

RIPTIDE FOR LIFE SCIENCES

Distributed Content out of ECM platforms



BACKGROUND

Crawford Technologies works with content system providers to provide major offer Life Sciences firms a solution that delivers automated output management for use in the process of getting a new drug to market. Given the high stakes involved, and the rigor of the regulatory environment, Life Sciences firms need to have the assurance that they secure every possible advantage while eliminating every risk.

Life Sciences companies operate on a worldwide basis with over tens of billions of dollars in revenues annually. As a result, business process inefficiencies have big impacts, especially ones that involve the product approval process.

Crawford Technologies worked with a firm that researches, develops, and manufactures pharmaceutical products for patients with life-threatening and other serious medical conditions. Their portfolio of biotechnology products includes treatments for cancer, asthma, behavioral disorders, cardiovascular and a range of other diseases.

The Challenge

A Life Sciences firm's business model is a three step process: Discovery, Development, and Marketing. As with all biotech companies, the process is closely regulated by global regulators. In the US, the latter part of Development and the Marketing steps are controlled by a four phase review process overseen by the Food & Drug Administration (FDA). The FDA recently raised the bar for this process by publishing electronic reporting requirements in the Code of Federal Regulations (CFR) Part 314.

After a therapeutic compound has been discovered, it is easy to assume the hard work is over; in many ways, it is just beginning. Physicians and potential consumers have to be assured the compound will do more good than harm. This is the role of the New Drug Application (NDA) process, which centers on gathering and reviewing data from clinical trials. Rigid protocols are set and followed for the trials, focusing on proving safety and efficacy. A clinical data management system (CDMS) is the tool used to manage the data of a clinical trial. The analyzed data is compiled into the formal clinical study reports and sent to the multi-national regulatory authorities for approval.

At a Glance

Benefits for Life Sciences

Riptide for Enterprise Content Management provides these benefits:

- Eliminate print "bottlenecks" associated with desktop printing.
- Save time by spooling multiple print jobs from separate applications for printing.
- Eliminate the need to open documents in their native application for printing associated with manual assembly of client packets.
- Increase productivity with value-added functions.
- Reduce costs associated with manual assembly of client packets.
- Increase productivity with value-added functions.
- Platform and Content System Agnostic



At this company, data flows into their Content Management ECM platforms at two primary locations – a domestic West Coast location and an East Coast location. Reports are generated and reviewed by a broad audience including clinicians, statisticians, independent reviewers, and FDA reviewers.

One of the long standing challenges in Life Sciences is that the patent protection clock starts at the transition from Discovery to Development. The number of years spent in the phases of FDA review before the product goes to market significantly impact the total profitability of a new drug's life cycle. Keeping the review cycles short translates to millions of dollars of additional profitability.

The Solution

Because each check point impedes the process, impacting the ROI, this Life Sciences firm implemented the CrawfordTech Riptide solution to accelerate the output management of queries for documents made against the IBM FileNet Content Manager ECM. Aggregated documents from queries are now output as PDF/A documents in a streamlined automated process that cut days off the total process.

The installation was done successfully on a server that is 'fully qualified' to FDA specifications.

Looking ahead, the biotech company plans to further leverage CrawfordTech's capability to transform documents. Documents that are going to be retained will be converted to the standard PDF/A format prior to archival in order to achieve additional savings and improve response to FDA queries.

Summary

The Life Sciences firm, working with Crawford Technologies and IBM, has put itself in a position to increase profits by potentially millions of dollars through improving the turnaround time of thousands of automated responses to queries. The firm's management realizes that document aggregation and delivery will play a key role in their future revenue streams and profitability.

CrawfordTech Solutions

Crawford Technologies develops software and solutions to help enterprises optimize and improve the secure and accessible delivery, storage and presentment of their customer communications.

With over 1,800 customers on six continents, Crawfordtech solutions and know-how enable the largest banks, insurers, healthcare providers, utilities and print services companies to use their existing technologies, documents and data in new ways. We help them navigate the challenges in leveraging legacy applications in the platforms and applications of the future.

CrawfordTech's products, services and domain expertise reside at the nexus of content, data, and output management and are essential components of our customers' digital transformation, output management and document accessibility strategies.