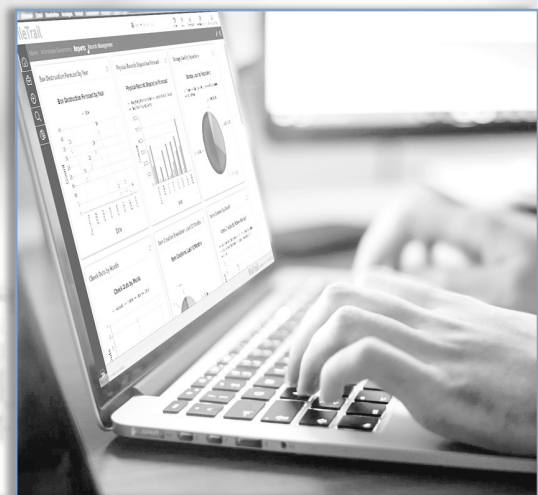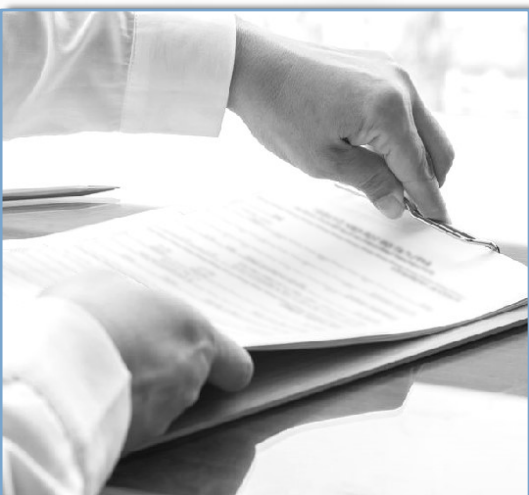# COMPLIANT GxP DOCUMENT AND RECORDS MANAGEMENT

Pressure to bring new products to market faster has never been greater. At the same time, records and information management are growing more challenging by the day. Isn't it time you upgraded your records management system?

For research-based pharmaceutical and biotechnology companies, effective records management plays a critical role in every stage of the product lifecycle — from R&D and clinical trials to regulatory approval, manufacturing, quality assurance, and sales and marketing.

FileTrail modernizes records management. We've worked with leading pharma and biotech companies, as well as the FDA, providing solutions that streamline the way organizations can manage not only their physical records but also their electronic information.

Read more about how FileTrail automates and simplifies key processes including records tracking and retrieval, retention and disposition, and demonstrating compliance during audits.

"As far as technology goes, the fact that we use FileTrail shows regulatory bodies, including the FDA, that we have progressed into the 21st century."

Project Delivery Manager

10,000-employee global life sciences services, technology and manufacturing solution provider

FileTrail provides a platform for streamlining records and information management in GxP environments. Powerful search capabilities and RFID tracking of the location and chain of custody of physical records are just some of the reasons the FDA has implemented FileTrail in 14 divisional offices, and why global biotech and pharmaceutical companies depend on FileTrail for records management.

FileTrail GPS unifies management of physical and electronic records, supporting GxP and regulatory compliance by enabling Records, Quality and Information Management teams to:

SEARCH AND LOCATE PHYSICAL RECORDS MORE EFFICIENTLY

Looking up and finding the physical records you need should be as easy as finding your electronic documents. And with more staff spending more time working remotely, it saves time to be able to search for the physical records you need without having to send an email or submit queries in person each time.

FileTrail provides fast, accurate information about the status and location of physical records of all types including files, binders and notebooks. Retrieval requests can be submitted via the FileTrail system by authorized users, simplifying the process for both the records center as well as users.

CONTROL ACCESS TO PHYSICAL AND ELECTRONIC DOCUMENTS

Regulatory compliance requires restricting access to documents and other information assets to those who have legitimate need and authority. Automating access management eliminates the need to manually look up permissions for each user, and helps to protect confidentiality and privacy.

FileTrail provides powerful security tools to restrict who may browse a record within a secured area, check a record out of the secured area, or limit what inventories they can see listed in the first place. Additional permissions control user access to view, add, or change descriptive metadata within FileTrail based on department, category, specific record, or field-by-field. FileTrail also makes it straightforward to manage records subject to legal holds, and tag and protect items subject to HIPAA/HITECH, GDPR and other data privacy regulations.

DOCUMENT CHAIN OF CUSTODY

Is your current process for checking records "in" and "out" and documenting chain of custody as efficient as it could be? If your records team has to input the same information in multiple systems, or enter information manually which could be scanned, it's time to rework your process.

FileTrail provides a flexible and intuitive web-based interface to collect the specific information required for each different type of document, and store that data in a single system. As records are submitted and retrieved, your organization can generate unique item numbers, print and scan labels, and scan the IDs of the person collecting and returning each item. All updates and chain of custody changes are documented with an e-signature process.

STREAMLINE AUDITS AND REPORTING

Many pharmaceutical and biotech companies end up spending a significant amount of staff hours chasing down physical records during FDA audits, as well as audits by other regulatory bodies, partners and customers. Delays in delivering paper documents to FDA audits can result in warnings and penalties, causing firms to incur additional costs as well as delays in getting products to market.

FileTrail saves time for staff and has helped many leading pharmaceutical companies sail through FDA audits. With FileTrail, locating and retrieving records is straightforward, enabling analysts, quality and records staff to respond quickly when specific records are requested as part of an audit. In addition, FileTrail automatically captures a record of all activity and makes it easy to generate reports and answer questions if they arise.

MANAGE RETENTION ACROSS ELECTRONIC & PHYSICAL RECORDS

As the use of electronic records in the pharmaceutical and life sciences industry grows, some of the biggest challenges of maintaining GxP and regulatory compliance have to do with complexity and scale. Managing retention schedules via an Excel spreadsheet is no longer sufficient, and other tools still require IT, information governance and records managers to track and find a large volume records manually.

FileTrail enables IT, information governance and records managers to unify physical and electronic records management through a single system. FileTrail integrates with your document management system, so that you can control records in all formats. Using FileTrail, authorized users can get a comprehensive overview of records across all repositories. Retention policies can be stored within FileTrail or synchronized with other systems, then mapped to the appropriate records based on the relevant departments or categories.

In competitive evaluations with other solutions, pharmaceutical companies consistently tell us that FileTrail stands out due to the following features:

FLEXIBILITY AND CONFIGURABILITY

Naming conventions for records and how they are classified can vary widely by company, department and product. FileTrail offers a very flexible and configurable system that allows your IT, IG, quality or records team to specify the categories, sub-categories, terminology and metadata fields to use.

AUTOMATED WORKFLOWS AND VALIDATION TOOLS

Automating retention workflows can eliminate back-and-forth emails and help streamline approvals. FileTrail enables you to implement a wide range of workflows, including workflows for destruction of records, capturing a complete record of all approvals automatically. In addition, FileTrail's validation tools help to ensure that information entered into the system is correct and complete.

INTEGRATION WITH OTHER SYSTEMS

Information silos develop when you have multiple systems that don't integrate. FileTrail is designed to integrate with other enterprise applications, so you can see where both electronic and physical records reside across your organization. The flexibility and security of the platform has also enabled many of our pharmaceuticals customers to use FileTrail to manage records in various departments, such as Legal, HR, Tax, Finance, Property and Marketing.

QUALIFIED OR VALIDATED

FileTrail has been deployed and implemented in FDA-regulated environments with support for 21 CFR Part 11 and FDA validation requirements. The system can be deployed as a qualified (non-validated) system or as a validated system (compliant with 21 CFR Part 11). A validation package is available.
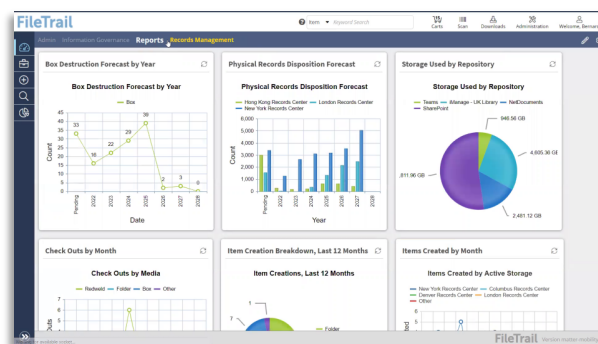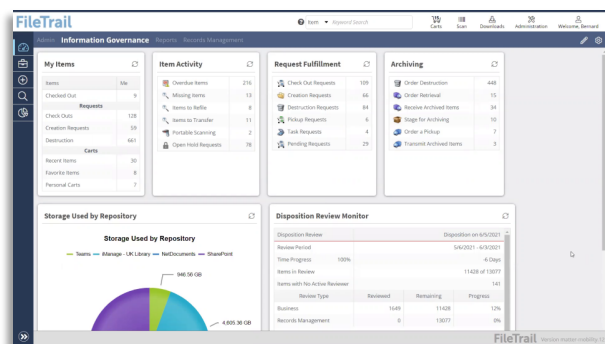
RFID TECHNOLOGY

FileTrail leverages RFID technology to add unique control capabilities with dramatic, wide-reaching impact:

- Hunt for misplaced items like using a metal detector.
- Conduct audits in 85% less time than with barcodes.
- Automate tracking with RFID sensors in offices, cubicles, and doorways.
- Prevent remove through alarmed exits.

Key Benefits of FileTrail

➡ **AUTOMATED COMPLIANCE:** FileTrail maintains and implements compliance rules, preventing accidental violation and risk exposure.

➡ **INCREASED EFFICIENCY:** Easy access to GxP document information saves staff time when locating, requesting and retrieving physical records.

➡ **PROVEN & RAPID ROI:** Automating manual processes and controls presents an immediate and long-term ROI.

➡ **SIMPLIFIED AUDITS:** Produce physical records on demand, reduce the time spent locating documents during audits, and ensure compliance.

FileTrail®

FileTrail is reshaping the information risk management landscape, enabling organizations to meet critical regulatory demands, pass audits and address compliance rules with a modern approach to records management and information governance.

FileTrail centralizes, simplifies and automates the information governance life cycle, including policy management, document review and disposition — integrating across physical records and electronic repositories.

It's time to move beyond records management, and FileTrail is leading the way.

For more information about FileTrail's records management and information governance software solutions visit **www.filetrail.com.**