CLIENT CHALLENGES

Regulatory Affairs organizations are facing a challenging balancing act, leading to the reevaluation of current operating models. Emerging markets, increasing regulatory requirements, the introduction of innovative products, as well as ongoing cost/margin pressures are all market forces resulting in companies needing to reconsider alternatives best suited to meet the competitive landscape. Companies are assessing substitute or parallel sourcing models to adapt to these current market forces.

WHY REGULATORY OPERATIONS?

Regulatory Affairs is a vital unit that spans across the life cycle within a life sciences organization. It is also a pivotal unit that can be leveraged to reduce entry-to-market time line. In that context, building a best-in-class Regulatory Affairs organization is becoming critical to gain competitive advantage. The role of the Regulatory Affairs organization varies from a basic “compliance” function to a sophisticated and strategic organization that helps drive value to the business. Regulatory Operations is a highly process-focused function within Regulatory Affairs that makes it a prime candidate for outsourcing and shared services. The primary decision is whether to segment the activity by type (e.g. publishing, annual reports) or by product portfolio (e.g., end-to-end management of the maintenance of mature products) with the trend towards full life-cycle maintenance of mature products.

Evaluating the life sciences regulatory operations function for alternate sourcing models

Life sciences companies must answer three key questions:

1. How do we become more strategic and plan proactively?
2. How do we streamline and keep our processes lean?
3. How do we stay nimble to quickly adapt to changes?
OUR ASSESSMENT APPROACH
KPMG will analyze Regulatory Operations’ current state model, existing processes, and tools and technologies to develop a focused sourcing analysis. This information provides a foundation for reviewing alternative operating models for further consideration.

Five key questions help determine the most appropriate operating and service delivery model:

- **Why?** Drivers for change, priorities, constraints
- **What?** Function, cycle, process, activity, task
- **By Whom?** Internally distributed, internally centralized, internal shared services, outsourced
- **Where?** Onshore, nearshore, offshore, multishore
- **How?** Governance, organization, practice, policy, process

HOW YOU CAN BENEFIT
KPMG can help reduce operating costs, create greater efficiencies, and improve compliance processes by identifying specific operations that are most conducive to meeting the requirements of an alternate sourcing model. We conduct both qualitative and quantitative analyses on our client’s current processes and help identify operations that may be better suited for an outsourcing/shared services model. A rigorous financial assessment along with evaluation of Regulatory Operations’ processes against predefined criteria will provide your organization with critical information about key processes and activities within Regulatory Operations. Identifying the best candidates for alternative sourcing will allow your organization to (1) acquire greater resource capacity, (2) achieve greater resource flexibility, (3) reduce cost of operations, (4) acquire new capabilities, and (5) harmonize global processes.

SURVIVE IN A COMPETITIVE LANDSCAPE
Increasing competitive and regulatory challenges require companies to re-evaluate their existing state of operations and consider methods to increase effectiveness. Strategic outsourcing of core Regulatory Operations activities is a well-established, continuously maturing, successful, and proven business approach. Many of the Top 50 life sciences and pharma companies currently have some component of strategic sourcing within their operating models. Through this assessment, KPMG can help optimize your organization’s operational functions, be proactive, and prepare strategically to thrive in a competitive landscape.

Five key questions help determine the most appropriate operating and service delivery model:

- **Why?** Drivers for change, priorities, constraints
- **What?** Function, cycle, process, activity, task
- **By Whom?** Internally distributed, internally centralized, internal shared services, outsourced
- **Where?** Onshore, nearshore, offshore, multishore
- **How?** Governance, organization, practice, policy, process