

# Arbor Pharmaceuticals Streamlines Change Control and Document Management with TrackWise Digital®



Arbor Pharmaceuticals, a privately-owned pharmaceuticals company based in the U.S. state of Georgia, develops and markets prescription products for use in the oncology, pediatrics, endocrinology, and cardiovascular arenas. As a virtual pharmaceutical manufacturer with over 40 contract manufacturing organizations (CMOs) and more than 400 change control records per year, the company relies on its quality management system (QMS) to streamline document approval and storage, for improved stability control.

## THE OPPORTUNITY: A User-Friendly System and Better Change Control Process

Arbor's existing quality management approach combined a manual, paper-based change control system with a resource-intensive document management system, which was used for reviews and approvals of Protocols, Risks Assessments, Stability Protocols and Stability Data.



### COMPANY OVERVIEW

**NAME:**

Arbor Pharmaceuticals

**INDUSTRY:**

Pharmaceutical

**DISTRIBUTION:**

Global

**EMPLOYEES:**

400+

**SOLUTION:**

TrackWise Digital

"People don't like change," notes Emily King, quality operations analyst at Arbor. "But our quality management system—really more of an electronic document management system—wasn't helping us close the loop on action items with our many CMOs. We needed something more effective."

"When we received change request from a CMO, we first had to manually log it into an Excel sheet," explains King. "We then had to go to a QA admin to get a folder and label, label the folder, hole-punch it, type up the change control document, route it to three departments, and wait for the CMO document saying that they'd implemented the change."

Quality team members then needed to scan each form and all supporting documents — a packet that could easily be hundreds of pages — for entry into the quality management system. To make matters worse, the team struggled to locate documents once they were stored in the system.

When looking for a document for approval, "someone would search for a particular lot number, nothing would come up," says King. "It seemed like we just had a bunch of PDFs floating around. Getting document approval was more difficult simply because those documents were so difficult to find."

With hundreds of change control records each year, the current methods created an unacceptable burden on the quality team. In addition, the document management system wasn't user-friendly.

"We sometimes felt like no one knew how to use it," explains King. "Everyone was almost afraid to log into the system."

Arbor needed a QMS that simplified workflows around change control and document access.

## THE SOLUTION: An Effective, User-Friendly QMS Built on the Largest Cloud Platform

After consulting with its CMOs and reviewing QMS solution options, Arbor chose to switch from its existing manual quality approach and document management system to TrackWise Digital.

Part of the appeal for Arbor was the use of the extensive and reliable Salesforce platform. With access to Salesforce's built in technology, extensive training resources and expansive, well-known toolset, Arbor was able to simplify integration with its infrastructure — and those of its CMOs.

"We no longer need to go through all that work in Excel or store all those folders," says King. "Retrieving all that physical space alone is a big help."

The QMS now has active users across the Quality, Regulatory, Manufacturing and Validation departments. These users access TrackWise Digital daily to review and approve documents. And those workflows now look quite different.

NEW STREAMLINED  
WORKFLOWS SAVE  
MORE THAN

**800**  
HOURS PER YEAR



After receiving an approved change request form, an Arbor quality team member enters the data into TrackWise Digital.



Tasks can then be assigned to different departments based on role and workflow.



Upon completion of these tasks, an autogenerated email notifies all groups that the change is closed.

## THE RESULTS: Easier Retrieval and Faster Approvals

King reports that the digital maturity of the new TrackWise Digital solution has been a boon for Arbor.

"The availability of the system is fantastic," she says. "All the change records are at our fingertips now. The search capability is our favorite feature; it's much more robust than our old QMS. Plus, we can configure and customize TrackWise Digital workflows to meet our exact needs."

As a result, Arbor has been able to improve both timeliness and efficiency. The company has significantly reduced the length of time that change requests remain open with its CMOs. King estimates that the new streamlined workflows save at least a few hours per record, easily adding up to more than 800 hours per year.

"Approval times are faster now," reports King. "The Tasks feature is so helpful. Being able to assign tasks to various departments, and tell them exactly what they need to complete, makes everything run more efficiently."

Perhaps even more important: End users no longer dread the QMS. IT help requests are minimal, and periodic retraining – as well as best practices info from Sparta Systems – has eased the transition for the Arbor team.

"When people have questions now, they're usually about internal procedures – not how to use the QMS software," says King. "I don't think anyone would choose to go back to the old system now. TrackWise Digital makes life easier. I only wish that all of our CMOs were using it."

King's next challenge? Transitioning other processes, such as deviations, CAPA, and effectiveness checks, into the QMS.

"If I had my way, I'd put all our systems into TrackWise Digital right now," she says.

### Get in Touch

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