Case Study:

Global Regulatory Redesign Achieves Optimal RIM Platform Implementation

RESULTWORKS
An astrix Business

OVERVIEW:

Large Global Pharmaceutical organizations are faced with increased market competition, downward price pressures, and growing complexity of worldwide regulatory reporting requirements. These challenges are accelerating the need for drug development throughput and increased right-first-time regulatory submissions, without a proportionate increase in resources.

While smaller organizations may find desktop tools adequate for their operations, larger organizations require holistic, integrated platforms and streamlined business processes. The financial impact of delays in new drug applications, are well documented to run into millions of dollars per day. Tallying the hidden costs of delays in other submissions (e.g., INDs and post-marketing changes) is more arduous, however, these costs are similarly significant when aggregated for portfolios over time. In this case study, we discuss how one large global pharmaceutical company leveraged ResultWorks services to optimize their RIM Platform implementation.

BUSINESS CHALLENGE

A global pharmaceutical client chose to address this new reality head-on by initiating a multi-year program to implement an integrated Regulatory Information Management (RIM) platform. The client had successfully implemented specific technical capabilities; however, the corresponding business transformation was trailing the technology. User adoption, and therefore true value delivery, was not performing to business and IT leadership expectations.

HOW RESULTWORKS ENABLED SUCCCESS

ResultWorks was engaged to collaborate with the client on the RIM business solution and on their program execution methods. The objectives for the engagement were to:

1. Design an agile approach for RIM release planning and execution to accelerate value creation across the global organization.
2. Elucidate the RIM release business and technical requirements needed to align critical processes & capabilities across key business areas, support configurations, and accelerate adoption.
3. Accelerate ongoing migrations associated with initial release capabilities while planning for and executing rapid onboarding of new users and migration of additional legacy information supported by each subsequent release. This in turn, drove the timely decommissioning of legacy systems and tools.

The scope defined by leadership crosscut all submission types in both pre/post-marketing on a global basis addressing the following areas:

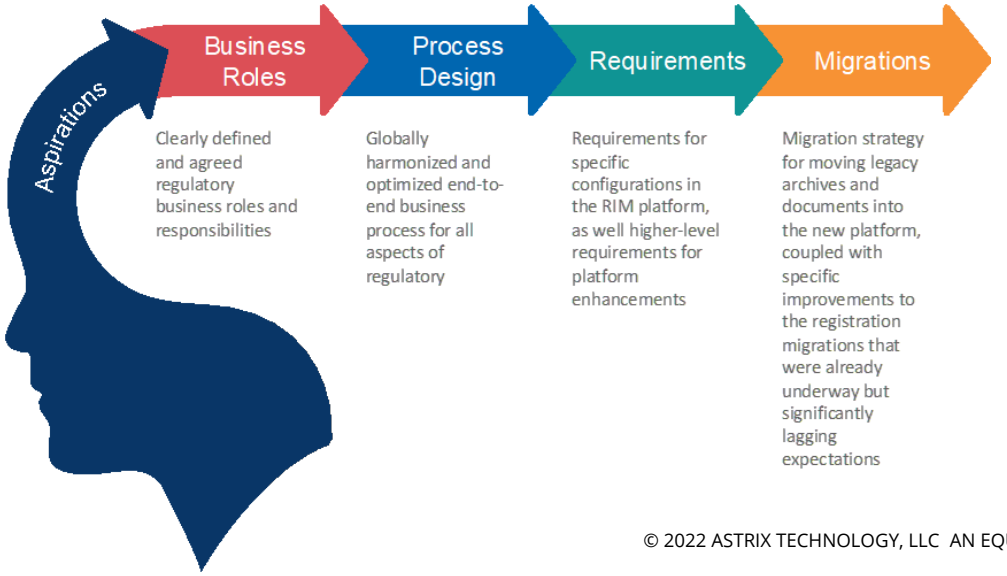
- Registration and Submission Planning
- Submission Tracking and Management
- Content Planning
- Content Authoring
- Publishing
- Archiving and Correspondence

The initial effort leveraged our ResultMethodology℠ to perform a rapid assessment of the client's global processes that encompassed investigational work, global registration planning, content planning and authoring, publishing, archiving, correspondence, registrations, and related processes. The assessment identified several common themes including:

- Diverse regional differences
- Disparate systems and solution gaps, and
- Duplicate and inconsistent data

To expedite the definition and design work, each working session included "strawman" materials on the topic at hand. ResultWorks' seasoned life sciences consultants provided strong stakeholder facilitation, drawing out reserved participants, guiding stakeholders to agreement, and ensuring that the teams avoided "analysis paralysis."

The deliverables for the Regulatory redesign and RIM platform implementation program included:



THE RESULTWORKS IMPACT - KEY BENEFITS

The ResultWorks team delivered a plan for RIM capabilities to be implemented over three releases during the course of one year. In fact, two of the three releases were delivered within the first six months with dramatically improved alignment, communications, execution, and adoption. The business and IT teams were aligned on the approach for execution and leveraged an agile-like approach for the planning, definition, and delivery of each release.

This global organization was able to change the course of the RIM program, positioning themselves to deliver successfully over the remaining phases of their multi-year journey, through the end-to-end process design, requirements definition, and migration strategy work our team delivered.

In addition, and of equal importance to the successful execution of this program, this global pharmaceutical organization's RIM program enjoys the lasting operational benefits of being:

> *ResultWorks team is doing a great job and addressing a gap that we have been trying to fill since the beginning of the RIM program.*
> *— Regulatory Tech Lead*

For more information, visit our website at www.resultworksllc.com or www.astrixinc.com.