enLabel 21 CFR PART 11 REQUIREMENTS CHECKLIST

The following section assesses enLabel is fully compliant with the U.S. Food and Drug Administration 21 CFR Part 11 Requirements.

ELECTRONIC RECORDS		
System Controls		
21 CFR Part 11 Requirements	**Compliant?**	**Comments**
The system shall be validated to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records.	✓	enLabel has been thoroughly validated by EnLabel Global Services, Inc, but the customer retains the responsibility of performing the necessary validations for their intended use at their site. A critical part of our product offering is providing our customers with superior validation support.
11.10(b) The system shall be able to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review and copying by the FDA.	✓	▪ By Print out. ▪ Export of data in text (delimited) and graph format.
11.10(c) Protection of records to enable their accurate and ready retrieval during the record retention period.	✓	Storing data in the enLabel database until the DBA performs data archiving as per their procedures. enLabel backs up data on weekly basis. Customer is encouraged to perform timely backups of the database.
11.10(d) Limiting system access to authorized individuals (Physical access).	✓	▪ By login username and password. ▪ Enable Windows NT authentication.
11.10(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actins that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for FDA review and copying.	✓	Audit Trail is ALWAYS enabled and it works automatically in the background: - The Audit Trail may be configured to capture all fields of the modified label, and highlights the modified fields. The Audit Trail includes the User Name, User Id, Date and Time that the transaction was committed. - enLabel utilizes the database server date and time to stamp all transactions. This feature guarantees the integrity of your records, and avoids confusion if the workstation date and time is intentionally or unintentionally changed. The customer is responsible of providing the appropriate measures to ensure that the security features implemented in enLabel are not bypassed. EnLabel Global Services recommends disabling access to the Date/Time applet in the Microsoft Windows Control Panel, providing automatic server/workstation date/time synchronization

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		services, and restricting physical and network access to the database server.
11.10(f) Use of operational system checks to enforce permitted sequencing of steps and events as appropriate.	✓	Configurable - to provide warnings whenever required data is missing or inappropriate (i.e. number vs. alphanumeric) or when an individual tries to perform operations that are not allowed by his security privileges.
11.10(g) Authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	✓	enLabel has security on different levels. User access privileges can be set to View Only, Data Entry or Administrator. User access can be further restricted to specific departments, menu options, label directories, and modules. The user can be prevented from performing certain activities like creating new revisions or changing existing labels. The administrator is able to control the access of the users to the system.
11.10(h) Use of device checks to determine, as appropriate, the validity of the source of data input or operational instructions.	CR	Customer Responsibility
11.10(i) Determination that persons who develop, maintain, or use electronic record / electronic signature systems have the education, training to perform their tasks.	CR	Customer Responsibility
11.10(j) Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	CR	Customer Responsibility
11.10(k) (1) Adequate controls over distribution of, access to, and use of documentation for system operation and maintenance.	✓	• Customer Responsibility. • enLabel Global Services Inc. provides manuals for system usage and maintenance.
11.10(k)(2) Revision and change control procedures to maintain an audit trail that documents time sequenced development and modification of systems documentation	✓	EnLabel Global Services follows change control procedure to ensure the customers have the proper manuals and documents.

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11.30(g) The system shall support document encryption or digital signatures to ensure, as necessary under the circumstances, record authenticity, integrity and confidentiality. (this requirement applies to opens systems only)	✓	enLabel supports internet protocols and encryption as well as SSL.

ELECTRONIC SIGNATURES

enLabel supports electronic signatures using four different methods:

- User Id / Password combination – the basic method utilized by enLabel. No additional hardware or configuration is necessary.
- I-button – an electronic button that the user places in a cradle when the signature is executed. The button contains a unique Id. The I-button has additional memory that can be used to store user information.
- Signature pad – the user signs his handwritten signature in the pressure sensitive pad. The system then compares this signature with the one stored in its database. The pressure sensitive feature adds extra security over bitmapped signatures.
- Finger scan (biometrics) – the most secure of the methods supported by enLabel. This method scans the fingerprint of the user and compares it with the one stored in the database.

21 CFR Part 11 Requirements	Compliant?	Comments
General Requirements		
11.100(a) Uniqueness of the electronic signatures.	✓	
11.50(a) The system shall specify the printed name of the signer, date and time and the meaning of the signature on the record.	✓	
11.50(b) The items identified in paragraphs 11.50(a) of this section shall be subject to the same controls as for electronic records or as part of any human readable form of the electronic record (such as electronic display or printout)	✓	

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11.70 Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	✓	
Component and Controls		
11.200 (a) (1) Signatures NOT based on biometrics shall employ two distinct components such as identification code and password.	✓	enLabel's basic authentication method is based on User Id / Password combination. This combination is required to login into the system and apply a signature.
11.200 (a)(1)(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.	✓	Both User ID and Password are required to be input at each signing
11.200 (a)(2) The signature can only be used by their genuine owner;	✓	The customer must provide adequate training and controls to ensure that their users comply with this requirement.
11.200(c) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	CR	Customer Responsibility
11.200 (b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	✓	Optionally enLabel supports biometrics technologies that ensure that their respective owner can only use them.

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Controls for Identification Code and Password		
11.300 (a) Uniqueness of each combined identification code and password.	✓	enLabel does not allow duplicate User ID's.
11.300 (b) The system shall ensure that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such event as password aging).	✓	Customer Responsibility - The feature can be enabled by the customer.
11.300 (c) Following loss management procedures to electronically de authorize lost, stolen, missing or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	CR	Customer Responsibility
11.300 (d) The system shall prevent and detect any attempt of unauthorized use of identification codes and passwords. The system shall report in an immediate and urgent manner any attempt at unauthorized use of identification codes and passwords to the system security unit, and as appropriate, organizational management.	✓	enLabel enforces a customer configurable maximum number of login attempts. The user account is deactivated if this maximum is reached, and the system administrator is notified via email.
11.300 (e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	CR	Customer Responsibility

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