

Illuminated Research chooses Change-Pro® Premier to make comparing documents even more consistent and reliable.

Background

Illuminated Research®, a consulting and medical writing firm, provides document drafting services that assist with the development of pharmaceutical drugs and medical devices. With advanced degrees and industry experience, team members produce detail-oriented documents for submission to regulatory agencies, develop complex messaging, and ethically present scientific results obtained in clinical research studies. The firm has experience with regulatory submission documents for a variety of therapeutic categories.

Challenge

The Texas-based company produces summaries of many medical products' efficacy and safety, along with the information that must be supplied to regulatory agency briefings before they receive approval. Involving what is clearly complex, technical language, its work must also comply with specific format requirements. Failure to comply with any

such expectations will mean inefficient delays.

President of the company, Cullen Vogelsson, explains: "We will often have situations where, for one reason or another, a client only has a PDF of a certain document, but we need to make the updates to a Microsoft Word document ourselves. You cannot easily compare across the two formats..."

"Word of course has the track-change feature as a comparison tool, but our clients will want a redline version that really focuses on the details of the change."

Solution

In March 2018, Illuminated Research bought and implemented Change-Pro Premier for document comparison from Litera Microsystems.

Vogelsson continues, "Change-Pro Premier can export information as either

a Word or a PDF document, so we can send it to clients in whichever format is simplest for them. Regulatory agencies also need a formal redlined version to compare, (e.g., one version of a protocol, to another), and with Change-Pro we can submit that to them ready to go."

Illuminated Research was already using a similar tool—Workshare Compare—but as the time for Vogelsson to renew the license approached, he decided it would be sensible to re-evaluate any competitor products in terms of both key features and value for money.

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Vogelsson already had experience



- A high-throughput consulting and medical writing services firm.
- An experienced team of medical writers, helping pharmaceutical and medical device clients with regulatory reports and submissions.
- **Challenge:** Illuminated Research needs to provide regulatory agencies with formal redlined versions of documents to show specific changes. They often need to compare across document types (e.g., PDF to Word), and save and send in both Word and PDF formats depending on client preference.
- **Outcome:** The company implemented Change-Pro Premier. Change-Pro Premier surpassed the initial needs of Illuminated Research and provides future opportunities to save time and enhance document quality.

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with the company's DocXtools for Life Sciences platform. This application is used to help draft, review, and finalize electronic common technical documents (eCTD) for formatting compliance, and avoid unnecessary delays to the submission and approval of regulatory agencies.

"The fact it's consolidated within the same company also provides me with some useful familiarity and continuity," he says. "I already know exactly who to speak to if I have a question."

"The service and support is fantastic—I always get a near-immediate response to

a problem, which isn't always the case in other companies. Solving any problems quickly already amounts to a time savings, and there was also very little learning curve when adapting it to our needs. It's very fast and easy to install, and a generally fluid experience. Even merely reducing business frustration—allowing you to maintain focus on the task in hand—is a time saving and advantage to me."

Outcome

Illuminated Research can now provide regulatory agencies with the detailed redlines they require, regardless of the type of document they receive. This is all

done within the preferred user interface of Change-Pro Premier, and a familiar company with trusted support.

Vogelson also sees scope for further benefit in the future, "There is one feature that enables many-to-one comparison—up to five documents at once—and while we haven't yet had the demand for that, we do receive submissions from multiple reviewers of documents, so I can certainly foresee that being a useful addition to the toolset."

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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.