



Distributed Content out of IBM's ECM platforms

At a Glance

Benefits for Life Sciences

Riptide for IBM 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.

" Riptide helped increase profits by potentially millions of dollars."

RIPTIDE LIFE SCIENCES

Summary

Crawford Technologies and IBM are teaming up to provide a major Life Sciences firm with a solution that provides 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, this Life Sciences firm need to assure itself that it had secured every possible advantage while eliminating every risk.

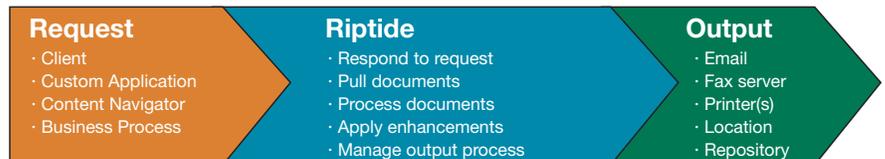
Life Sciences companies operate on a worldwide basis with over tens of billions of dollars in revenues annually. As a result, business process inefficiencies have big impacts, especially ones that involve the product approval process.

Crawford Technologies is working 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 Situation

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





## A little about Crawford Technologies

Crawford Technologies streamlines high-value document management solutions that encompass all aspects of post composition Customer Communications Management (CCM) including print file transforms, workflow automation, operations management, intelligent mail tracking, Multi-Channel Customer Communications Management (MC3), archiving/ECM and document accessibility.

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 this company, data flows into their IBM FileNet Content Manager 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 new 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.

