

Tools for FDA 21 CFR Part 11 Compliance

In 1997, the Food and Drug Administration (FDA) issued the final Part 11 regulations providing acceptance criteria under certain circumstances. These regulations, which apply to all FDA program areas are intended to permit the widest use of electronic technology compatible with FDA's responsibility to protect the public health.

With the release of EASYLABEL® 5 Platinum, Tharo Systems Inc is providing a collection of tools for FDA 21 CFR Part 11 compliance. Using these tools and based on your company's internal requirements and those of your FDA inspector you will be able to set up a compliant system.

EASYLABEL 6 features a new extensive reporting, logging and label reprint application called the EASYLABEL Print History Console which may also be of interest to those must comply with FDA 21 CFR Part 11.

What follows is a list of the options added To EASYLABEL to provide tools for FDA 21 CFR Part 11 compliance. Any or all of these options can be used as part of your company's FDA 21 CFR Part 11 compliance solution.

Keep in mind that it is up to you to make sure your company is in compliance with the FDA. Any labeling software can only provide you with the features to help you correctly and consistently comply with the 21 CFR Part 11 regulations.

Updated User Sign-on and Password Options:

- User ID and passwords can now be up to 16 characters long. This gives you more options when setting up a minimum password length and allows more descriptive User IDs.
- The User Description field on the User Configuration screen allows the system administrator to add descriptive notes for each User.
- The administrator can select a minimum length for User ID and Password. This will eliminate single letter passwords that are easy to circumvent.
- The administrator can set password expiration by number of days so that users are forced to change passwords periodically. The periodic expiration of passwords adds to the security of the system.
- User accounts can be "locked" so that the User-ID cannot be used until it is unlocked. This can be used to temporarily block a user from accessing the software.
- The administrator can set a password re-use policy to prevent users from reusing old passwords. Using new passwords instead of a password that may still be written down somewhere minimizes the chance that EASYLABEL's passwords will be compromised.

- New "complex password" option to force passwords to contain at least one numeric or other special character. Passwords that contain numbers and/or special characters are more difficult to crack.
- A user authorization option enables or disables the user's ability to change their password during login giving the administrator complete control of when passwords are updated.
- A user authorization option that requires the user to reenter their username/password any time a file is updated/saved from within EASYLABEL.

New User Logging Options

- There is an option to log changes that are made to the user configuration. This would include the addition, deletion or change of a user and/or their rights making it easy to review changes at a later date.
- There is an option to log user events such as: login success, login failure, logoff, and password changed. The administrator can set the maximum size and location of this log. This option provides an easy way to archive these events for future reference.
- A separate log file viewer makes it easy to view logs on screen or create printed reports of user logs without having to have EASYLABEL[®] running.

Audit Trail Options

- It is possible to save an image file of a label format. This makes label approval easy since the label images can be attached to E-mails or enclosed in documents. The images of the formats can then be reviewed and approved, even by someone that doesn't have EASYLABEL installed!
- To keep track of the printed labels there is an option to save an image file (EMF) for all print jobs. With this option turned on, an image of the first label of the job is created for every print job. The image can be named automatically or by the value of a special field on the format. This image name is then saved in the format tracking report. This option gives a clear depiction of what was actually printed.
- To keep track of label changes, there is an option that requires the user to enter a comment when a label format is saved. The comment should describe the reason the label format was changed. The User-ID of the person who made the change is also saved. This comment would help provide documentation to provide an audit trail of a format's development life cycle.
- There is an option to save a history of all changes made to a specified label format. This option creates a backup format file anytime the format is saved. These backups can then be used to replace a format if any inappropriate changes were made.
- There is an option to keep track of file deletions. The 'delete log' will record the user, date, time, and pathname of any files that were deleted using the

file→erase command through EASYLABEL's menu. This makes tracing unauthorized deletions as easy as looking at the log file.

- The database logging option will copy any updated database records to another database to keep a historical record of database changes. These backups can then be used to reconstruct the database if any incorrect changes were made. Database logging will only work with EASYLABEL 5's new internal Access based database structure.

Print History Console

- The Print History Console provides a central location for your EASYLABEL reports and logs. Multiple copies of EASYLABEL can connect to the Print History Console allowing for centralized logging and reporting. It is no longer necessary to comb the network for your EASYLABEL user logs, change logs and format printing reports, now they can be stored in a single location.
- The Print History Console provides reports that can be searched and sorted and can be viewed or accessed in the provided interface or any other application that can access a Microsoft SQL table. The Print History Console can be made part of your existing SQL server or you can choose to install Microsoft SQL Express when setting up the Print History Console.
- The Print History Console is secure. You can control access to the Print History Console and protect sensitive information by specifying who can view the reports; prevent unauthorized users from reprinting labels; or simply restrict all users' access.
- The Print History Console provides a complete label reporting solution. Print jobs can be reviewed in a list containing such data items as the Date/Time the job was sent, status of the last job, computer the job was sent from, label format printed, printer the job was sent to and number of labels printed. Every field value is listed for every label in the batch similar to EASYLABEL's current "Tracking Report By Batch" option. You can use a search to find field values from printed labels from the main page. Also, a label preview image is presented for each printed label batch. You can limit the number of jobs shown to any range of time: 24 hours, 7 days, 30 days or just show all labels ever printed.
- The Print History Console keeps track of changes. You can track all changes made to a specified label format. The Print History Console will create a backup and log the reason for a change anytime the format is saved. These backups can then be used to replace a format if any inappropriate changes were made. The Print History Console also will log changes made to user configurations, including additions, deletions or changes to a user and/or their rights. There is an option to log user events like login success, login failure, logoff and password changes. Print History Console provides an easy way to archive these events for future reference.
- The Print History Console peacefully co-exists with EASYLABEL's "old" text-based logging and reporting system. You can use either one or both. If you have amassed many of the current logs and reports and would like to use the



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Print History Console there is a tool for importing data from the existing logs and reports.

- Easily reprint any damaged label with the Print History Console by clicking on a label in the list and selecting reprint. You can select a specific label in the job, for example only reprint label number 35 out of 100. The Print History Console also has the ability to reprint a selected range of labels from the job or the entire job. Reprinted labels are themselves logged and are flagged as reprints in the report for absolute label tracking.
- EASYLABEL's Print History Console is a powerful tool that can meet the needs of companies requiring very strict control over their labeling system.