White Paper

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GENERATING REGULATORY AFFAIRS IMPACT

Enhancing CMC regulatory compliance with Lean Digital℠

Life sciences companies are experiencing increasing pressure to demonstrate Chemistry, Manufacturing and Controls (CMC) regulatory compliance across their global product portfolios and supply chains. The potential consequences of non-compliance include legal sanctions, liability, damage to brand, failed business strategy, and risk to patient safety. It pays, therefore, to determine any gaps and remediate to ensure products are manufactured to the standards and specifications outlined in the registered regulatory documentation. A strategic approach to compliance initiatives that focuses on applying external domain expertise in a manner that leverages Lean principles, digital technologies and process excellence can maximize value and transform the business for growth and success.

Regulatory compliance challenges the life sciences industry

The narrative of the pharmaceutical industry over the past decade has posed many challenges to CMC regulatory compliance. Waves of merger and acquisition activity have impacted regulatory and manufacturing functions with significant risks to CMC regulatory compliance such as inadequate change control systems, reliance on multiple databases and third-party manufacturers, high levels of staff turnover and large portfolios of mature products.

In parallel to this, the pressures on the business and the need to ensure CMC regulatory compliance have never been greater (see figure 1). The negative implications of non-compliance are significant. FDA data suggests that companies undergoing consent decrees have reported billions of dollars of financial impact across litigation, penalties, stock value, brand perception, third-party controls, and product recalls. In recent years, driven by these pressures and a need for growth, an increasing number of companies have opted to proactively address the CMC regulatory compliance requirements of their global supply chains and product portfolios.

An opportunity for compliance transformation

At the core of any CMC regulatory compliance initiative is the comparative (gap) analysis of registered CMC information (ICH CTD Module 3 or equivalent) against the plant documentation used in the manufacture, testing, and release of a product to market. On identification, potential gaps are reviewed and confirmed by regulatory and quality teams, and classified by criticality; from there, any ongoing post-authorization activities to close the issue are pinpointed.

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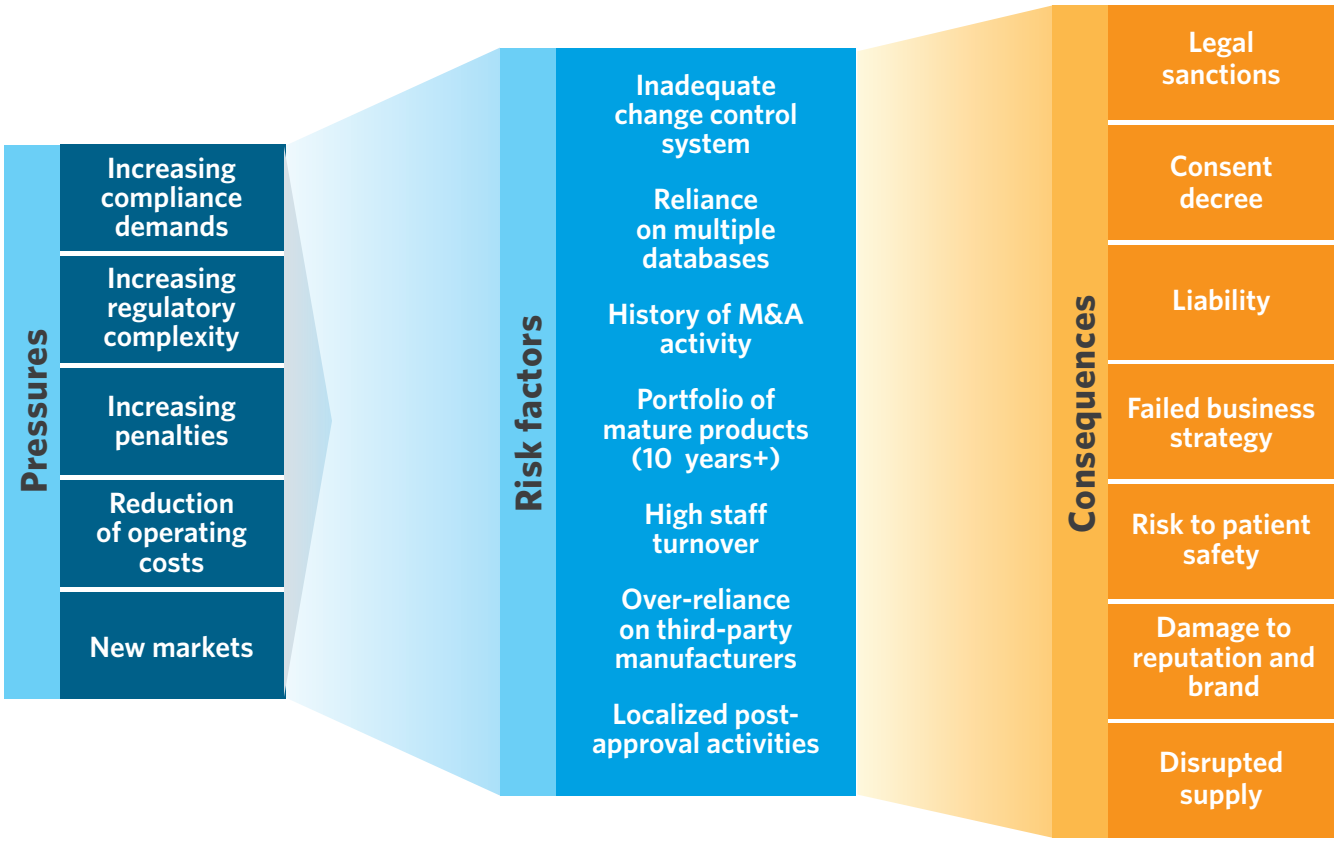


Figure 1: *Pressures, risk factors, and consequences of CMC non-compliance*

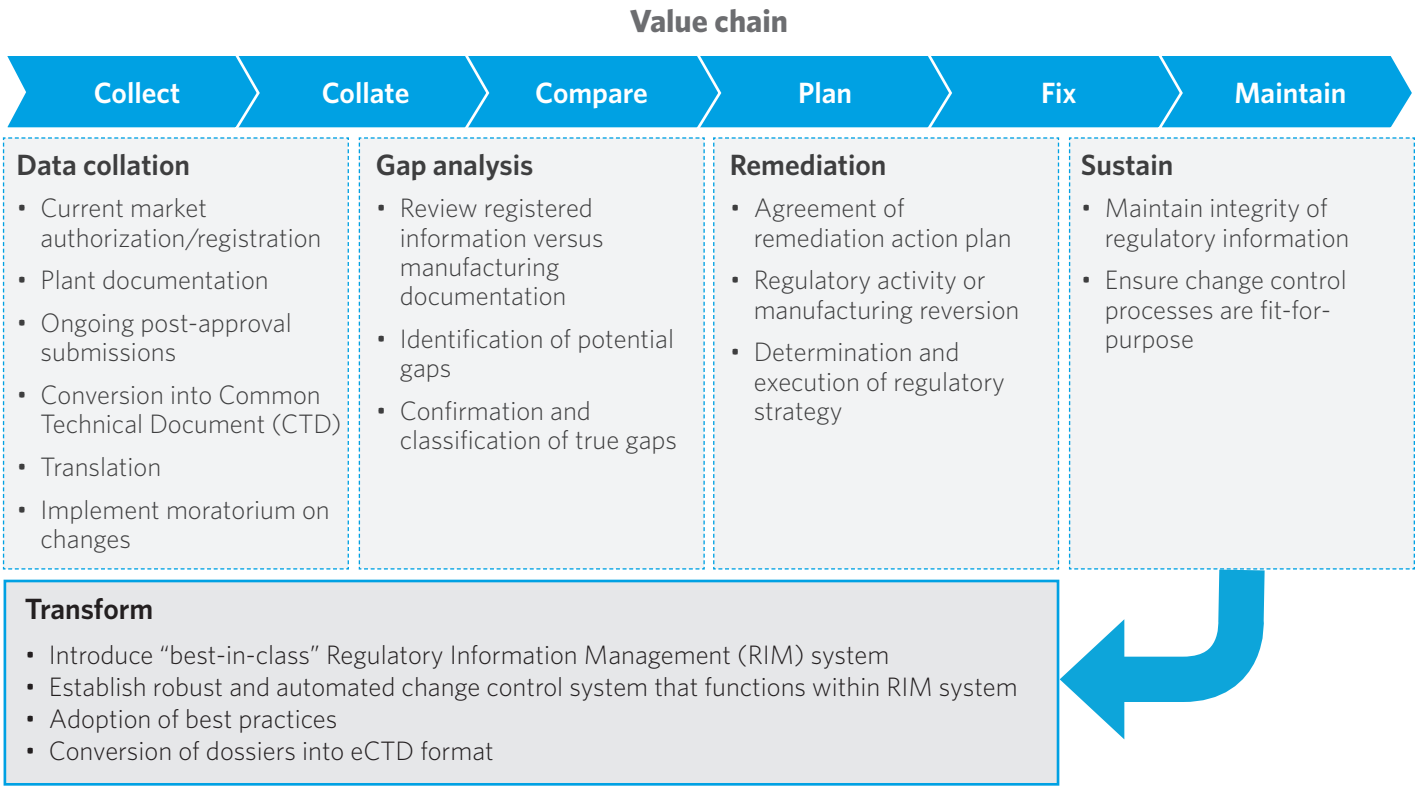
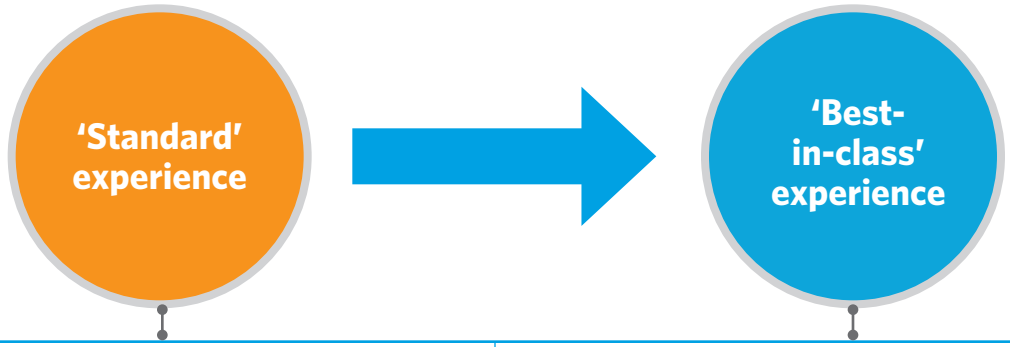


Figure 2: *CMC Regulatory compliance methodology*

Subsequently, remediation plans are agreed upon and implemented, either through regulatory submissions or manufacturing reversion.

Large-scale CMC regulatory compliance initiatives can also provide an organization with transformational opportunities across the value chain, as well as a robust platform for future compliance and growth as shown in figure 2. Increasingly, these solutions are digital in nature, such as in Regulatory Information Management (RIM) and associated automated change-control systems.



Proactive or agency-enforced	Proactive
Maintains status-quo	Transformative
Housekeeping	An opportunity to build a platform for future growth
A distraction from business-as-usual activities	Dovetailed seamlessly with business-as-usual activities
Non-revenue generating	An opportunity to redirect internal expertise to revenue generating streams
Negative experience	Positive experience

Figure 3: *Standard vs "Best-in-Class" experience*

The adoption of a consolidated best-in-class regulatory and change-control system, alongside the global review of CMC compliance and adoption of best practices, provides an opportunity for sustained, automated compliance through the use of advanced process-centric digital solution such as Systems of Engagement™. Planned and executed in an agile and progressive manner, CMC regulatory compliance initiatives have now moved beyond the historical experience of a negative, non-revenue generating housekeeping activity into an opportunity for growth and revenue generation (see figure 3).

The ability to keep internal resources focused on revenue-generation activity. In many cases, the external expertise of a service partner is both scalable and flexible, which ensures the right resources are available for the right duration and in the right location. Subject matter experts in CMC regulatory compliance can be strategically placed at both a central location and also at manufacturing sites or local affiliates across the globe. While the use of a centrally-based team provides the potential for cost-saving efficiencies and synergies across products and reviews, the placement of local consultants provides the opportunity to harness deep technical, language, and cultural expertise as required.

A more cost-effective solution than internally resourcing. An experienced partner, focused on service delivery and costs, will drive efficiencies and deliver a solution that can be readily scalable and flexible by nature and specialized in the field of CMC regulatory compliance. Potential cost-effective models may be based on fee-per-service (priced by each Marketing Authorization reviewed and remediated) or centered on precise resource requirements.

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In the long term, such models for compliance activities can deliver significant benefits that increase the value of the investment in a compliance initiative.

Depth of knowledge and best practices for establishing successful and sustainable compliance activity. Such global initiatives are necessarily nuanced in nature, with the potential for complex discussions with a number of key internal and external stakeholders, including regulatory authorities across the globe. Beyond a purely transactional approach, the insights, analysis, knowledge, experiences and best practices of an

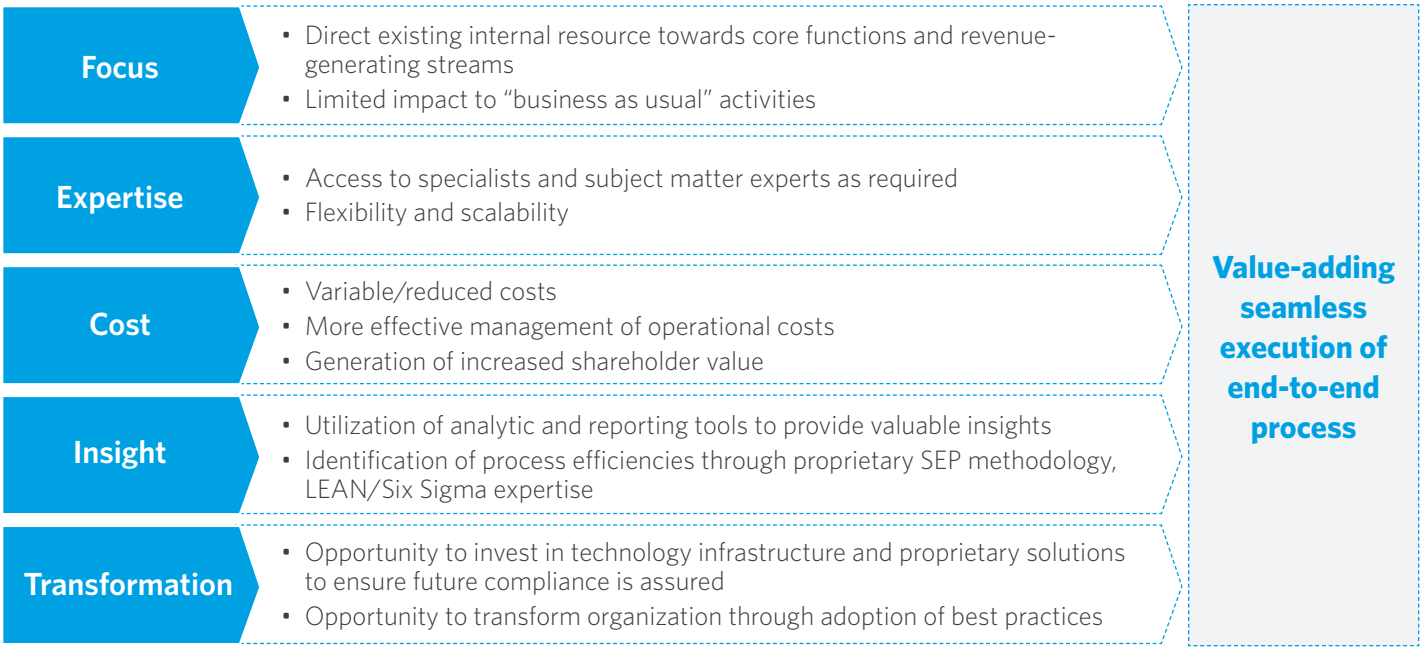

Figure 4: *Delivering value through advanced operating models*

experienced provider play an important role in the strategic planning and execution of a global CMC compliance initiative.

Maximizing customer value through the utilization of Lean Six Sigma methodologies. Partners with proven history of implementing Lean Six Sigma projects and granular, data-driven, process improvement methodologies like Smart Enterprise Processes (SEP℠), which uses sophisticated diagnostics and cross-functional benchmarks, can proactively drive measurable gains, maximize process effectiveness, and create a seamless process improvement environment.

Digital solutions that allow for sustained, automated compliance. Sustainable compliance will necessarily rely on robust processes and systems interfaces. Process-centric digital solutions that complement existing electronic document management, change control systems, and regulatory information management systems ensure better visibility on process performance and compliance initiatives across the value chain. They also help effectively deploy more advanced operating models, such as shared services and outsourcing.

Conclusion

CMC regulatory compliance initiatives are a requirement to avoid the serious repercussions of non-compliance. There is a significant opportunity to evolve CMC regulatory compliance from a matter of good practice and housekeeping into a central, transformative driver of an organization's future growth and success.

Often perceived as negative experience, CMC regulatory compliance initiatives can provide an organization with transformational opportunities across the value chain, becoming a platform for future growth through assured compliance, robust regulatory information management, process optimization, and digital innovation.

A strategic approach to compliance initiatives leveraging advanced operating models supported by the right regulatory partner that helps combine Lean principles, digital technologies, and domain and process expertise can ensure that compliance across the global supply chain is sustained to maximize value and transformation to a best-in-class process.

This paper was authored by Dr. Ivan Fisher, Assistant Vice President, Global Regulatory Affairs, Genpact Pharmalink

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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. We architect the **Lean Digital**[SM] enterprise through our patented Smart Enterprise Processes (SEP[SM]) framework that reimagines our clients' operating model end-to-end, including the middle and back offices. This creates Intelligent Operations[SM] that we help design, transform, and run. The impact on our clients is a high return on transformation investments through growth, efficiency, and business agility. For two decades, first as a General Electric division and later as an independent company, we have been passionately serving a few hundred strategic clients including one-fourth of the Fortune Global 500, and have grown to over 70,000 people in 25 countries, with key offices in New York City. The resulting business process and industry domain expertise and experience running complex operations are a unique heritage and focus that help us drive the best choices across technology, analytics, and organizational design..

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