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**Steven Marks**

ITS - Business Applications  
Abgenix, Inc.

# Abgenix, Inc. - GMP Documents

Life sciences company gains control of their files with FileTrail.

## Client Profile

**Headquarters:** Fremont, CA

**Industry:** Life Sciences

Abgenix, Inc. is a leader in the development and manufacture of therapeutic antibodies for serious health conditions. Headquartered in Fremont, California, the company's product research and manufacturing generate extensive GMP documentation which is subject to regulatory audits and reviews. After achieving a quick ROI in the legal department, Abgenix implemented FileTrail to track and manage its work product in 2005.

**FileTrail Implementation:** 2005

## FileTrail Products Implemented

- **FileTrail Professional** - On-demand service for file tracking and records management.
- **FTColorLabel** - On-demand printing of color-coded folder labels.
- **FTPortable™** - Low-cost portable scanner for file tracking and auditing.

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...because Paper Happens<sup>®</sup>  
<http://www.FileTrail.com>

## Background

Like many life sciences companies, Abgenix (now part of Amgen) faces unique and challenging issues in handling manufacturing-related records. While many records have been transitioned to electronic format, many records are still used in paper-based format that are subject to regulatory compliance, auditing and reporting.

An existing Documentum system managed the electronic documents, but controls for paper-based records remained largely manual. Each department managed its own data independently in Excel spreadsheets. Ensuring compliance was tedious and manual.

Abgenix implemented the FileTrail solution in 2005 to automate tracking and compliance related to 200 types of paper-based records in 16 departments within facilities, quality engineering and quality control.

“The FDA expects us to present an auditor with any requested document within one hour of the request. We would not be able to do this without File Trail,” said Steven Marks a Technical Analyst in ITS - Business Applications.

## Automating Compliance

For paper-based records, compliance means controlling access to the documents, as well as information that describes the documents. Restrictions must consider the user, department, and type of document, as well as accommodate case-by-case exceptions.

FileTrail's enterprise-class security gives Abgenix precise control over all methods of access. Permissions control who may view or modify document information, plus who may browse a record within a secured area or check a record out of the secured area.

Permissions are set by *User* and *User Group* and utilize *inheritance* to simplify administration. Item-based permissions provide additional controls over special cases. Permissions are implemented both in file room functionality and in tools at the user's desktop for searching and requesting.

“FileTrail allows our quality and manufacturing staff to better manage our GMP documents that are subject to FDA regulation,” according to Amit Syal, a Validation Specialist for Abgenix.

## Increasing Efficiency

FileTrail automates many processes related to locating or moving paper-based records. Common transactions like searching, requesting, request fulfillment, and re-filing are streamlined. Other processes such as check-in, check-out, archiving and desk audits are made easier and faster using bar code technology.

## Application Highlights

- FileTrail manages a centralized, secure file room and is actively used by over 120 staff in 16 departments.
- FileTrail was configured to perfectly fit the descriptive terms used by each department for 200 different types of records.
- The Rapid Transition performed by FileTrail bar coded all records in a short time, easing the transition for staff to new processes.

## Key Results

- **Automatic Compliance** - FileTrail maintains and implements compliance rules, preventing accidental violation and exposure.
- **Increased Efficiency** - Easy access to records information save staff time in locating, requesting, and retrieving paper-based records.
- **Demonstrated ROI** - Automating manual processes and controls creates a quick ROI.
- **Simplified Audits** - Sail through audits by producing paper-based records on-demand and demonstrating solid compliance processes.

## Customer Insight

Flexibility was key for us. We were concerned about getting buy-in from departments that had been operating autonomously. We had to deal with the differences in data fields and terminology for 200 types of documents. The flexibility in FileTrail helped us minimize the impact and implement a central solution. The fact that this was done without custom code or programming was fantastic.

FileTrail eliminated the need to think about compliance or research every access. Files cannot be checked out to staff who should not have them - the restriction is automatic.

## About FileTrail

FileTrail, Inc., is the leading provider of browser-based records management solutions. Companies of all sizes turn to FileTrail to streamline processes with the latest technology and most configurable software. Headquartered in San Jose, California, FileTrail has been providing solutions for records management since 2001.

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## Increasing Efficiency

Efficiency depends on software that's clear, accurate and intuitive. In a highly-regulated area, it's unusual to hear end-users speak positively about a compliance system such as FileTrail.

"File Trail has really improved our filing and retrieval system. It's not only saving time and effort, but provides uniform guidelines to identify and locate a particular file," according to Maureen Harper, a Document Specialist in Quality Assurance.

## Leveraging Configurability

FileTrail's powerful configuration tools allow each of 16 departments to describe their records using their specific terminology and data fields. The tools are point-and-click, so no programming resources were needed for configuration.

A total of 200 categories and sub-categories were defined to reflect the various types of records, each configured to collect a different combination of fields. Precise configuration to each record type simplifies data collection and enhances searching and reporting, ensuring high user adoption.

"I was quite impressed with how easy it was to configure the system to accommodate our very specific needs, including 26 main categories with many types of storage media," said Marks.

## Selecting A Solution

Abgenix selected FileTrail after an extensive review of alternatives. FileTrail was superior in the four key criteria Abgenix had established for a solution: 1) highly competent software, 2) great flexibility, 3) vendor domain expertise, and 4) cost.

One key element in the selection of FileTrail was competence. The FileTrail application reflects a solid understanding of the way people actually work with paper-based records. Processes are streamlined and controls are implemented without creating additional work.

Price was also a consideration. FileTrail's focus on being the best in one discipline - along with attention to low-cost delivery methods - gave them the edge.

"As the IT project manager, I configured security and screens, and coordinated with the departments," said Marks. He continued, "FileTrail contains a lot of powerful tools, but doesn't require an army of consultants to implement."

## Rapid Transition

FileTrail also performed a Rapid Transition project for Abgenix. FileTrail's transition technologies quickly convert a client's paper-based records to fit the newly automated filing system and labeling standards. The Rapid Transition project was timed to coincide with training and orientation for over a hundred staff.

FileTrail's Rapid Transition promotes an easy transition for staff and allows clients to begin realizing the benefits of FileTrail immediately. All of Abgenix's folders, bound books, binders and other media were bar coded and indexed in the FileTrail database in under two weeks by the FileTrail professional services team.

"FileTrail helped us make a rapid transition from our old labor-intensive record keeping process to a new streamlined process that saves everyone time and headaches," said Marks. "Our conversion to FileTrail was an outstanding success."

## Contact FileTrail Today!

For more information about the benefits of automating with FileTrail, call your local FileTrail representative at:

### FileTrail, Inc.

111 N. Market Street, Suite 715  
San Jose, CA 95113-1108

Telephone: 800-310-0314  
Website: [www.filetrail.com](http://www.filetrail.com)