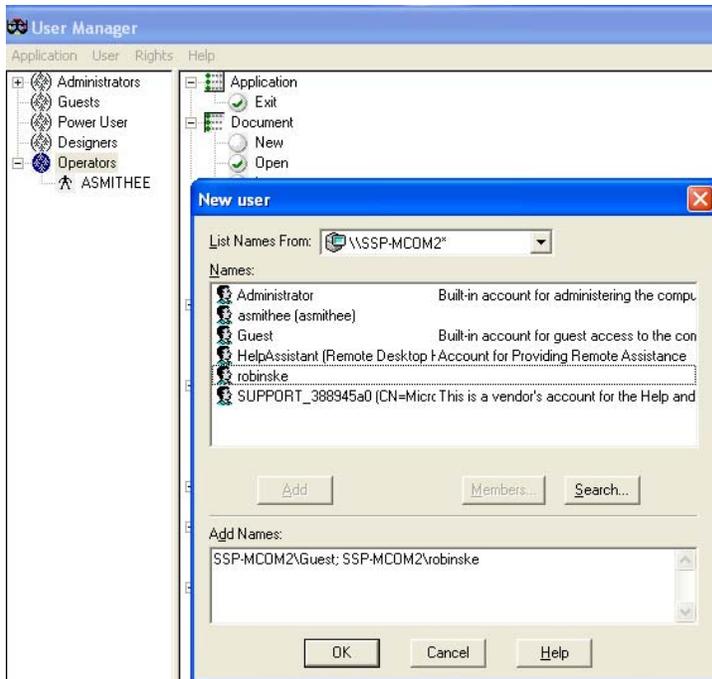


3. To add new groups, choose **New Profile** from the **User** menu.

By default all new groups will have Administrator rights. You will need to determine what rights you want your groups to have by checking/unchecking security rights for each group.

4. To add a new user, select the group you wish to add the user to and select **New User** from the **User** menu.

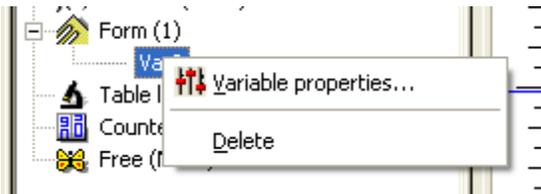
You will be able to select from existing user accounts on your network.



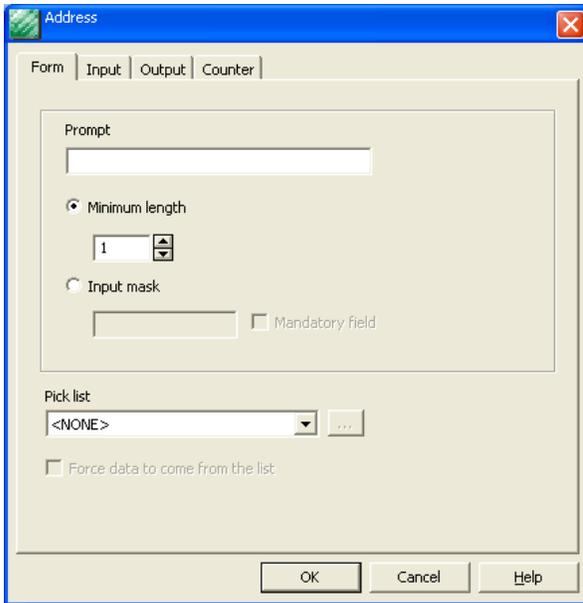
## Step II - Print entered and/or retrieved data only

### Clear Variable Fields After Print Jobs

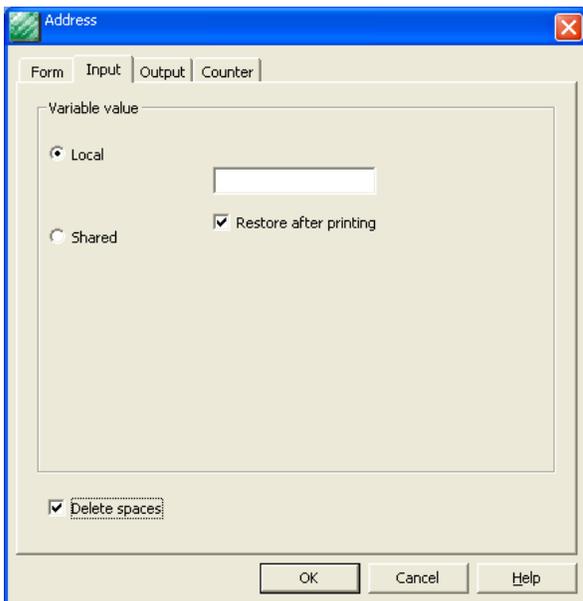
1. Right-click on an existing **Form** field and go to **Variable properties**.



The dialog box will display the **Form** tab.



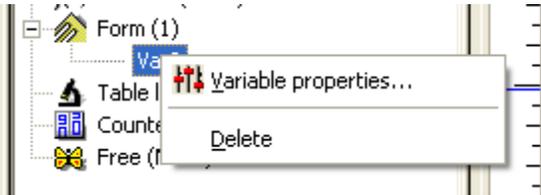
2. Ensure that you have minimum length set to an acceptable value for your label.
3. Click on the **Input** tab.



4. Make sure the **Local** variable option is selected and that the text box is empty.
5. Check the **Restore after printing** check box.

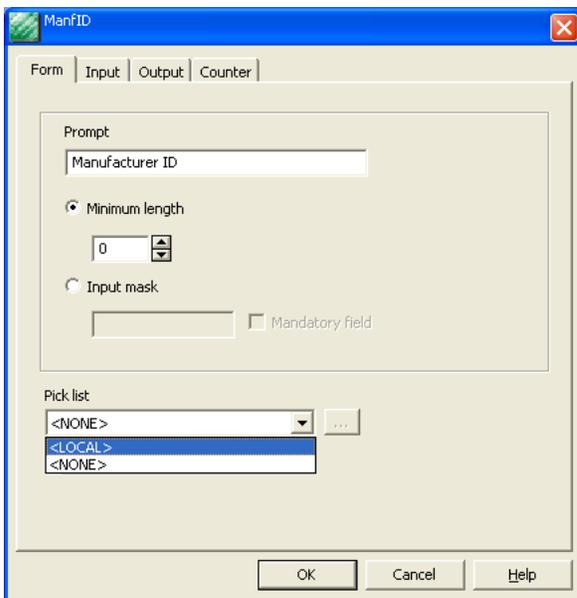
## Configure a Pick List

1. Right-click on an existing **Form** field and go to **Variable properties**.

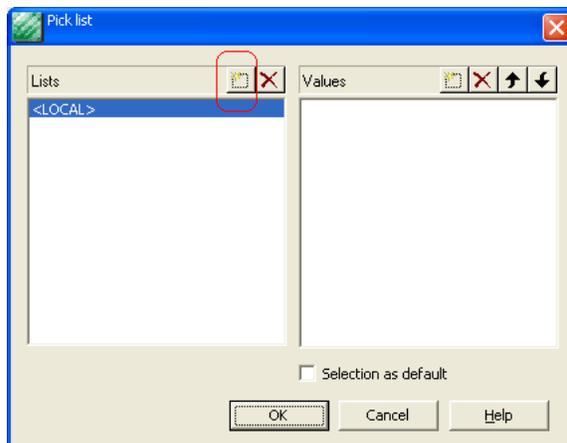


The dialog box will display the **Form** tab.

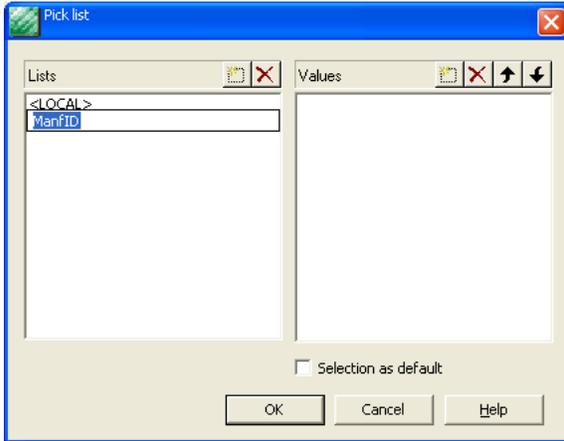
2. Change the value of the Pick List combo box from <none> to <local> and click the ellipses button.



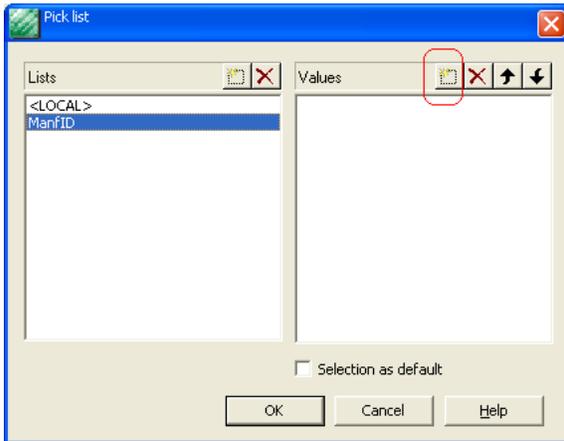
3. The Pick List dialog box will open. Click the New button on the Lists side of the dialog to create a new Pick List.



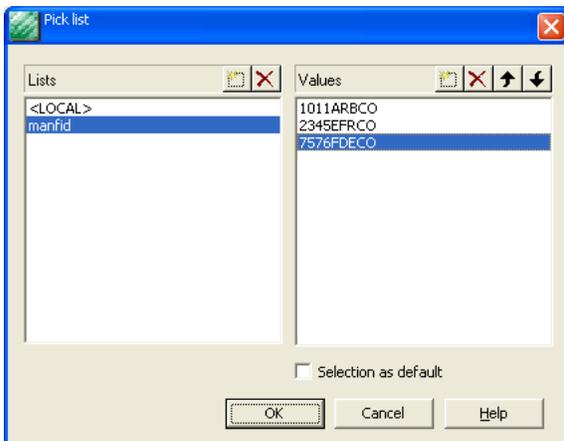
4. Enter a name for the new Pick List and press Enter to create the new list.



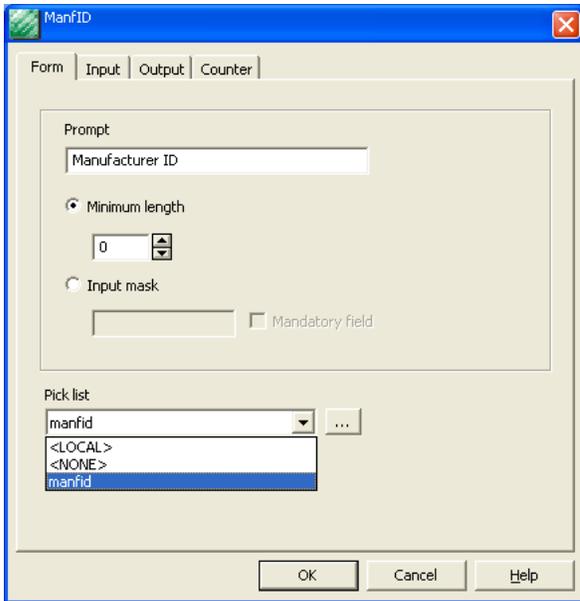
5. To add the values to the newly created Pick List, click the New button on the Values side of the dialog.



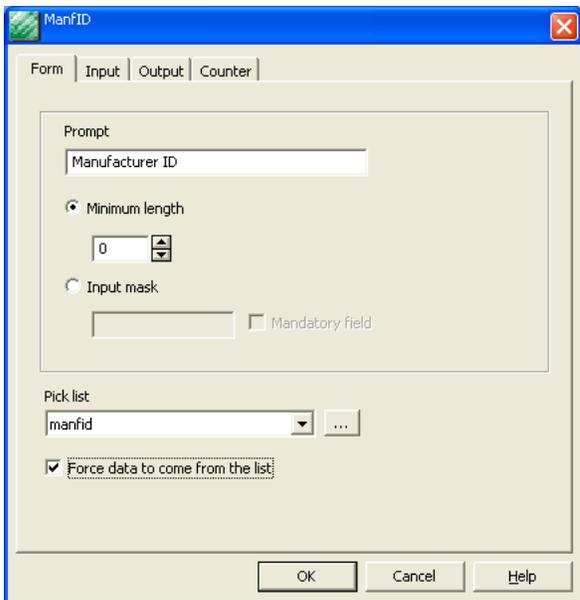
6. Press Enter after you type each value to add it to the list. Once you have entered all the values to the Pick List, click OK to exit the Pick List dialog box.



7. Ensure the Pick List you created is selected in the Pick List combo box.



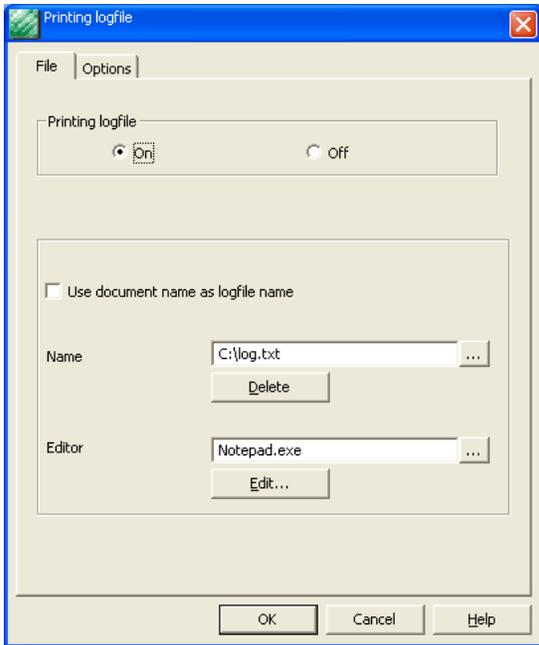
8. Enable the checkbox labeled Force Data to Come From the List.



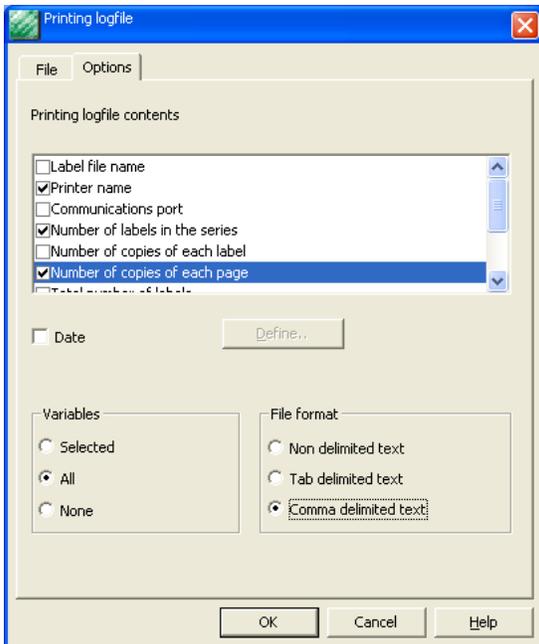
9. Click OK to save your changes to the variable.

### Step III - Save printed data to a logfile

1. Choose **Printer LogFile** from the **Tools** menu.



2. Click the **On** option to turn on logging.
3. Specify the logfile name and location.
4. Select the default editor for the logfile (Notepad and Microsoft Excel are examples).
5. Click on the **Options** tab.

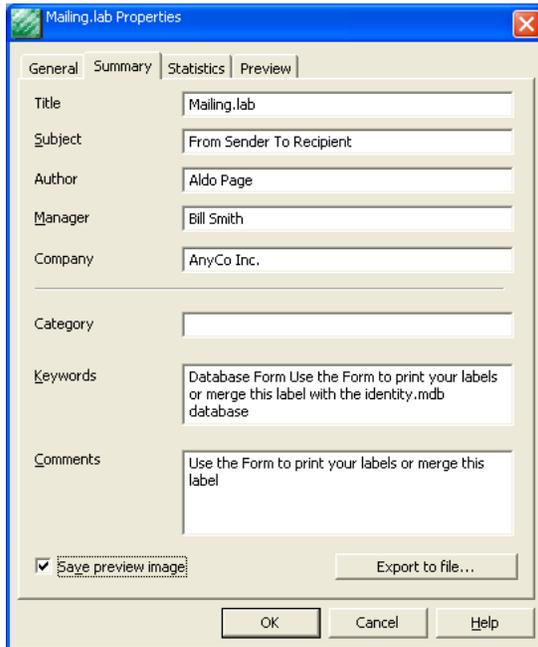


6. Select from the list of logfile content elements you wish to include.
7. Choose the **All** variables option.
8. Select a file format type.

9. Define a date stamp if you choose.

#### Step IV – Set up revision control

1. From the **File** menu, select **Properties**.
2. Click the **Summary** tab and enter the appropriate data for the label.



The screenshot shows the 'Mailing,lab Properties' dialog box with the 'Summary' tab selected. The fields are filled with the following information:

Field	Value
Title	Mailing,lab
Subject	From Sender To Recipient
Author	Aldo Page
Manager	Bill Smith
Company	AnyCo Inc.
Category	
Keywords	Database Form Use the Form to print your labels or merge this label with the identity.mdb database
Comments	Use the Form to print your labels or merge this label

At the bottom of the dialog, there is a checked checkbox for 'Save preview image', an 'Export to file...' button, and 'OK', 'Cancel', and 'Help' buttons.

3. Click the **Export to file** button.

This will create a text file that provides a description of the file structure and can be used control the latest version of the label format.

#### 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 CODESOFT.