

AstraZeneca & Microsystems Case Study

AstraZeneca

Pharmaceutical Market Leader Uses the Microsystems Knowledge Partnership to Achieve Comprehensive Quality Control of Submission-Ready Standards

AstraZeneca chose to implement the Microsystems Knowledge Partnership suite of software-based tools and utilize its expert services in order to supplement the work of its submission support resources to provide comprehensive quality control of documents that comply with submission ready standards. With Knowledge Partnership, AstraZeneca's document professionals can now take problem source documents and proactively upgrade them into "submission ready" Word documents that render as healthy PDF documents for electronic publishing as well. This results in a more effective and efficient submission process.

Situation

The advent of electronic FDA submissions allowed AstraZeneca to avoid the arduous task of publishing enormous paper-based documentations. Nevertheless, other challenges existed within the company's e-submission supply chains. Those methods and workflows that combined to produce an FDA-compliant paper-based submission may have resulted in navigation and publishing problems when the same content was output to PDF. Common problems involved fonts and bookmarks; other documents simply failed to render.

AstraZeneca assembled a global team to develop a process that addressed these document production challenges. When faced with these challenges, AstraZeneca turned to Microsystems and its Knowledge Partnership.

"Hundreds of law firms entrust Microsystems to tackle the complex document production issues of their sensitive legal documents," said Dee Reichle, Project Leader within AstraZeneca's US Development IS Applications. "Given that experience and Microsystems' close relationship with Microsoft, my team's executive management felt comfortable with exploring and ultimately choosing Microsystems to jointly tackle our document challenges."

Solution Overview

Company

AstraZeneca

Customer Profile

One of the top five pharmaceutical companies in the world, AstraZeneca is an international research-based pharmaceutical company engaged in the development, manufacture and marketing of ethical (prescription) drug products.

Business Situation

Senior level document professionals at AstraZeneca strive to deliver an ever-increasing level of FDA submission effectiveness in an environment where time is limited. To enhance its submission effectiveness, AstraZeneca focused on refining its quality control process to better ensure adherence to the FDA's submission-ready standards for final PDF, and to the company's own house styles authoring standards for Word source documents.

Solution Description

AstraZeneca chose the Microsystems Knowledge Partnership suite of software-based tools and expert services to supplement the work of its submission support resources to provide comprehensive quality control of documents that comply with submission ready standards while proactively upgrading problem source documents to "submission ready" Word documents that also render as healthy PDF documents for electronic publishing.

Benefits

- Discover, prioritize and repair problems and noncompliance areas in both documents and PDFs in a more orderly and proactive manner.
- Significantly reduce time spent by support staff identifying problem areas in source documents.

(more)

Solution

The Microsystems Knowledge Partnership provides AstraZeneca with software-based document production, clean-up, analysis and quality-control (QC) tools, as well as document troubleshooting, training and consulting services. AstraZeneca has developed and documented several new processes by utilizing Microsystems' software and services in order to enhance the quality control of its source documents:

- **DocXamine** quality-controls AstraZeneca's standard set of authoring templates and all submission cabinets of documents for its submission-ready standards.
- **DocXamine** analyzes all submission documents for risks prior to the submission date; it reports on properties that are potential failure points based on FDA submission guidelines and AstraZeneca's own house styles.
- **Document Emergency Room** is a collaborative diagnostic service provided by the Microsystems Support Center that helps AstraZeneca resolve a problem document quickly.

Together, these new processes allow the company's submission support professionals to significantly reduce their time spent identifying problem areas in source documents and proactively create "submission ready" Word documents that also render as healthy PDF documents for electronic submissions.

Benefits

AstraZeneca has been pleased with the cost/benefit of Knowledge Partnership. "During our internal selling of Knowledge Partnership, we explored the support resource costs associated with problem documents and their impact on critical stages of the submission timeline," says Richard Ware, Director, US Development IS Applications Regulatory Affairs. "Based on those numbers, we anticipated a one-year return on investment for the Knowledge Partnership's three-year investment. Given the results we've seen so far, that payback estimate is right on track."

"[DocXamine] allows us to gain and impart knowledge and expertise on how to structure healthy documents that will successfully render to PDF."

Donna Whiting, Associate Director of Regulatory Systems Management, AstraZeneca US Regulatory Affairs

Manually checking documents for compliance with submission standards is slow and laborious, which, as mentioned, increases unnecessary costs. DocXamine, however, cuts the time spent analyzing a document's submission compliance by as much as 90%, and its QC criteria can be customized (in definition and weighting of different document components) to fit your document formatting standards and house styles.

Donna Whiting, Associate Director of Regulatory Systems Management in AstraZeneca's US Regulatory Affairs, says: "Before DocXamine, my group used the trial-and-error method to triage a document that would not render to PDF. Now, we have incorporated DocXamine into our workflow and use its analysis report

Benefits, cont'd

- Maximize the probability of successfully rendering a healthy PDF document.
- Obtain quick, expert triage and resolution of problems with Microsoft® Word documents via Microsystems Support.
- Receive expert document troubleshooting knowledge, improving the skills of submission support employees.

Software

- DocXamine – document analysis and quality control.
- DocXtools – document diagnostics and clean-up.

Services

- Document Emergency Room service – Word experts who triage problem documents and provide reports on how to fix the document.
- Training and Consulting – Builds document production expertise throughout your company.

Country/Region

Global

Audiences

IT Senior Managers, Regulatory Directors, and senior-level document production professionals.

to triage every problem document. This process allows us to gain and impart knowledge and expertise on how to structure healthy documents that will successfully render to PDF.” She also states “We have reduced our support time to troubleshoot and convert legacy documents significantly with Microsystems tools.”

Microsystems’ Solutions Center experts provide the Document Emergency Room service that complements AstraZeneca’s Regulatory Affairs Author Support group during those times when particularly troublesome documents require an immediate response and resolution. The Solutions Center produces a report that articulates the problems within the document, as well as the solution for addressing those problems and transferring this knowledge for other potential problems in the future. This service is available 12 hours a day, during normal business hours, spanning the time zones across North America.

Adds Harry Postles, Senior Manager in AstraZeneca’s US Development IS Applications: “Before we had access to The Solutions Center, we would utilize resources looking at and triaging problem documents. Now, we have ready access to Word and document conversion experts who can assist us in more efficiently resolving our trickiest document issues.”

The combination of DocXamine and the Document Emergency Room service has provided AstraZeneca with an enhanced sense of security when the company needs to identify and remedy last-minute problems -- especially when authors deliver content close to the submission date.

“Knowledge Partnership helps (speed the time to market) by making the submission process more efficient and predictable.”

Joe Waldron, Executive Director for Drug Development IS, AstraZeneca US

“A primary objective for my team is to speed the time to market for our products,” says Joe Waldron, Executive Director for Drug Development IS at AstraZeneca US. “Knowledge Partnership helps us accomplish that by making the submission process more efficient and predictable.”

For More Information

For more information about Microsystems and the Knowledge Partnership, or to submit a collection of your company’s Word documents or templates for a Document Health Check, contact Microsystems Sales at 630-598-1100, e-mail sales.inquiry@microsystemems.com, or visit the Web site at <http://www.microsystems.com>

About Microsystems

Microsystems is the leader in providing complete, “first draft to final delivery” document lifecycle solutions to the life sciences and legal markets and other document-intensive businesses. The company provides more than 650 clients, including leading pharmaceutical companies such as AstraZeneca and Takeda, with an innovative combination of software products, consulting services, and training sessions designed to improve the total document creation, quality control, and delivery processes.

Microsystems is headquartered near Chicago in Downers Grove, IL.