MODERNIZING PHARMACEUTICAL RECORDS MANAGEMENT

Facility Implements FileTrail for Audit-Readiness

"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

CLIENT PROFILE

A global leader in providing integrated services, manufacturing solutions and delivery technologies to help life science clients develop and launch pharmaceuticals, biologics and consumer health products.

Its Midwest facility focuses on biologics analytical services, oral and specialty drug delivery, and clinical supply services businesses. Providing capabilities in contract laboratory outsourcing, contract manufacturing, and contract packaging, the site implements GMP across all phases of product development.

REPLACING AN AGING SYSTEM AND DRIVING TOWARD STANDARDIZATION

Manufacturing and testing records provide the bedrock of evidence that pharmaceutical companies have followed GMP. The ability to track and quickly retrieve documentation as needed to investigate trends, issues and complaints — and complete regulatory audits — is critical over the lifecycle of a product.

This organization's Midwest facility had been using a custom-built database for its Record Center over a period of 15 years. Over time, it had become apparent that the aging system was unable to scale to support the amount of data that the site was processing on a daily basis.

To address this, the Quality Systems team had added ancillary tools — including spreadsheets, Access databases, and other forms — to supplement the primary database.

"Once we started evaluating the processes and seeing how much we were spending on data management alone, it became very clear that we had to do something about this," says their Project Delivery Manager.

"The other issue was that this was a site-specific system, and we were relying heavily on individuals who had historical knowledge of how it worked. We decided to look for a new system that could be supported at the global level by IT support — particularly as our company as a whole is working toward more standardization of systems."

A MANUAL PROCESS

On average, the Midwest Record Center receives 2,500 documents each month — batch records, Certificates of Analysis, logbooks, notebooks, calibration documentation, validation documents for equipment and more — plus one-off items that arrive in binders.

Under the previous system, information about each document needed to be entered manually by staff at least three times into three different systems — including multiple spreadsheets in addition to the primary database — before getting filed away onto a shelf within the Record Center.

Retrieving an item from the Record Center required an initial step of trying to find where it was likely to have been shelved, confirming its location, and then updating forms and spreadsheets to check the item out.

"We were spending a lot of time duplicating efforts. It was a completely manual process," says the Project Delivery Manager.

> "We were spending a lot of time duplicating efforts. It was a completely manual process."

EVALUATING OPTIONS AND SELECTING FILETRAIL

The Midwest site evaluated three alternatives before choosing FileTrail as its new records management system.

"By far, FileTrail was the best solution that we were able to find," says the Project Delivery Manager. "None of the other systems could provide the same kind of configuration that FileTrail could offer."

The fact that the FDA itself uses FileTrail across 14 divisional offices was also a major plus.

"One of the biggest tipping factors is that FileTrail is preferred by the FDA. So we're confident that also gives some security and comfort with the auditors. Many other large pharmaceutical companies use FileTrail as well," he adds.

IMPLEMENTING FILETRAIL

The Project Delivery Manager led a team of four — from Quality Systems, the Record Center and IT — in setting up the new FileTrail Records Manager system.

The team was supported by Nick Burge, a project manager and consultant at FileTrail, in the implementation.

"Everyone we worked with from FileTrail has been steadfast in their commitment to our success," says the Project Delivery Manager.

"Nick gave us guidance through the entire process. We worked together on building the organizational structure we wanted in FileTrail Records Manager. He also spent two or three days with us onsite, so he could really understand our perspective, as well as the types of documents handled by our Record Center."

"Now, when we have questions or issues, we submit tickets to FileTrail through their help desk and they are very responsive," he says.

"It just speaks volumes to the entire business. They've all worked hard to make sure they're keeping us successful long term."

"Everyone we worked with from FileTrail has been steadfast in their commitment to our success.

"It just speaks volumes to the entire business. They've all worked hard to make sure they're keeping us successful long term."

ACCELERATING AND AUTOMATING RECORD CENTER TRANSACTIONS

In addition to taking in 2,500 documents a month, the Midwest Record Center is responsible for issuing logbook numbers for its contract manufacturing, contract lab and contract packaging services.

On a typical day, the Record Center could issue more than 60 unique ID numbers for logbooks so that all equipment including dedicated parts for specific manufacturers, ventures or clients can be traced. The Record Center also issues 15–20 notebooks a day for its contract lab organization. And on any given day, at least 15–20 documents were checked out of the Record Center.

Previously, the Record Center Associate would have to populate the information about logbooks numbers issued and notebooks issued into a spreadsheet, and record information about documents checked out of the Record Center in multiple locations.

Now, all tracking — of documents, logbook numbers and notebooks — is captured in FileTrail Records Manager.

"The FileTrail software offered the flexibility and configurability we needed to implement this additional functionality. We worked with the FileTrail team on configuring our system to handle all these different types of transactions," explains the Project Delivery Manager.

"Tracking logbook numbers in particular took slightly longer to implement, as it was outside of the usual scope of how other pharmaceutical companies have used FileTrail. But the good news is, it's working well and it will be straightforward for other departments to take advantage of this capability if they need it."

CONVENIENCE FOR END USERS

End users in the Midwest site will have access to FileTrail and be able to request logbook numbers to be automatically generated via the system.

When an analysts requests a notebook via FileTrail, the relevant information is sent to the Record Center, which prints out a sticker label which is attached to the notebook.

"The FileTrail software offered the flexibility and configurability we needed to implement this additional functionality. We worked with the FileTrail team on configuring our system to handle all these different types of transactions."

Then, an email is sent back to the analyst notifying them that their notebook is ready for pick up.

Previously, the process had required analysts to go to the Record Center physically to fill out a form with nine lines of information by hand and then wait for the notebook, while the Record Center team made a copy of the form, gave them the notebook, and then populated the information manually into the tracking systems.

"In other words, it's not just the Record Center, IT and Quality teams which are seeing the benefits of FileTrail," says the Project Delivery Manager. "The analysts and other users throughout our businesses will see a noticeable improvement."

"We've now given everyone an opportunity to find the information they are looking for themselves within FileTrail. Before, the only way you could find information was by going to the Record Center and asking them.

"Now analysts can use the keyword search or type in the unique identifier and find the items they need within the system."

STREAMLINING AUDITS

Each week, the Midwest site typically hosts one or two audits from clients. Audits from regulatory bodies such as the FDA can take place as frequently as once a year.

When auditors ask for supporting data and documentation, the request is processed by a dedicated customer team assembled in the "war room."

Moving forward, those requests will be submitted by the "war room" team to the Record Center via the FileTrail system. For the Record Center, locating the requested item has become easier than ever because each item is tied to a shelf location.

"They can easily walk over to that shelf, find that item, scan the barcode, and scan the requestor's ID, because we've built a barcode for every individual on site.

"When that person comes to the window to receive that item, we scan their ID. That item is now checked out to that individual, who didn't need to fill out any forms."

"Everyone we worked with from FileTrail has been steadfast in their commitment to our success.

"It just speaks volumes to the entire business. They've all worked hard to make sure they're keeping us successful long term."

The streamlined process will help to reduce time spent retrieving supporting documents from the Record Center during audits.

"Ensuring GMP compliance has always been a priority for our Quality Assurance team," says the Project Delivery Manager.

"The FileTrail system is bringing the efficiency of our QA and Record Center to a whole new level. I'm also excited to see FileTrail Records Manager implemented at multiple sites."

"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."

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**.