

FileTrail's E-Signature Module Achieves Compliance with FDA Regulation 21 CFR Part 11 Requirement

FileTrail's e-Signature Module allows companies in the Life Sciences and Pharmaceutical industry to save time and money by increasing their capabilities to manage their physical assets as well as compliance with industry regulations.

San Jose, CA – August 30, 2011 - FileTrail Inc. – <http://www.filetrail.com> – the leading provider of physical records management solutions, today announced they have achieved compliance with the Food and Drug Administration (FDA) Regulation 21 CFR Part 11 via their e-Signature Module. The part 11 requirement defines the criteria in which electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records. The e-Signature Module was first implemented by a global pharmaceutical company in early 2011 and the client already has witnessed dramatic benefits. By using the e-Signature Module, the pharmaceutical client has eliminated the need for a wet signature when checking out, browsing, or transferring GxP documents. The FileTrail solution as a whole has automated compliance and tracking of the pharmaceutical company's diverse set of auditable documents and biologic samples leveraging both [bar code](#) and [RFID](#) technology.

The e-Signature Module is fully integrated into FileTrail's configuration engine and is highly configurable – allowing configuration of which types of transactions require an electronic signature and if a reason code or textual explanation may be entered. Additionally, an electronic signature of a witness can be configured as optional or required for each type of transaction. Information about the signature is displayed in the item's history, including the initial electronic signature, reason, as well as the witness electronic signature. This information also is available in the audit report for presentation to internal and external auditors.

“FileTrail has actively served clients in the [Life Sciences](#) and Pharmaceutical industries since our initial product release,” said Darrell Mervau, President of FileTrail Inc. “Attaining compliance with 21 CFR Part 11 Regulation is another milestone achievement for FileTrail as we continue to develop best-of-breed solutions to not only meet but exceed the expectations of our clients in this industry. Most notably, our clients in the Life Sciences and Pharmaceutical industry are looking for both increased capabilities in managing their physical assets and compliance with industry regulations - with the new e-Signature features they are able to do just that, while saving time and money to achieve a quick ROI,” concluded Mervau.

About FileTrail

Founded in 2000, Silicon Valley-based FileTrail is the leading provider of records management software and RFID tracking technology. The company has worked with more than 400 organizations across the public and commercial markets to deliver file management and tracking solutions which reduce cost, ensure compliance, and streamline business processes. FileTrail's solutions feature a flexible deployment and hosting model and are available to customers worldwide through the company's deep community of resellers and service partners. Visit <http://www.filetrail.com> to learn more.

Media Contact

Jen Beltran
FileTrail, Inc.
408-289-1300 x301
jbeltan@filetrail.com