Sustainable operating models in life sciences regulatory affairs to improve compliance and lower costs

Operating models in life sciences regulatory affairs are no longer sustainable, with related costs increasingly being scrutinized by corporate CFOs. Regulatory organizations need to achieve the global scale and flexibility necessary to meet the challenges of complex regulatory requirements, while keeping costs under control. Success requires a strategic transformational approach that integrates a new vision of regulatory operating models, technology, and data management.
**Business challenges**

Regulatory affairs functions are hampered by sub-optimal operating models and siloed data in legacy technologies, causing operating challenges such as:

**Lack of strategic operating and sourcing models.** Preferred staff augmentation sourcing models have been piecemeal as there is a strong resistance to the perceived “complex” nature of outsourcing. Expensive and inflexible on-shore models result in low-value repeatable tasks being performed in the highest cost locations. Talent acquisition and retention has operated under a “do more with less” cultural philosophy, rather than a more holistic global resourcing approach.

**Inadequate technology systems.** Legacy technologies are siloed, out-of-date, and viewed as complex and expensive to run. At the same time, there is under-investment in technology that will adequately enhance business processes, decision making, and user experience.

**No single source of truth.** Regulatory databases are out-of-date, not consolidated, or integral to key business processes such as batch release. Master data management is poor and there is no single source of truth.

**Poor data, reporting, and analytics.** As a result of poorly managed data, organizations may not be certain about what is registered and where, the status of submissions, or the implementation dates required by the relevant health authorities. Management is frustrated by a lack of reliable information, reporting, and analytics.

**Inability to effectively manage regulatory affairs.** The result is the inability for regulatory management to scale robust global processes and meet changing business demands, adapt to new legislation, or contain costs while ensuring compliance.

**Genpact solution**

Reimagining global regulatory affairs requires a transformation program that establishes the future vision and a road map for change. Genpact Pharmalink provides a broad range of consulting and technology transformation services to help organizations reimagine their global regulatory affairs operating model, technology and information management.

**Operating model assessment and strategic roadmap.** End-to-end regulatory affairs target operating model engagements that start with assessing and diagnosing current operational effectiveness. From insights gathered, we help clients develop a future vision and road map for change, including the identification of core vs. non-core activities, outsourcing readiness, and transition-execution to an outsourced operating model.

**Technology strategies, and road maps.** Strategies, road maps, and data governance frameworks for technology transformation enabled by Genpact Systems of Engagement™ helps simplify, streamline, and standardize regulatory processes while optimizing automation, workflow efficiency, and process metrics.

**Data integrity and advanced analytics.** Improve data governance and integration of cross-functional internal and external data through new regulation readiness assessment, and related data remediation. Advanced analytics capabilities help drive deeper insights for regulatory compliance and intelligence across the enterprise.

**Why Genpact Pharmalink**

Genpact Pharmalink is the industry’s leading global regulatory services provider with:

- **Proven regulatory transformation expertise.** Reap the benefits of over 18 years of experience in providing high-quality, global regulatory affairs services to 8 out of 10 of the leading life sciences companies. Rely on our seasoned team of industry experts who have many years of regulatory experience across all major and emerging markets

- **Global regulatory affairs teams.** Leverage scalable, cost-effective global teams from over 300 regulatory professionals in our regulatory centers of excellence, strategically situated in life science hubs around the world

- **Local regulatory intelligence.** Leverage our proprietary Pharmalink Affiliate Network (PAN)
to provide local regulatory affairs expertise in the local language in any regulated market. Covering 166 markets globally, the PAN provides local regulatory insight, strategy, and intelligence in markets not covered by a global delivery center.

- **Flexible delivery models.** Choose from flexible service options that will meet your specific needs with onshore, offshore, and near-shore resources for greater efficiency and maximum value.

- **Technology-enabled services.** Access leading edge technology solutions that optimize automation and workflow execution while providing real-time analytics and operational insights to drive performance and regulatory lifecycle effectiveness.

- **Smart Enterprise Process (SEP℠) framework.** Benefit from our patented methodology, designed to transform regulatory processes into best-in-class for delivering maximum business impact.

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**Bio-pharma major boosts growth and business agility**

**Challenge**

A leading bio-pharma company looking to boost growth through market development, new product launches, and M&A was challenged with legacy RIM (regulatory information management) processes and technology infrastructure that increased the risk of non-compliance, led to cost escalations, and affected business agility.

**Solution**

Beginning with a current-state assessment of regulatory processes, data, and systems, Genpact Pharmalink helped structure the future-state RIM infrastructure for the client after evaluating their RIM related technology vendor, metric inventory, maturity indices, and prioritizing synergies from existing projects such as IDMP.

**Impact**

This helped the client drive an integrated RIM and RCM (regulatory content management) strategy that enhanced business agility, reduced the risk of non-compliance, and maximized return on investment by improving data integration and data access using best-in-class technology infrastructure.
About Genpact

Genpact (NYSE: G) stands for “generating business impact.” We are a global leader in digitally-powered business process management and services. Our Lean DigitalSM approach and patented Smart Enterprise ProcessesSM framework reimagine our clients’ operating models end-to-end, including the middle and back offices – to deliver growth, efficiency, and business agility. First as a part of GE and later as an independent company, we have been passionately serving strategic client relationships including approximately one-fifth of the Fortune Global 500, and have grown to over 70,000 people. The resulting domain expertise and experience running complex operations are unique and help us drive choices across technology, analytics, and organizational design.

For additional information, contact, lifesciences.solutions@genpact.com, and visit www.genpact.com/what-we-do/industries/life-sciences

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