

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 TAKE Solutions 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.

TAKE Solutions 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 TAKE Solutions 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 TAKE Solutions

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).

For more information

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