

## GLOBAL BIOPHARMACEUTICAL COMPANY COMPLETES QC CHECKS IN HALF THE TIME WITH DOCXTOOLS

### Background

The delivery of complex documents, like an electronic common technical document (eCTD) for regulatory submission, is an intricate, collaborative process. During a document's development, authors often face formatting, structure, and function issues that can slow document completion or negatively affect the overall quality of the work product, keeping important therapies from reaching the market.

Litera Microsystems software and services help document-intensive organizations meet the complex demands associated with document production. Our tools integrate with Microsoft® Word and are designed to find deviations from document standards quickly with features that identify and fix the incorrect usage of abbreviations, symbols, formats, and phrases. Additionally, drafting tools automatically create tables of contents, cross-references, appendices, figures, and tables.

### Challenge

A mid-sized biopharmaceutical firm was looking to save time. Its medical writing staff members were often challenged with competing priorities and wanted to expedite and standardize the formatting of technical documents so they could prioritize other work. These individuals authored documents regularly, so they had the most accountability for maintaining the company's style guide and meeting regulatory requirements.

"It was important our solution was easy to use and could integrate with our existing workflow," said the company's manager and medical writing editor. "We explored several options, but needed one that worked for everyone despite our varying skill sets and responsibilities."

### Solution

After a demonstration of DocXtools for Life Sciences showing how the tool can save time and improve quality, Litera

Microsystems provided a solution that focused on automation for the labor-intensive components of document management.

The biopharmaceutical company was particularly interested in the software's abbreviations manager and its ability to manage document formatting and simplify the company's review process. The Litera Microsystems consultant met with a core group of users to integrate the system into their workflow and configure the application to meet their style guide requirements. Litera Microsystems also conducted user-acceptance testing before rolling it out to the entire team and trained medical writing staff to ensure a smooth transition. The software was implemented across multiple teams at the organization.

"Microsystems worked with us to configure DocXtools to our practices, and it's really saving us a lot of time," said the manager and medical writing editor.

- An innovative, mid-sized biopharmaceutical firm
- Commercializes medicines so people with serious disease can lead better lives
- Research and commercial offices throughout the US, EU, and Australia
- **Challenge:** The biopharmaceutical firm was looking to expedite and standardize formatting, comply with the company's style guide, meet regulatory requirements, and enhance document quality so the medical writing team could spend more time on value added work.
- **Outcome:** The firm chose to implement DocXtools for Life Sciences, a solution that focused on automation for the labor-intensive components of document management. Just six months after the company began using DocXtools, it saw a 50 percent time savings and produced better quality documents, saving both money and resources.

“Microsystems is the industry leader in document preparation and support with a product that is easy to use and provides real value.”

“Their customer services team has been friendly and helpful—and with us every step of the way—as more of our document authors use it in their everyday work.”

When the consulting engagement ended, Litera Microsystems transitioned customer service calls to its help desk. The help desk is available 18 hours a day and equipped to answer a range of questions— from “How do I do this in Microsoft Word properly?” to “Can you suggest a way to improve our quality control check?”

### Outcome

DocXtools for Life Sciences made document formatting easier and faster for the authors at the biopharmaceutical firm, providing a 50 percent time savings on

their quality control check alone. The formatting changes and automated processes impacted their pdf conversion and usability as well, saving additional time, money, and resources.

“Microsystems is the industry leader in document preparation and support with a product that is easy to use and provides real value,” said the manager and medical writing editor at the biopharmaceutical firm. “They are easy to work with and the help desk is amazing. We can’t imagine anyone being better.”

### Conclusion

Just six months after the implementation of DocXtools for Life Sciences, this biopharmaceutical firm has seen

quantifiable improvements in its efficiency across multiple teams and its ability to create documents that are compliant with style guidelines and industry regulations. In addition to the time saved, the overall document reliability and quality have increased throughout the organization.

### 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.

Microsoft® is a registered trademark of Microsoft Corporation.

“Their customer services team has been friendly and helpful—and with us every step of the way—as more of our document authors use it in their everyday work.”