

DOCXTOOLS FOR LIFE SCIENCES IS HELPING AKROS PHARMA TO ACCELERATE THE COMPLETION OF MORE ACCURATE DOCUMENTS FOR REGULATORY APPROVAL.

Akros Pharma Inc—the US arm of JT Pharmaceuticals—is a small business that identifies and develops innovative new medications to treat diseases for patients the world over. It's clear that it operates in an industry where process efficiency could scarcely be more critical. There's a great deal of document processing that goes into bringing these products to market, but wasted time is ultimately time that new medications are not improving the wellbeing of patients and saving lives.

Clinical research scientist Jason R. Healy, Ph.D., for example, is currently focused on combating cardiovascular and autoimmune diseases.

"My team is responsible for very large volumes of medical writing," he says. "There is a lot of documentation that needs to be processed and delivered through regulatory stages, which ultimately go to the relevant national agencies for new drug approval."

Clearly, the team needs to produce that paperwork as quickly as possible. However, simply speeding through it is not an option to achieve business objectives and goals. Consistency and accuracy are paramount in preventing problems from materializing later in the process.

"You could describe our group's biggest challenge as avoiding a form of 'tunnel vision' around the heavy workload," says Healy. "When you are looking at the same documents for extended periods of time, sometimes you can start to lose focus on the little things—formatting inconsistencies or minor grammatical errors, for example, which of course still need to be absolutely correct before the paperwork is presented."

That calls for a very disciplined proofreading process. "We consistently need to forward our work to other pairs of eyes to review, and then create updated versions," Healy continues. "Depending on the edits, we may send and receive a document two

or three times over before we reach a final version."

Quest For Quality

As of September 2016, however, the writers have been able to call on some additional help—DocXtools from Litera Microsystems. This is a software solution that integrates with Microsoft Word and helps to automate the quality-checking processes, and effectively productizes the company's style guide into an automated analysis. It reviews points such as paragraph styles, document formatting, key phrases, and abbreviations for compliance with the guidelines surrounding them, and ultimately makes documents submission-ready that much faster.

Moreover, with the pharmaceutical industry frequently using terminology you don't often encounter in other walks of working life, the application can even catch spelling mistakes that might manage to make it past Microsoft Word's routine check for typos.



- A small business that identifies and develops innovative new medications.
- **Solution:** DocXtools for Life Sciences
- **Challenge:** Akros Pharma needs to produce paper work as quickly as possible, but it also has to go through a rigorous proofreading process to prevent problems, like formatting inconsistencies or grammatical errors, from materializing.
- **Outcome:** DocXtools is helping turn around work much faster by automating quality-checking processes, document formatting, and abbreviations. It also catches spelling errors that most routine spell checks would not.

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– Jason R. Healy, Ph.D.

"Microsystems picks up exactly those smaller items that people like me might otherwise find they miss when reading," says Healy. That makes it especially useful when introducing new features to a draft for the first time, such as abbreviations. "Immediately, it is a less arduous job for the regulatory group, in particular, and I have certainly had feedback from colleagues in other departments that they save at least a few hours, if not a half day, compared to reviews in the past.

"But the biggest time-saver for me personally is when I perform my own quality check on a piece of work, before sending it out to others within the organization for review. When you are under a really tight deadline, you simply do not have the time to re-read something three or four times over.

"Another advantage is that you don't need to re-read the entire document and take notes of where things take place to return

and correct them.

"You can input the terminology, and work out if anything is missing very quickly—whether that is from a list of possible abbreviations, for example, within tables and figures, or the main body of text itself."

He continues: "The functionality around abbreviations is probably what I am using the most myself at the moment. With DocXtools you can import the correct abbreviations from a ready-made list on the screen as you are typing in real time, but also determine whether you do need to shorten to the acronym form or rather ought to spell the words out in full."

Easy Does It

Akros currently has four individuals using the technology. However, after a recent upgrade to a new version of the software, Healy expects to introduce it to several more users, most specifically in the

forementioned regulatory division of the business. "It would help them with a lot of other tasks that are separate to our clinical research—I know they will see a lot of added value," he says.

He was also very impressed with the straightforward, user-friendly implementation process overseen by the Litera Microsystems team. "Installation only takes about 20 minutes, and I can do that on our other computers myself with the help of a simple how-to guide we received. There was also a day and a half of initial introductory training. But, with the upgrade we only needed an hour teleconference to discuss some of the new features and how they will help with some issues that we have had.

"It is too early to put a percentage on how much more efficient it will make us all, but I am very excited as I can see that it is going to help us to turn a lot of work around much faster in the future."

About Litera Microsystems

Litera Microsystems is the leading provider of software for drafting, proofreading, comparing, repairing, and cleaning documents in the legal and life sciences industries worldwide.

Our core products empower users to generate, review, and distribute high-quality content quickly and securely, from any device.

Today, Litera Microsystems supports thousands of document-intensive organizations across the globe, helping them satisfy the complex demands of clients and regulators.

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