



Global Pharmaceutical Company Meets Increase in FDA Submissions with Knowledge Partnership Software

The Medical Writing Operations team at a global pharmaceutical company uses Microsystems Knowledge Partnership suite of software and services to automate its quality control checklist and support the company's increased submissions pipeline. With Knowledge Partnership, the company performs quality control checks on protocols, clinical study reports, and other regulated documents to comply with FDA and company style standards in 60% less time.

Company Overview

This research-based global pharmaceutical company is engaged in the development, manufacture, and marketing of ethical (prescription) drug products.

Situation

The company's Medical Writing Operations team anticipated an increase in the number of large FDA submissions it would produce, reinforcing the need to efficiently perform quality control (QC) checks on protocols and clinical study reports to ensure they comply with FDA submission and company style standards. Not meeting FDA filing deadlines due to non-compliant submissions can push back the time to market, which can in turn lead to millions of dollars in lost revenue.

Solution

The company has been using Microsystems Knowledge Partnership software (DocXtools) for its document QC for the last seven years. Recently, representatives from Microsystems and the pharmaceutical company collaborated to configure DocXtools to automate the QC checklist used by the company's Document Support Technicians. This configuration was done to continue to reduce the company's time to submission and to ensure compliance with FDA and company standards.

"We use DocXtools to analyze protocols and clinical study reports for issues with compatibility, character (char) styles, nested tables, style inconsistencies, orphan numbers, multiple languages and more," said a Document Support Technician at the company. "DocXtools not only identifies, but corrects these problems."

Solution Overview

Company

Global Pharmaceutical Company

Company Profile

This research-based global pharmaceutical company is engaged in the development, manufacture and marketing of ethical (prescription) drug products.

Situation

Anticipating an increase in the number of large FDA submissions it would produce, the company's Medical Writing Operations team sought to more efficiently perform QC checks on protocols and clinical study reports to ensure that they comply with FDA submission and company style standards.

Solution Description

The company uses Microsystems Knowledge Partnership software (DocXtools) to automate the document QC checklist used by its Document Support Technicians to ensure compliance with the FDA's and its own submission standards, thus supporting the increased pipeline of submissions.

The company also uses the Microsystems Document Emergency Room as a "safety net" for submission document issues it either cannot solve or does not have the time to address.

Benefits of Knowledge Partnership

- Grows efficiencies of medical writing teams to produce an increasing quantity of FDA submissions without increasing headcount
- Reduces the time to submission filing
- Provides a safety net for problem-documents
- Builds Microsoft Word knowledge to buoy document production capabilities

Software

- **DocXtools** – document assessment, cleanup and problem-solving tools

Services

- **Document Emergency Room Service** – analyzes and fixes unstable and problematic Word documents when immediate repair is critical and internal resources need assistance correcting the problem.
- **Educational Services** – provide transfer of knowledge to build document production capabilities. On-site and online education and training are provided.

The company also uses the Microsystems Document Emergency Room (DocER) as a “safety net” for submission document issues it either cannot solve or does not have the time to address. The DocER is a team of document experts who analyze and fix unstable and problematic Word documents and templates when immediate repair is critical. In addition to fixing unstable and problematic documents, the DocER also provides a report of the steps taken to resolve the issue(s) in an effort to transfer the knowledge to the client.

“No matter how careful you are, problems arise due to the number of persons working within the documents,” said the company’s Medical Writing Operations Manager. *“The DocER promises a two-hour turnaround of a problematic document, yet it is often faster than that. Having this level of support is an important insurance policy for our submission effort.”*

Business Benefits

Increased Efficiency of Medical Writing Teams

“Manually checking documents for compliance with submission standards is time-consuming and laborious,” said the Document Support Technician. *“DocXtools cuts the time spent analyzing a document’s submission compliance by as much as 60%, which supports our increased workload and pipeline.”*

DocXtools analyzes the protocols and clinical study reports for instances that do not meet the company’s document QC standards or the FDA’s submission standards, then navigates to the problem area and offers the user a simple way to correct the problematic instance.

Reduces Time to Submission Filing

“Because the QC process of our submission documents is automated, we have decreased our processing time while also increasing our QC quality, which together reduces our submission development time to the FDA,” said the Medical Writing Operations Manager.

Builds Word Knowledge

Knowledge Partnership is designed to transfer document production knowledge to assist document-intensive businesses in improving and expanding their in-house document production capabilities. The transfer of knowledge happens via training, educational support, and resources built to increase document production knowledge and capability.

“In addition to providing onsite and online education and training, Microsystems also offers excellent resources on its website that provide step-by-step instructions to resolve document-related issues,” said the Document Support Technician. *“I keep a shortcut to the Word tips and tricks provided on Microsystems’ website.”*

[About Knowledge Partnership](#)

Knowledge Partnership is a collection of document clean-up and re-styling software, services and support that proactively addresses problems with Word and PDF documents. By automating QC checklists with Knowledge Partnership, Life Sciences organizations save 80% of the time typically spent overcoming common document issues.

[About Microsystems](#)

Founded in 1995, Microsystems is a global leader in document lifecycle software and services designed to improve the total document creation and quality control processes of document-intensive businesses. The company helps more than 650 client firms and companies increase document production efficiencies and reduce costs and risk. Microsystems is based near Chicago in Downers Grove, Illinois. For more information call 630.598.1100, e-mail sales@microsystems.com or visit www.microsystems.com.