



GENERATING **REGULATORY AFFAIRS** IMPACT

# Transforming lifecycle management in regulatory affairs through Systems of Engagement<sup>TM</sup>



Effective management of the product lifecycle seems out of reach for many pharmaceutical companies as they struggle with fragmented technology and processes. These operational challenges result in limited visibility and collaboration across the enterprise on activities related to regulatory affairs and often lead to delayed time to market, escalating costs, and compliance risks.

Success requires reimagining end-to-end regulatory affairs processes and related organizational transformation. An agile, process-centric technology layer that complements existing systems of record can help accelerate and sustain the transformation.

## Business challenges

A dying blockbuster model, tightening regulations and stringent healthcare authorities, and payers sharply focused on value have made lifecycle management of late-stage products extremely important. Done well, it can help life sciences companies maximize product value by being compliant at all times with applicable regulations, keeping products in market longer, and entering new markets faster. However, most life sciences organizations struggle with maximizing the effectiveness of lifecycle management due to the following reasons:

**High costs.** Manual processes are prevalent in 60% of regulatory and safety lifecycle processes of late-stage products. The ad-hoc engagement of multiple suppliers to address peak volumes also minimizes economies of scale.

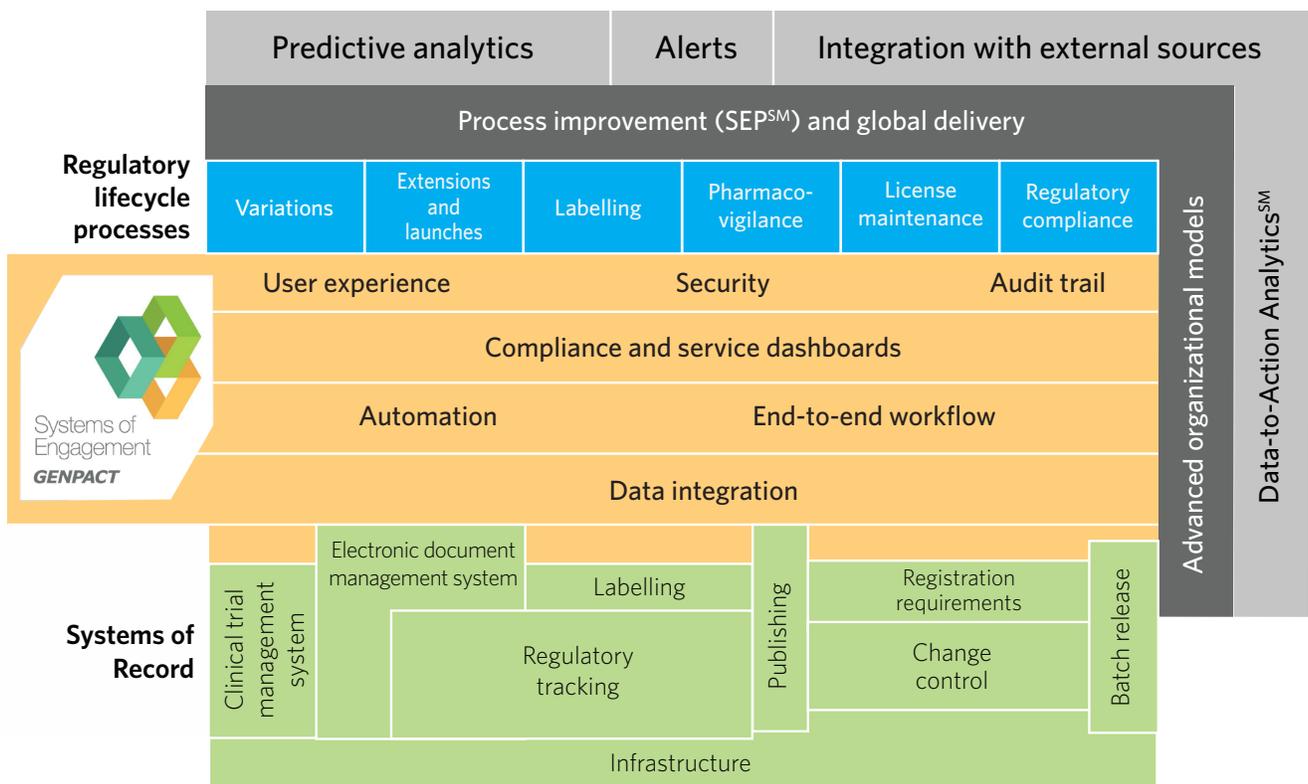
**Fragmented technology and processes impact time to market.** Product lifecycle management needs an integrated approach across multiple functions—R&D, manufacturing, marketing,

commercial operations, safety, regulatory affairs—and regional operating companies. However, regulatory systems of record are siloed and do not address the end-to-end lifecycle. Multiple localized systems and the proliferation of manual spreadsheets, used by managers and knowledge workers, lead to delays in accessing critical regulatory information.

**Compliance risks are increased due to limited visibility and collaboration.** There is often a lack of effective communication between company headquarters and local regulatory affairs organizations. Data housed in disparate systems is not effectively updated or integrated into regulatory business processes. Often, there is a lack of transparency and effective measurement of resources, costs, and enhanced value delivered.

## Genpact solution

Genpact provides a flexible, cloud-based **Systems of Engagement™** that layers on top of the existing systems of record and helps automate regulatory lifecycle workflows, aligning systems and data to



**Figure 1:** Systems of Engagement™ for regulatory affairs lifecycle management

regulatory processes and user roles. The highlights of the solution are:

- **Connect disparate systems of record** data to application data models, enabling data to securely flow within critical business processes and to users and managers who need that information
- **Simplify user interfaces** with role-based functionality
- **Customize workflows** to support key regulatory lifecycle processes with automation of routine tasks
- Use process-oriented **analytics and visualization** tools
- **Measure and track process efficiency** and effectiveness with compliance and service dashboards
- **Rapidly customize** agile, client-specific applications

Our approach leverages deep domain knowledge in end-to-end regulatory affairs to streamline processes, embrace best practices, and standardize, where possible, while customizing to meet the unique requirements of each environment. The scientific process and metrics definition, role-based access, seamless data flows, and standardization encourage collaboration within functions and enable more effective leveraging of advanced organizational models such as outsourcing. Process owners or managers can easily assign tasks to resources, give them secure access to required information, have them collaborate with internal resources, and effectively measure and monitor their performance.

Analytics experts further extend the power of the solution by combining the readily available regulatory data with other external data sources to provide alerts about potential regulatory, safety,

or competitive risks by applying sophisticated predictive analytics.

## Potential impact

Genpact optimizes regulatory and product change processes with dramatic improvements in efficiency and the potential to reduce costs by up to 40%. Our **Systems of Engagement™** platform enables companies to rapidly respond to business and process changes, independent of difficult-to-change systems of record.

We help improve data quality and governance for critical regulatory information through intuitive user interfaces and process-based dashboards that incorporate refined metrics and key performance indicators (KPIs) for real-time insights and controls. Realizing full end-to-end capabilities, key regulatory processes are extended to manufacturing and the supply chain.

## Why Genpact?

**Lean Digital<sup>SM</sup> approach** drives choices that complement existing technology environments offering advanced digital solutions for rapid impact.

**Regulatory affairs experience** encompasses 18 years of deep domain expertise in end-to-end regulatory affairs across 150 markets. We support nine of the top 10 life sciences companies in their transformation initiatives.

**Impact-focused approach** provides greater agility to quickly respond to changing business requirements and regulatory processes. Genpact expedites time to market by meeting regulatory deliverables with reduced compliance risk or failures. The impact can result in up to 40% slowered operating costs and up to \$25 million in annual cost savings potential.

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## 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 Digital**<sup>SM</sup> approach and patented Smart Enterprise Processes<sup>SM</sup> 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.

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