

What's the best Regulatory resource model for my business?

Benefits

The Regulatory Sourcing Assessment utilizes proprietary consulting tools and techniques which provide Regulatory Leaders with a

- Global Sourcing Strategy Model aligned to business objectives
- Analysis of current operations
- Performance review based on Navitas Life Sciences benchmark insight
- Sourcing recommendation including cost estimates and location strategies
- Business Case for Leadership to drive sourcing initiatives and decision-making
- Tailored Implementation roadmap

The cost and complexity of meeting global regulatory requirements continue to increase as a result of stricter regulations and increased scrutiny and expectations from regulators worldwide. Increasing cost focus across industry also demands greater operational efficiency. 'Doing more with less' is becoming the norm.

Smart, cost-efficient sourcing solutions supported by technologies provides the flexibility, scalability and oversight needed to support the increasing workload while controlling costs, all without sacrificing quality. Understanding the potential of alternative sourcing models has become a key remit of Regulatory Operations Leaders to balance the need for cost control while maintaining a compliant, efficient and value-adding global organization.

Navitas Life Sciences has a proven approach to support you in the finding the right Regulatory sourcing strategy

Define objectives | Alignment of regulatory operations sourcing strategy with business objectives

Collect activities in scope | Review and analysis of activities and stakeholders (internal/external) currently performing responsibilities

Prioritize activities | Scoring and prioritization of activities in scope according to Risk and Degree of fit for offshoring / outsourcing

Analyze work effort

- Analysis of core vs non-core activities (volume, effort and value)
- Assessment of overall regulatory operations performance and productivity using Navitas benchmark insights
- Identification of opportunities for transformational improvements through technology and process enablers

Implement optimized resource model | Phased roadmap and implementation plan

Deliverables

- A Balanced Score Card for Regulatory operations and performance indicators for measurement of outcomes of the sourcing approach
- Mapping of activities by role; activities analyzed in terms of Risk and Degree of fit for alternative sourcing models
- Clearly defined opportunities for work streamlining / activities bundling to ensure minimal effort duplication, cost of transition / risk and maximum return on investment (ROI)
- Effort estimation and cost analysis leading to a business case
- Phased roadmap and implementation plan

About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelnet—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

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