Today's regulatory affairs function needs to balance the twin objectives of maintaining regulatory compliance of mature products with the demands of new product development required to drive growth. Success requires an operating model that leverages process efficiency and technology to drive new levels of operational excellence in regulatory compliance and safety.
**60-70% of regulatory and safety resources typically focused on lifecycle management activities**

In many of today’s life sciences organizations, existing operating models for regulatory and pharmacovigilance are strained by the requirements of expansion into new markets, securing new product approvals, and increasing speed-to-market, while managing increasing regulatory complexity and maintaining compliance of mature products.

In a competitive market, balancing resources in regulatory affairs is increasingly challenging. There is a need to focus on growth through innovative new product approvals, but resourcing post-marketing maintenance activities dominates workload for the function.

With nearly 70% of regulatory and safety resources in life sciences focused on lifecycle management activities for mature products, such as license maintenance and product extensions, capacity is a key constraint as they balance the diverse regulatory requirements of mature products with the need to enhance speed to market of new products.

To solve capacity issues, outsourcing has become commonplace in the past ten years, which generally has the added benefit of cost-efficiency at a time when budgets are under pressure and costs are increasing. Regulatory affairs and safety organizations are turning more and more often to outsourcing operational activities.

Over time, however, a piecemeal or multi-vendor approach that is not part of a holistic strategy may result in adverse effects that the organization has to manage in addition to workload:

- Productivity leakage due to lack of end-to-end oversight
- Multiple vendors to manage and diminished economies of scale
- Lack of transparency into costs, resource demands and value
- Limited strategic change management impacting the retained organization

**A strategic approach to lifecycle management, enabling cost reduction and improved compliance**

A strategic approach to lifecycle management may provide the solution; delivering the right mix of people, process, analytics and enabling technology to solve these challenges and create new value for the organization – providing scalable, global regulatory resource at a cost reduction of 30-40%, and improved compliance.

With nearly two decades of domain expertise and operational excellence in regulatory and safety means Genpact Pharmalink understands lifecycle management. Leveraging our global regulatory and safety organization and industry-leading capabilities in process, technology, analytics and transformation services we provide an end-to-end lifecycle management service platform for all regulatory and pharmacovigilance requirements for mature products.

Tailored to client’s portfolio and geographical needs, these services include:

- **License maintenance**: Variations, annual reports, renewals, CPPs, labeling updates, change control evaluation, authoring, DMF maintenance, filing strategy, CDS
- **Regulatory operations**: Submission management, publishing (eCTD, Nees, paper), ancillary documents, archiving
- **Emerging market submissions**: Country-specific adaptation of core dossiers, completion of supporting documentation, agency meetings
- **Regulatory information management**: Database maintenance and updates, master data governance, XEVMPD/ISO IDMP maintenance, change control administration, correspondence tracking
- **Compliance**: Identifying and remediating compliance gaps, guaranteed and transparent maintenance of systems and databases
- **Risk management/pharmacovigilance**: QMS, literature search, aggregate reporting, signal detection, risk management
Genpact Pharmalink’s lifecycle management service platform

Genpact Pharmalink’s lifecycle management for mature products is based on four essential pillars that solve the challenges of lifecycle management activities and improve on existing outsourcing models.

1. **Process:** Standardized processes for lifecycle management configured to drive efficiency and ensure compliance

   Using our proprietary Smart Enterprise Processes (SEP℠) framework, Genpact Pharmalink optimizes current client processes and defines standardized processes that leverage regulatory and safety best practices. SEP℠ enabled processes for all aspects of lifecycle management are streamlined to provide maximum efficiency, as well as the metrics to support visibility and opportunity to gauge performance improvement.

2. **Technology:** Systems of Engagement™ technology provides efficient workflows with globally consistent data

   Genpact’s advanced technology solution is a thin layer of technology that orchestrates business processes; overlaying and interacting with existing client systems of record. It provides a simplified method for achieving effective integration between systems to easily deliver a more efficient and unified process workflow, allowing us to deliver and track services and interact with client systems, maintaining global data integrity across the lifecycle.

3. **Operational excellence:** Experience and operational know-how ensures flawless global delivery services, minimized risk and maximum value

   Working in close partnership with clients, we seek to understand our client’s processes, goals and objectives in order to design, transform and run a lifecycle management solution. This process knowledge and our proven, phased approach for outsourcing transitions ensures clients receive a thoughtful, seamless, no-surprise transition and high-impact delivery. Based on our experience of over 5,000 projects in the industry, it leverages best practices to ensure minimal business disruption with comprehensive risk mitigation, and complete transparency and control.

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**Figure 1:** A lifecycle management operating model to maintain global compliance and extend product registrations

- Standardized process for lifecycle management
  - License management
  - Compliance
  - Regulatory operations
  - Pharmacovigilance
  - Emerging markets
  - Information management

- World-class analytics
  - Performance analytics to alert compliance actions
  - Provides complete transparency through metrics
  - Blend internal and external data sources to drive new client insights

- Operational excellence
  - Global delivery footprint
  - Transition and process excellence based on 5000+ projects
  - Proprietary Smart Enterprise Processes (SEP℠) framework

- Technology platform
  - Single source of product maintenance data
  - Interconnects multiple systems for efficient coordination
  - Cloud based
  - Dashboards with real-time status information
4. **Analytics**: World-class analytics improves compliance and visibility of the regulatory lifecycle

Meaningful KPIs in combination with our Systems of Engagement™ for lifecycle management delivers real-time performance analytics and dashboards (desktop and mobile) for regulatory lifecycle management activities. The Systems of Engagement™ analytics and dashboard can be configured to specific client requirements, providing a transparent view of all lifecycle management metrics, as well as productivity, cycle time, staff utilization, and other relevant metrics.

**The Genpact Pharmalink advantage**

Genpact Pharmalink is the specialist provider of lifecycle management services, uniquely combining expertise and capabilities focused on driving regulatory and safety impact for our clients:

- **Global regulatory and safety teams.** Leverage scalable, cost-effective global teams from our global pool of regulatory and safety professionals.

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**Figure 2**: Systems of Engagement™ Centralized technology solutions to overlay existing client systems

**Figure 3**: Genpact’s phased approach to lifecycle management outsourcing
professionals strategically situated in centers of excellence, on-, off- or near-shore. Access broad experience in all aspects of regulatory and safety at all levels, and regional/local regulatory knowledge and Health Authority interaction

- **Proven transformation expertise.** Rely on nearly two decades of deep regulatory experience providing holistic regulatory and safety solutions, integrating a proven approach to program and change management, based on over 5000 projects.

- **Technology-enabled services that drive performance and data integrity.** Access leading technology solutions that enhance workflow, enable automation and provide real-time insight into performance and effectiveness in the regulatory lifecycle.

- **Smart Enterprise Processes (SEPSM) framework.** Rely on our patented methodology designed to optimize regulatory and safety processes, transforming them to best-in-class and delivering maximum impact.

### Global pharmaceutical company transforms lifecycle management for mature products

**Challenge**
The client needed a scalable and flexible operating model for the Regulatory Affairs (RA) function to meet fluctuating and demanding regulatory resource requirements, including capitalizing on emerging market growth opportunities, and improve compliance with global regulatory requirements. They also wanted to streamline vendor management and identify cost efficiencies.

**Solution**
Genpact Pharmalink supported the client’s operating model evolution, providing sustainable outsourcing of regulatory requirements of lifecycle management of mature products, and evolving the client service model to a strategic partnership with shared outcomes. This supported efforts to streamline processes and operationalize low-risk activities, such as ancillary document preparation, license renewals, annual reports, etc. The new model included consolidation of divisional support into global shared-service hubs, working across therapies and business divisions.

**Impact**
- 30% cost savings
- Released client’s strategic resources to focus on value-added activities
- Generated efficiency gains in lifecycle management processes, including CMC document authoring, license renewals, and ancillary documents processes
- Streamlined maintenance processes and improved process management across global operations
- In 2014 alone, Genpact Pharmalink delivered:
  - Post-marketing maintenance >1500 variations
  - Change control >17000 requests
  - Compliance >5000 licenses

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Genpact (NYSE: G) stands for “generating business impact.” We architect the Lean Digital™ enterprise through a unique approach based on our patented Smart Enterprise Processes (SEPSM) framework that reimagines our clients’ middle and back offices to generate growth, cost efficiency, and business agility. Our hundreds of long-term clients include more than one-fourth of the Fortune Global 500. We have grown to over 70,000 people in 25 countries, with key management and a corporate office in New York City. We believe we are able to generate impact quickly and power Intelligent Operations™ for our clients because of our business domain expertise and experience running complex operations, driving our unbiased focus on what works and making technology-enabled transformation sustainable. Behind our passion for technology, process, and operational excellence is the heritage of a former General Electric division that has served GE businesses since 1998.

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

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