

# MANAGING GMP RECORDS



## Paper-based GMP Records

FileTrail manages paper-based GMP records and compliments your existing DM system:

- **Compliance** - Manage and control paper-based GMP documents
- **Efficiency** - Save staff time in requesting, locating and retrieving paper-based records
- **Economics** - Automate traditionally manual business processes for a quick ROI
- **Exposure** - Apply rules to control who may access paper-based records
- **Audits** - Reliably produce paper-based records on demand and breeze through compliance audits

## Users Speak Out

Here's what users are saying about managing paper-based GMP records with FileTrail:

*"FileTrail allows our quality and manufacturing staff to better manage our GMP documents that are subject to FDA regulation."*

Amit Syal  
QE Validation Specialist

*"FileTrail really saves us time and is easy to use. It's much more intuitive than our other systems."*

Maureen Harper  
QA Document Specialist

*"The FDA expects us to present an auditor with a requested document within one hour of the request. We would not be able to do this without File Trail."*

Steven Marks  
IT Business Applications

# FILETRAIL™

...because Paper Happens®

<http://www.FileTrail.com>

## Good Manufacturing Practices

Life Sciences organizations are facing increasingly stringent regulatory requirements for their operations processes in the manufacturing and quality areas. Many already have DM systems to manage electronic documents and automate business processes, but find they lack efficient tools to control the paper-based records that remain and perform many manual processes related to handling those records.

With FileTrail, organizations streamline business processes, reduce exposure to risk, enforce compliance to Good Manufacturing Practices (GMPs), and boost Return On Investment (ROI) by reducing the time staff spend retrieving and handling paper-based records. FileTrail supplements your DM system, completing the automation and control over records in all formats.

## The Importance of Paper-Based Documentation

Maintaining adequate, detailed, and validated records is the cornerstone of GMP and covers every aspect of a product's lifecycle. Quality assurance, quality control, regulatory affairs, and manufacturing personnel still need an efficient way to locate and retrieve paper-based records for deviations, compliance and materials, as well as test records, batch production records, change requests, and any resulting corrective and preventive actions.

## FileTrail Saves Time and Implements Controls

FileTrail provides a flexible and intuitive interface to collect the specific information required for each different type of document. Powerful search tools and location tracking provide fast and accurate access to information. The ability to browse or check out records is controlled by automated security, while audit trails and the accurate location of records streamline regulatory audits.

## Demonstratable Compliance

With FileTrail, organizations can easily demonstrate compliance with regulations, defend internal policies and actions and avoid legal, monetary, and procedural penalties while protecting intellectual resources and the corporate image. All this while freeing staff time to focus on higher-value work.

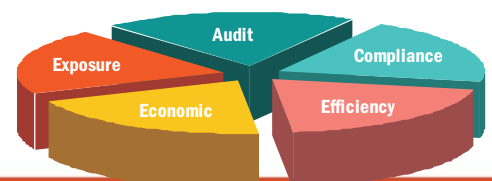
## Solutions For the Product Lifecycle

You face tremendous pressure in trying to bring products to market, decrease cycle time, ensure compliance, and increase productivity. The last thing you need in any phase is to have staff physically searching for paper-based records.

FileTrail can help you throughout the entire product lifecycle, from research and development, regulatory, clinical studies, manufacturing, quality, and sales and marketing.

FileTrail addresses the primary needs of managing paper-based GMP records:

Compliance, Efficiency, Economic, Exposure and Audit



## Managing GMP Records

FileTrail simplifies tracking and management of paper-based GMP records:

- Automatically applies higher standards for data and validation
- Integrates with upstream systems to automatically load and synchronize data
- Achieves compliance with regulated record-keeping requirements
- Automates requesting, retrieval and checkout of active records
- Automates archiving and retrieval of inactive records
- Tracks retention and applies rules uniformly and automatically
- Controls and logs access to records throughout their lifecycle
- Automates file room operations

## FileTrail Advantages

FileTrail's unique offering is the result of several factors:

- **Focus** - We focus on one thing - being the best at paper-based records management
- **Flexibility** - FileTrail is the most flexible records management system available, with easy-to-use configuration tools
- **Expertise** - Our experience really shows in our product's competencies - and our customers rave about it

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## End The Search for Paper-Based Records

Staff spend too much valuable time trying to chase down paper-based records. Penalties apply if you cannot deliver requested paper documents to an FDA Auditor in a timely manner.

FileTrail saves time for staff and helps you sail through FDA Audits. Fast and easy tools for tracking log the location of files, binders and notebooks, making location and retrieval fast and simple.

## Control Access to Paper-Based Records

Regulatory compliance requires restricting access to documents to those who have legitimate need and authority. Applying these rules and documenting the chain of custody is almost impossible without automation.

FileTrail provides powerful security tools to restrict who may browse a record within a secured area, versus removing the record entirely. Additional Permissions control a user's access to view, add, or change descriptive meta data within FileTrail based on department, category, specific record, or field-by-field.

## Complete Records Lifecycle Management

FileTrail gives you control of paper-based GMP records through the records lifecycle. Common business processes, including creation, circulation, archiving, and destruction are automated and documented.

FileTrail ensures that records are transitioned through each stage of their life in a uniform and timely way. Our processes are clear and minimize labor requirements, incorporating regulated record-keeping requirements from initiatives like Sarbanes-Oxley, HIPAA, and others.

## An Enterprise Solution for the Enterprise

FileTrail is so flexible and secure that it can even serve the administrative parts of your organization. Clients use FileTrail in various HQ departments including: Legal, HR, Tax, Finance, Property, and others.

## Contact FileTrail Today!

For more information about the benefits of automating your clinic, contact FileTrail or your local FileTrail representative at:

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