Case Study:

Global Pharma Streamlines Regulatory Labeling Process

OVERVIEW:

Pharmaceutical labeling is a highly complex and regulated process and needs to be working effectively to ensure safety and quality. Companies are, however, constantly facing compliance issues mainly while they are involved in marketing to multiple countries. This is an issue with the regulatory authorities and a top priority for the company.

The major impact to the organization due to labeling issues could be a partial or complete market withdrawal or a huge penalty from the health authorities due to data inconsistency with the reference label data. This further creates ongoing challenges for organization as the processes are scrutinized by the regulatory authorities.

Companies may lose a huge amount of revenue and time towards product approvals and renewals. Given this situation, it is critical for organizations to ensure their submission processes are solid.

Regulatory Information Management Systems/Software, or RIMS, are platforms that have emerged to assist pharmaceutical companies in submitting products for regulatory review.

In this case study, we discuss how a global pharma company leveraged Astrix's expertise to:

- Define business processes to support transition to new Veeva RIM Solution.
- Develop Use Cases to drive configuration sessions.
- Manage sessions to facilitate discussions, track configuration items and enhancements, and produce a summarization of findings.
- Define Release Plans to support implementation of Labeling capabilities.

BUSINESS CHALLENGE

A global pharma company was looking to move to a RIM solution and needed to integrate functionality to support all regulatory submissions globally. Additionally, they needed to implement labeling capabilities within the enterprise Regulatory Information Management system.

Astrix was brought in to assist with the process. The client's stakeholders included:

- CM&C
- Global and Local Labeling Coordinators
- Global Regulatory Affairs
- Packaging and Development
- Information Technology
- Vendor team members
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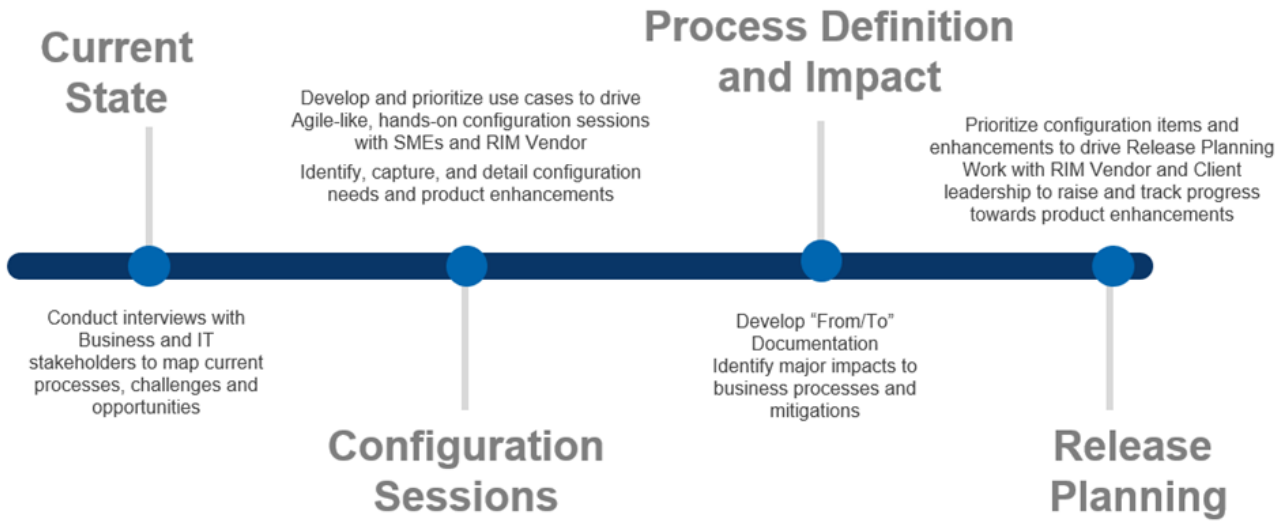
HOW ASTRIX ENABLED SUCCESS

Astrix worked closely with the client's stakeholders to define their requirements and the configuration needs including:

- Mapping current and future business processes along with impacts and risks.
- Developing release plans and timing for implementation of capabilities into production.

Astrix's approach to this strategic initiative is shown in the graphic. Foundational to this type of effort was an engagement with the business and IT stakeholders on the current state and the challenges to be addressed, potential solutions to be considered, and ultimately the priorities that offer the highest business value.



In multiple sessions, conducted by Astrix with the client, use cases were reviewed to drive Agile-like, hands on configuration sessions with subject matter experts and RIM vendor to recognize, capture, and detail configuration needs and product enhancements.

Astrix also developed “From/To” documentation to identify major impacts to the business processes and migrations. From there, configuration items and enhancements were prioritized to the drive configuration timelines and release planning work with the RIM vendor. Dashboards were created to monitor progress, raise issues, and maintain timelines for prioritized configurations and product enhancements.

THE ASTRIX IMPACT - KEY BENEFITS

The benefits achieved by this major biotech organization through this project included:

- A defining of the current and future state business processes, including impacts to business processes, risks, and mitigations to support transition to RIM solution.
- Developing use cases to drive configuration sessions to identify configuration needs and product enhancements for labeling authoring, planning, and tracking
- Managing sessions, including facilitation of discussions, tracking of configuration items and enhancements, summarization of findings in sprint readouts and prioritization of use cases throughout Sprint sessions.
- Defining Release Plans to support implementation of labeling capabilities within the client’s RIM solution.

Astrix continues to provide ongoing program management support, including adoption planning and management, integration planning, configuration/enhancement item management, etc.

For more information, visit our website www.astrixinc.com.