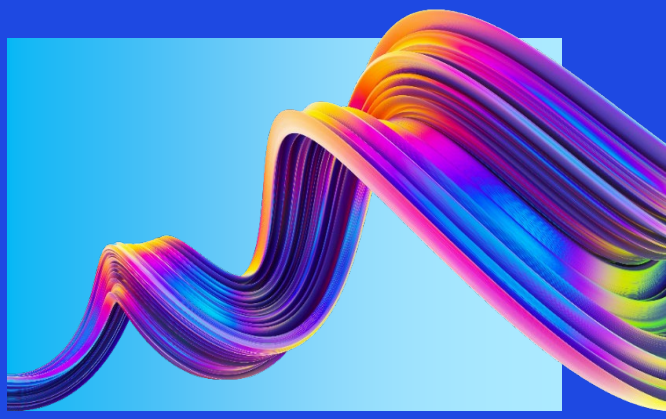
Enabling Value through RIM Process and Technology Optimization



Enable your Regulatory Affairs organization through process optimization and ongoing innovation

Over the last several years, the Regulatory Affairs function has been evolving, with a focus on being a strategic business partner to the broader organization – helping bring products to market that are safe, effective and compliant.

Technology, people, processes and data all have a big role to play in this evolution, as legacy ways of working and manual processes will not be sustainable and won't enable the function to deliver transformational value.

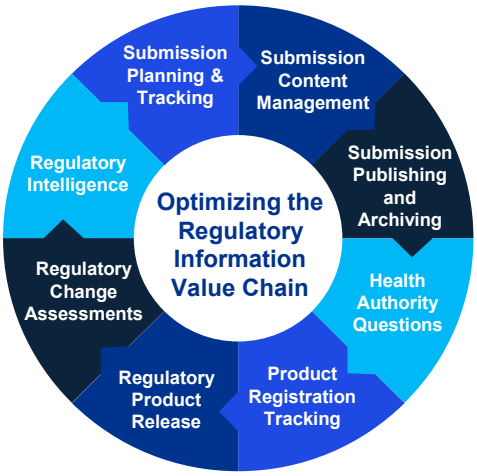
Key questions to consider

Technology – how do we maximize value from our technology investments and deliver ongoing innovation within our organizations?

Process – what processes must be harmonized and/or optimized in order for any technology solution to be successful?

People – what new competencies, roles and/or teams are required to enable a digital workforce and data centricity?

Data – how do we align RA data with the broader organization, align on single sources of truth for key information, and increase how data is used for decision making and strategic insights?



How we can help?

KPMG LLP has expertise supporting RIM programs at any stage of RIM process and technology transformations – from initial assessment through implementation and post implementation optimization efforts.

Readiness and Planning

- Readiness assessments including external comparisons and benchmarks
- Target operating model – across people, process, technology and data
- Business requirements definition
- Technology roadmap and sequencing
- Solution evaluation support
- Business case development
- Process harmonization readiness and strategy
- Data readiness and migration approach

Implementation Support

- Design and harmonization of supporting processes, including data entry model and governance
- Global data collection/harmonization
- Cross-functional integration design, including MDM approach
- Iterative design review sessions
- Business scenario testing and UAT support
- Training development and/or delivery
- Project management
- Organizational change management and business readiness

Post-Implementation Optimization

- Implementation and monitoring of KPIs
- Triaging and sequencing of business enhancement requests
- Ongoing assessment, testing and validation for software release cycles
- Further process optimization in areas of most need
- Data quality monitoring and/or data quality improvement programs
- Ongoing training and optimizing IT and business support models
- Strategic change management interventions to drive further adoption

Why act now?

Life Sciences companies are facing increasingly complex regulations, heightened demand for data (both volume and complexity), innovative product and commercial models, pressure to increase speed to market, and continued global expansion that puts pressure on legacy operating models.

To address these challenges, provide value to the organization and support ongoing growth, it is critical for RA to evaluate and implement optimized processes for managing submissions and related regulatory content across the enterprise.

Example client engagements

1

Digital transformation strategy project

- Led project to create digital transformation strategy for the Global Regulatory Affairs organization that outlined key investment focus areas for transforming processes, technology, and data
- Included significant stakeholder involvement to gather cross-functional input via collaborative workshops

2

Three-part transformation program for the RA function

- Led all business-facing activities for the global RIM project (solution design, data collection, and training)
- Supported eIFU solution implementation, including process design, solution design, and training
- Facilitated process design and business adoption of system to be used for global UDI and EUDAMED

3

RIM change management support

- Conducted a detailed stakeholder assessment and led functional change impact workshops
- Defined a robust change management and communications plan
- Provided business-facing change management support for 8,000+ impacted stakeholders

4

Business readiness support for adoption of global RIM solution

- Developed a change management strategy and business readiness checklist
- Collaborated with business stakeholders to drive completion of readiness checklist within each BU
- Executed change management activities including introduction presentations, group demos, and workshops

Why KPMG

Extensive experience on complex projects – we can provide references on request

Deep industry expertise, comparators and accelerators – we have tailored approaches specific to Regulatory Affairs

Highly trained team members – our team has Regulatory Affairs professional and software certifications

We provide a combination of business and technical expertise – we can help you solve a wide variety of challenges

Contact Us

Brian Williams
Managing Director, KPMG LLP
T: 312-995-3582
E: bewilliams@kpmg.com

Meghan Cox
Director, KPMG LLP
T: 630-247-4545
E: meghancox@kpmg.com

Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates or related entities.

#KPMGLifeSciences
kpmg.com/socialmedia