

Winchester's 21 CFR Part 11 Compliance Product

ComPac from Winchester is a self-contained, compliance package module that can be "bolted on" to an existing Lotus Notes application. Once bolted-on, the application can become compliant with Part 11. Winchester has placed the proper compliance directives into the program code of ComPac.

ComPac is designed exclusively for regulated companies, especially those governed by FDA-regulations. ComPac is specifically designed to help regulated organizations achieve Part 11 compliance. ComPac does not require the expenditure of additional technology investments.

ComPac provides an enhanced level of security, built-in business rules, and best practices to help organizations achieve compliance with the FDA's regulation 21 CFR Part 11.

ComPac is a modular component of every application product developed and supplied by Winchester. This use of ComPac ensures integrity, commonality of design, and consistency of application.

ComPac is offered by Winchester to qualified clients for their development staffs to use to upgrade existing and legacy applications to become compliant with Part 11.

Lotus Notes®, the Ideal Infrastructure for Regulatory Documents

— Electronic Records.....

It's all about audit trails! ComPac produces an electronic record audit trail that captures the "value" or content of each desired or field to be tracked in a document. The audit trail is recorded in a record that is "separate" from the master document being tracked.

Whenever a new master document is initiated, an audit trail record is generated by ComPac as well. The "document id" of the master document is captured to track all changes to the master document after it was initiated. Each time a master document is "opened" in to be edited, a snapshot is taken of the tracked fields and their respective values.

When the master document is "saved," a snapshot is taken again of the tracked fields, if any tracked field has been changed, a message is written to the audit trail record describing the field name and both the "before" and "after" values. The user's id file and profile is interrogated. The user's name [digital signature] and the date and time of the save event are written to the audit trail record.

Key Features

AUDIT TRAIL

- Field Level Audit Trail
- Who, When, Old/New Values
- Transaction Time-stamps
- Snap in Sub-form
- External Logging
- Configuration and Set Up Form
- Optional Reason for Change

AUTHENTICATION

- Password Control
- Challenge/Response on Save
- NSA Standards for Encryption
- Expiration/Renewal Dates
- Public/Private Key Authentication

ACCESS LOGGING

- Database Entry
- Document Viewing
- Length of Access
- Failed Login Attempts

ACCESS CONTROL

- Auditable Access Changes
 - > Levels
 - > Roles
 - > Responsible for Change
- Database Lock-Down
- Configurable Permission Module
- Terminations Management
- ACL Clean-up

DIGITAL SIGNATURES

- PKI Based Authentication
- Stored Permanently in the Record
- Web or Notes Authentication

Audit trail records are not kept in the same location as the master documents. Some companies choose to keep them in an entirely separate ComPac database where the only access is “read only” to an authorized user. A “tab” may be inserted on the master document which would allow an authorized user to “view the audit trail documents” in chronological order.

— Features of ComPac’s Approach to Electronic Records:

- * Specific Forms and Document Types may be selected to generate audit trails
- * Specific fields are selected or not-selected on a document/form to be tracked
- * Audit trail documents cannot be edited, changed, or deleted
- * Audit trail documents contain the before and after values of any field that was altered during a specific edit session
- * Audit trails contain the unique, Lotus Notes-issued document id of the master documents being tracked
- * Audit trails contain the name of the user that made the change as well as the date and time the change was saved by the user.
- * The audit trail can contain the profile id or “electronic signature” of the person that made the change.
- * Once deployed, audit trails are a natural part of the specific application.

—Electronic Signatures.....

ComPac’s approach to electronic signatures is built upon a password and electronic signature approach that can be unique to each and every Lotus Notes application or database.

1. Check for Access —When a user opens an application for the very first time, the Access Control List (ACL) is checked to determine what level of access that the user may have – groups from the company’s name and address book are included. The user must have at least “Reader Access” to open the application otherwise access is denied to the user.
2. Access is Allowed — If the new user is allowed access, the ComPac interrogates the user for a new “profile” password that will be recorded within the application. That password will be required to create/compose a new document or edit an existing document.
3. If the User can Create or Edit a Document — If Author or Edit access is permitted to the user, the user is queried for the user’s application-specific password at the end of the session when the user tries to “save” the document the user has either created or edited.

Design Considerations — Application-specific passwords can be forced to have specific characteristics — the National Security Agency (NSA) suggests that the lower limit to password length be eleven characters.

— Features of Compac’s approach to Electronic Signatures:

- * A special field exists on the actual document being created/saved that contains the electronic signature (bit configuration taken from the user’s id) of the last person that saved the document
- * The profile password that is used for the application is unique to the application. The application password is different to the user’s login password to Notes and to the user’s Network.
- * Winchester’s Approach to application password is completely web-compatible.
- * The password configuration can be determined as a matter of client-company policy and can meet both FDA and NSA suggested formats.
- * Documents that are created or composed or edited and saved within the application require that a correct profile password be entered by the user.
- * Winchester’s Electronic Signature approach can be a component of Winchester’s Electronic Record approach.
- * Profile passwords expire and must be updated by the user according to the organization’s policies.

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