LITERA MICROSYSTEMS
REPUTATION MATTERS

CASE STUDY

DOCXTOOLS FOR LIFE SCIENCES FROM LITERA MICROSYSTEMS HELPS PHARMACEUTICAL FIRM MACROGENICS TO ENSURE THAT ELECTRONIC SUBMISSION DOCUMENTS FOR REGULATORY APPROVAL ARE ALWAYS FORMATTED RIGHT THE FIRST TIME.

MacroGenics is a biopharmaceutical company that discovers and develops antibody-based therapeutics for the treatment of many forms of cancer, as well as autoimmune disorders and infectious diseases. Through a range of proprietary protein-engineering platforms, it is currently conducting clinical trials for antibodies and antibody-like molecules that hold potential across a wide array of solid tumors and hematological malignancies. This includes a pivotal study of an investigational antibody in combination with chemotherapy for metastatic breast cancer.

It can take more than 300 days for a regulatory agency to approve any new drug application. This means, the document-processing work that underpins these clinical investigations not only needs to be as efficient as possible for all concerned; but also, the finished document needs to be presented in exactly the format that the regulator requires for the product to make it to market.

And this has recently become more complicated. As of May 2017, any NDA (New Drug Application), aNDA (Abbreviated New Drug Application), and BLA (Biologics Licence Application) submitted to the US Food and Drug Administration (FDA), must be submitted in Electronic Common Technical Document format (eCTD). Any submissions that do not adhere to the published guidance surrounding eCTD format will receive a technical rejection from FDA.

That places additional pressure on individuals such as Vanessa Kelly, Regulatory Operations Specialist III at MacroGenics, whose job is to verify that the eCTD is entirely present and correct before it's sent out. "I'm a formatter and publisher," she explains. "It's my responsibility to ensure that everyone adheres to MacroGenics' style guide, industry standards, and regulations with respect to eCTD."

Moreover, that formatting comes as the culmination of a complicated process of document drafting, checking, and redrafting.

A Clear Convert

In 2016, Kelly was therefore part of the team that identified and implemented DocXtools from Litera Microsystems: a piece of automation software that promptly identifies and corrects errors or inconsistencies in Word documents, such as with tables, appendices, cross-references, abbreviations, and symbols——as well as key phrases, and of course spelling or grammatical errors. The essential final stage is conversion of the content-final Word documents into Adobe PDF format, which is the document format required for eCTD submissions.

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>
> **– Vanessa Kelly, Regulatory Operations Specialist III**

MACROGENICS

- A biopharmaceutical company that develops antibody-based therapeutics for treatment of many forms of cancers, autoimmune disorders, and infectious diseases.
- **Solution:** DocXtools for Life Sciences
- **Challenge:** It can take nearly a year for a regulatory agency to approve any new drug application. MacroGenics needed a way to make their document-processing work efficient. They also needed to make sure their finished document adhered to the company style guidelines, industry standards, and regulations for eCTD.
- **Outcome:** DocXtools saves time by allowing easy conversion to new templates, increasing efficiency, and speeding up the collaborative process. The added benefit is MacroGenics can now focus on delivering life-changing therapies to the market faster.

However, there's a real danger that when a company makes that final conversion, the PDF loses the carefully honed formatting. Compounding this challenge, MacroGenics recently switched the templates it uses for these documents.

"My personal go-to feature with DocXtools is converting from an old template to a new one—and it's wonderful," says Kelly. "The technology automatically removes all the old document styles, which is something I would otherwise have to manage manually."

That's clearly a useful time-saving feature in and of itself, but Kelly has also noticed efficiency gains in the time it takes for the documents to reach her in the first place.

"It has definitely sped up the collaborative process," she says. "The end goal is always quality control and full compliance. However, there's no doubt it has also made the drafting process more efficient, and the automatic filtering for inconsistencies means all users can spend less time focusing on the smaller details and more on the big picture."

In terms of Kelly's individual workload, for example, the straightforward ease of document conversion frees her to spend her time more productively. "I work with all departments that author documents for eCTD submissions," she explains. "So, having DocXtools on hand to help means I'm that much more available to provide formatting support and training."

She was also particularly impressed with the level of attention and service from Litera Microsystems throughout the implementation and training period to get to know the product. "My team works with the IT department, but of course they have very different areas of expertise," she says. "One thing that was very useful is Microsystems' ability to speak both groups' languages.

The return on investment is clear: faster time to market with life-changing therapies and a more satisfyingly productive working life in the process.

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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.