

## Case Study:

# CRO's Global Regulatory Affairs Group Creates Successful IT Vision and Strategic Roadmap

## OVERVIEW:

Pharmaceutical companies and CROs need to establish both a vision and strategy to ensure that operations, processes and technology align to comply with present and anticipated regulatory requirements and guidelines.

Ensuring success in a timely manner sometimes requires involving the right partner who understands the possibilities and has enabled similar organizations to succeed in developing effective roadmaps. In this case study, we review how a CRO collaborated with ResultWorks – an Astrix business, to develop an effective IT vision and strategy for their Global Regulatory Affairs group.

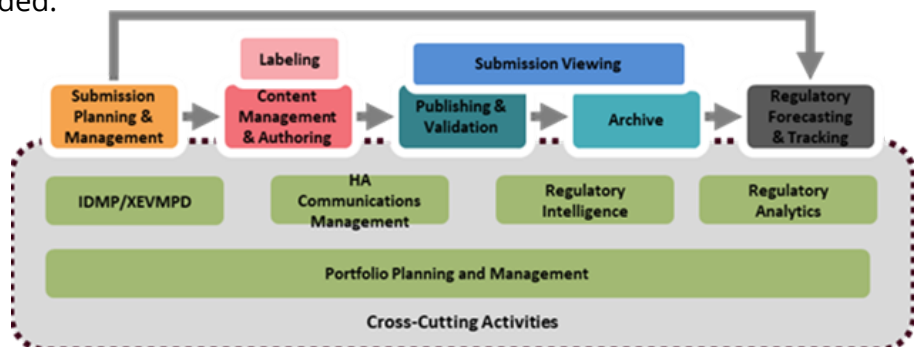


## BUSINESS CHALLENGE

Driven by a strategic partnership with a global pharmaceutical company, a growing CRO needed to revisit and develop a future-facing IT vision and strategy for its Global Regulatory Affairs group. The partnership afforded opportunities for the CRO to leverage and rationalize IT systems and business services offerings across both organizations as well as for other clients.

The CRO engaged ResultWorks to help understand the nature of the Regulatory IT systems currently in place with its partner, within its own organization, and commercially. In order to develop a technology roadmap to support its future business operations. Considerations for systems selection, against future business direction, included:

- Keep our own systems and enhance
- Adopt the partner's system in whole or as a starting point for future enhancement
- Acquire a new technology solution



## HOW RESULTWORKS ENABLED SUCCESS

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ResultWorks applied its proven methodology to first establish a credible baseline for the current situation, this included:

- Inventory of the current Regulatory IT systems at both the CRO and at the partner organization and mapping those systems to the business capabilities they support
- Conducting a rapid RFI process to assemble capability and budgetary pricing information for commercial software solutions in the Regulatory space

ResultWorks then used its' collaborative ResultSessionSM approach to bring together business and IT stakeholders to achieve alignment on:

- The CRO's future business strategy in each of the regulatory business capability areas
- Consideration of new technologies and platforms moving forward
- Selecting the best solution configuration to support future business needs

The outcomes from the ResultSessionSM activities generated a strategic roadmap containing details essential to supporting business objectives entailing the timing and scope of future systems acquisitions and implementations. To enable business justification decisions budgets were developed alongside the roadmap.

## THE RESULTWORKS IMPACT - KEY BENEFITS

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**Business IT Strategy Alignment:** A best fit and forward-looking technology strategy was rapidly developed to support the future portfolio of Global Regulatory Affairs business offerings.

**Realistic Roadmap with Costs:** A clear strategic technology roadmap was produced to support future business decision making with essential associated costs and dependencies.

*"You are the most impressive consultancy I have ever worked with. Strategic thinking, good approach and methodology that allows adaptability to specific client situations."*  
- Regulatory Program Lead

For more information, visit our website at [www.resultworksllc.com](http://www.resultworksllc.com) or [www.astrixinc.com](http://www.astrixinc.com).