

# How can regulatory affairs drive greater value for the patient and for the business?

**GENPACT**  
**Pharmalink**  
GLOBAL REGULATORY AFFAIRS



**Exploring the  
key considerations ...**

**How do you combat the rising costs of regulatory affairs?**

**What's the best operating model for a truly agile regulatory function?**

**How do you improve regulatory quality and speed of delivery?**

**How can you improve data quality and regulatory compliance with existing regulatory systems?**

# Introduction

In regulatory affairs, competing demands to secure new product approvals, maintain compliance and do more with less have intensified during the last decade, with no sign of slowing. Scrutiny of the regulatory function continues to increase, as does the need to control rising costs.

Against this backdrop, achieving the organization's goal of enhanced patient value is challenging. It raises doubts about the value and sustainability of the way regulatory affairs are structured to do business. It questions the current regulatory affairs operating model.

An operating model optimized to meet the global needs of the organization would enable the regulatory affairs function to manage the emerging and continuous demands placed upon it, shifting the perception of regulatory affairs as a cost center to being a valued asset for the business.

Desired results would include improved quality and speed of delivery, as well as the employment of the most valuable regulatory resources on only the highest-value tasks – and in the most cost-effective and sustainable way.

Genpact Pharamalink is the industry's leading global regulatory services company, providing regulatory support for nearly two decades to 8 out of 10 of the leading life sciences companies.

For over 18 years, we have built deep domain expertise, global delivery capabilities and service models that drive regulatory impact and year-on-year cost-efficiencies for our customers.

Here, we consider what an optimized operating model might look like and answer some of the questions facing regulatory professionals in the global life sciences sector.

# How do you combat the rising costs of regulatory affairs?

The median cost of regulatory affairs is growing at over 10% year-on-year, driven by increasing complexity of global regulatory requirements, emerging markets expansion and greater compliance challenges.

These trends are set to continue for the foreseeable future. Life science companies need a strategy to contain regulatory costs, and address productivity and scalability to meet these resource demands.

Outsourcing is increasingly leveraged to help meet these objectives. Currently, 65% of life sciences companies are outsourcing within the regulatory function. This may include staff augmentation with regulatory 'clone' consultants or by individual projects, eliminating fixed costs of adding employees and providing support in peak periods of activity.

Outsourcing may also be undertaken by more than one service provider, adding multiple supplier management to the function's remit. While there may always be a place for these outsourcing options, they are a 'piecemeal', costly and reactive approach to outsourcing, rather than a holistic strategy that drives long-term, sustainable value.

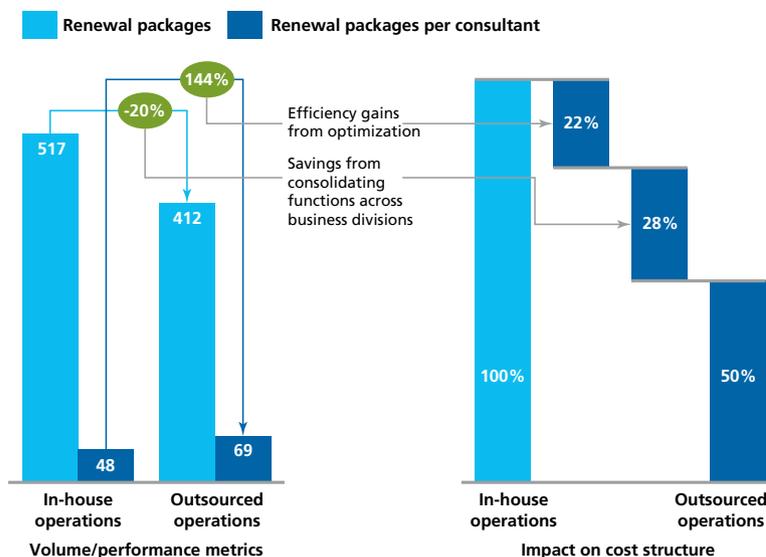
Some organizations are already investigating how to optimize regulatory operating models for cost reductions, and to transform the function to an asset with the capacity to innovate and execute with speed and at scale.

Key to this is the use of "sustainable outsourcing" in the regulatory capability mix. The outsourcing partner takes on responsibility for an entire function,

role or portfolio of products. In these models, use of a streamlined, focused process reduces cost to the client and releases precious internal resources for higher value activities.

These models consolidate functions across business divisions and geographies, and use process optimization, such as Lean Six Sigma, on transactional and voluminous tasks to achieve even higher levels of efficiency. Our research shows that sustainable outsourcing of preparing CMC renewal packages, where a process optimization methodology is applied, can deliver savings of 50%, as shown in Figure 1.

Figure 1: Efficiency gains in preparation of CMC packages from outsourcing



\*Source: Cutting Edge Information; Regulatory Affairs, Safeguarding Submission Success and Product Development Strategy

# What's the best operating model for a truly agile regulatory function?

Many organizations employ outsourcing of regulatory capabilities for cost advantage. Focusing on the operating model as a pivotal point for initiating transformational change of the function may yield greater results than reducing costs.

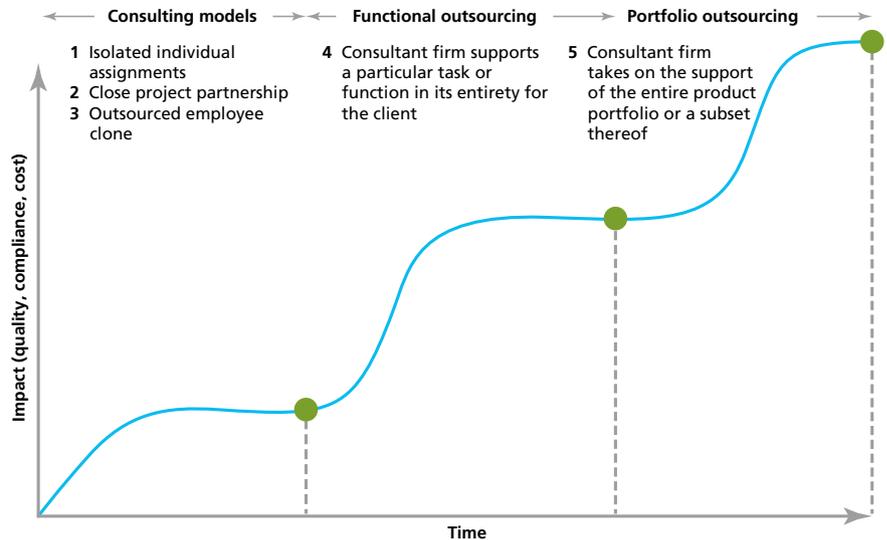
Some organizations have considered how these services need to integrate to enable business agility and, over time, outsourcing has been incorporated into the regulatory resourcing mix in different ways, from isolated individual assignments and supplementary staffing through to the outsourcing of entire functions.

Early adopters have embraced operating models based directly on mature models in other industries, where they are proven platforms for delivering both quality and compliance. This experience can help define a business strategy that uses agility as a source of competitive advantage and delivers maximum impact on patient value.

Outsourcing of regulatory maintenance activities, or lifecycle management, is an example of this. In this model, the regulatory service partner assumes responsibility for an entire portfolio of older, established products.

In these situations, organizations need an "end-to-end" outsourcing partner to effectively manage all maintenance activities, except the strategy of the portfolio. This enables the client to redirect scarce strategic resources to activities and products critical to business growth, and which deliver most value to patients.

Figure 2: Regulatory outsourcing operating model



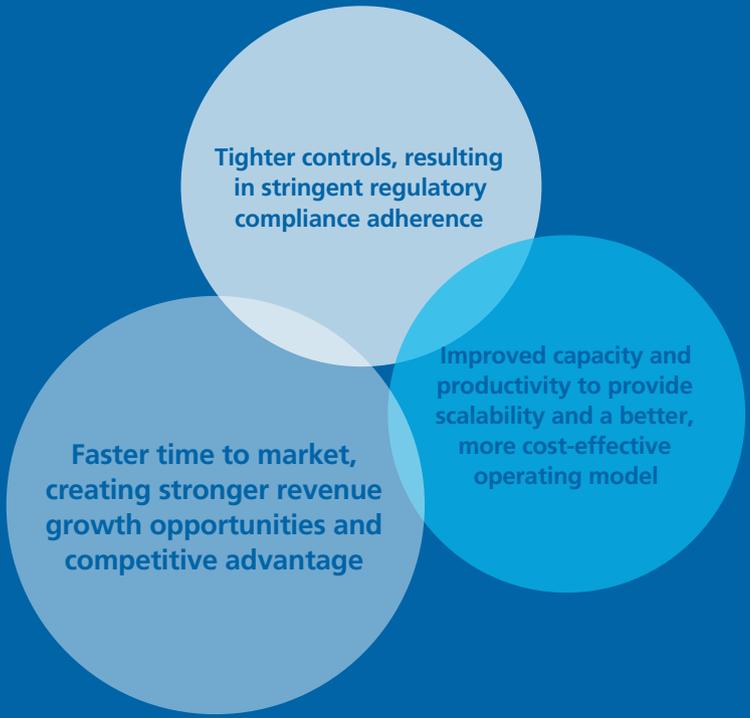
# How do you improve regulatory quality and speed of delivery?

In the highly competitive global pharmaceuticals markets, regulatory strategy and quality of submissions are integral to achieving new product approvals and speed to market.

Further, as the time and effort needed to respond to health authorities' inquiries escalates, designing the operating procedures for "first-time-right" deliverables is critical to ensure timely responses.

In the context of the regulatory operating model, improved quality requires robust, optimized regulatory processes that minimize waste and rework, with a focus on value-added activities that deliver the key business outcomes.

Genpact's Smart Enterprise Process (SEP<sup>SM</sup>) is a unique methodology designed to optimize regulatory, safety and compliance processes. As an assessment that uses granular data analysis, diagnostics and cross-functional benchmarks to maximize process effectiveness, SEP is steeped in Lean Six Sigma. By focusing on identifying the critical factors that influence delivery of regulatory business outcomes, SEP targets them to achieve maximum impact, including:



**Tighter controls, resulting in stringent regulatory compliance adherence**

**Improved capacity and productivity to provide scalability and a better, more cost-effective operating model**

**Faster time to market, creating stronger revenue growth opportunities and competitive advantage**

# How can you improve data quality and regulatory compliance with existing regulatory systems?

Genpact research shows that 72% of senior executives in the life sciences sector cite ensuring regulatory compliance as one of their three most important challenges, outweighing the need to decrease costs at 46%. Technology is a key part of the regulatory operating model.

Over the last 20 years, life sciences companies have collectively invested many millions of dollars in R&D IT systems and databases to control and manage their regulatory information. It is widely accepted that these investments have not delivered to their full potential, for a variety of reasons.

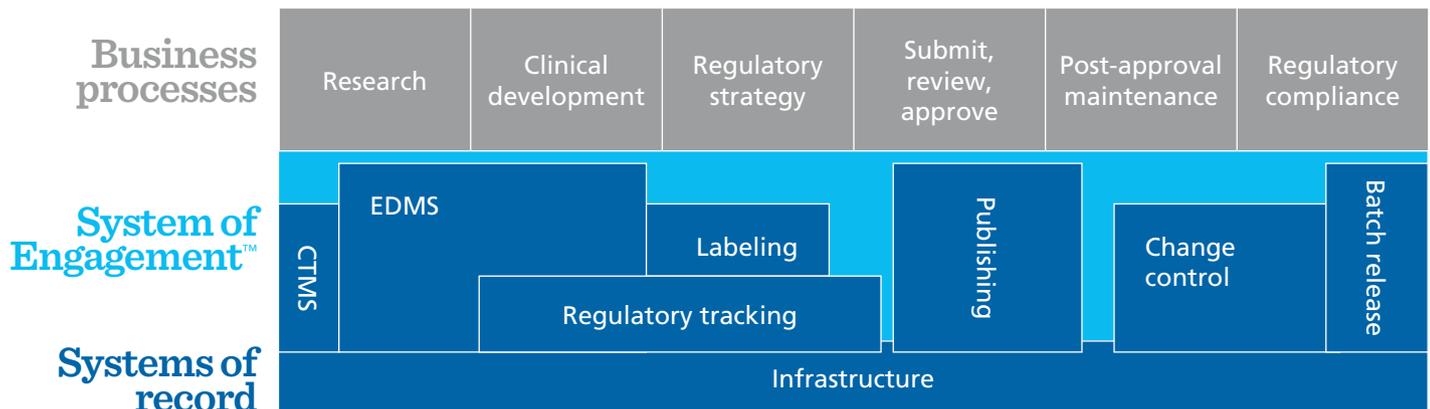
Users are frustrated at the lack of an end-to-end view, and management is dissatisfied at frequent compliance failures and a lack of quality data and analytics.

These frustrations are a result of system silos with no master data to connect them. Gaps between the silos are plugged by users creating ever more numerous and elaborate spreadsheets, "systems of record", while dipping in and out of various systems for process data. Regulatory professionals in local operating companies are critical to the provision of high-quality global regulatory data, yet the existing R&D IT systems are rarely deployed with this user community in mind.

Currently, there is no single end-to-end SAP-like platform for regulatory compliance on the market. There is, however, a proven technology solution that can accelerate regulatory activities by taking a process-based view and embracing smart technologies.

A System of Engagement™ sits on top of existing systems of record and orchestrates business processes, using a thin layer of technology in a flexible and adaptable way as the business evolves.

With built-in capabilities for automation, global collaboration, mobility and analytics, it will dramatically accelerate the efficiency and effectiveness of regulatory organizations and significantly reduce regulatory compliance failures.



# Summary

There is clear and compelling evidence that those companies committed to rapidly evolving their business architecture in order to innovate and execute with speed and at scale will win. Regulatory organizations are under pressure to add more value to the business. A strategy that evolves the regulatory operating model by re-thinking the role of outsourcing and the impact of technology-enabled, lean processes is the key to meeting these goals.

We offer regulatory support through all phases of the product lifecycle – regulatory strategy, authoring, and all aspects of established product maintenance, including submission management, publishing, health authority interaction and everything in between.

## **Our successes to date include:**

- Creating an advanced CMC operating model for a Fortune 500 biopharmaceutical company and achieving 25% cost savings
- Bringing over 11,000 product licenses into compliance with global regulatory standards
- Delivering global CMC change management systems and processes in support of the merger of two top-10 pharmaceutical companies

As an end-to-end service provider in regulatory affairs, Genpact Pharmedlink has the global expertise, capabilities and tools to help you become an agent of change for your business and create an optimized operating model capable of delivering enhanced patient value.

# ***GENPACT*** **Pharmalink**

GLOBAL REGULATORY AFFAIRS

**Genpact Pharmalink is the global regulatory affairs organization of Genpact.**

## **About Genpact**

Genpact (NYSE: G) stands for “generating business impact”. We architect the Lean Digital<sup>SM</sup> enterprise through a unique approach based on our patented Smart Enterprise Processes (SEP<sup>SM</sup>) 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<sup>SM</sup> 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, visit [www.genpact.com](http://www.genpact.com).

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