Laserfiche®

Run Smarter®

Laserfiche and FDA 21 CFR Part 11 Compliance

- Maintain the Integrity of Electronic Records
- Safeguard Electronic Signatures
- Track Activity and Promote System Validation

The FDA enforces Title 21 of the Code of Federal Regulations (21 CFR) across a wide range of organizations, but does so particularly rigorously in the pharmaceutical and biotechnology industries. Part 11 of 21 CFR requires companies to develop, document and enforce policies and procedures that ensure the security of electronic records and signatures. Laserfiche has built-in technical controls to help you implement and enforce Part 11-compliant procedures and policies.

Maintain the Integrity of Electronic Records

Part 11 governs not only the technology used to manage electronic records, but also the environment within which that technology works. Thus, no product can guarantee Part 11 compliance. However, Laserfiche has a number of features that make it Part 11-capable, and that provide an ideal foundation upon which to build Part 11 compliance processes.

- A password-protected repository, with user- and group-specific access rights, prevents unauthorized viewing, modification, distribution and deletion of electronic records and signatures.
- Granular security controls restrict access at the folder, document, metadata and individual word levels.
- Metadata tracking keeps a record of documents' authors, creation dates and modification dates.
- Customized watermarks added to printed documents denote the time the documents were printed and the person who printed them.

Laserfiche Records Management Edition (RME) is not required for Part 11 compliance, but it facilitates the implementation of good laboratory, clinical and manufacturing practices. RME helps you:

- Automate records retention cycles, with support for time- and event-based dispositions.
- Manage scanned records alongside electronic records, e-mail and audio and video files.
- Track records that exist in multiple locations.
- Fulfill legal obligations with enforced records freezing.
- Quickly screen records that are eligible for destruction or other actions.

Address: 3545 Long Beach Blvd.
Long Beach, CA 90807

Website: www.laserfiche.com
E-mail: info@laserfiche.com

Toll Free: 1-800-985-8533
Tel: 1-562-988-1688

Safeguard Electronic Signatures

Part 11 requires organizations to maintain the relationship between electronic signatures and their documents, as well as to detect unauthorized access attempts and take action against them. Laserfiche has partnered with Algorithmic Research (ARX) to provide a Part 11-capable electronic signature solution. Using the ARX CoSign product with Laserfiche, your organization can meet Part 11 electronic signature requirements.

- Electronic signatures cannot be removed or extracted from documents and records.
- Signing electronically requires a username, password and signature meaning, such as "approved" or "rejected."
- Auditors can easily view graphical representations of handwritten signatures.
- Signatures include a representation of the signer's name, date and reason for signing.
- Signers cannot repudiate the signed record.
- Electronic signatures can be verified anywhere at any time.

Track Activity and Promote System Validation

To guarantee the integrity of electronic records and signatures, you must be able to document all activity within your system. This documentation is also essential for FPA validation. Laserfiche offers comprehensive auditing features that help you monitor system activity and detect security threats.

- Record actions of individual users, such as viewing, modifying, distributing or deleting records.
- Track failed actions and automatically alert your system administrator or security officer.
- Generate customized Web-based reports, which you can view offline.
- Keep records of all searches performed in the Laserfiche repository.
- Require users to submit reasons for printing, e-mailing and exporting documents and records.
- Monitor attempts to change user rights, privileges and passwords.

The Next Step: Please call **(800) 985-8533** or e-mail **info@laserfiche.com** for more information.