

**CASE STUDY**

# A healthier compliance prognosis

How a life sciences leader transformed regulatory operations to drive compliance and boost growth

## **WHO WE WORKED WITH**

One of the world's leading pharmaceutical companies, with operations in over a 100 countries.

## **WHAT THE COMPANY NEEDED**

- Better visibility into regulatory compliance processes
- Transformed regulatory policies and processes related to chemistry, manufacturing, and controls (CMC) to ensure sustainable compliance
- Improved speed to market for new products

## **HOW WE HELPED**

We harnessed flexible resource support to transform the company's governance and compliance operating model. That included implementing targeted technology interventions such as a real-time program dashboard for project reporting and insights.

## **WHAT THE COMPANY GOT**

- A compliance process that improves visibility into regulatory operations for over 1,300 consumer health product licenses and 40 manufacturing locations
- The program dashboard integrates regulatory data across locations to enable real-time reporting. When combined with the transformed processes, this helps improve process efficiency and reduce cycle times - While the sustainable compliance process positions the company for growth

## CHALLENGE

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### Get a grip on compliance

Companies have to prepare for a wide range of risks as they adapt their businesses to changing regulatory and market-driven pressures, such as market expansion, new technology, and evolving stakeholder expectations.

This global leader lacked visibility into existing compliance and regulatory processes and data. The registered information related to products was stored in multiple formats across markets globally, and product dossiers were often in local or legacy formats. In addition, disparate technology and data-capture systems resulted in a fragmented view of regulatory and compliance information that was shared from local markets to global operations, putting the organization at risk of being non-compliant.

## SOLUTION

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### Build a better view

Genpact provided flexible resource support to help the company transform its operating model, developing an end-to-end compliance initiative without disrupting business as usual. We assessed the current operations and found an urgent need to transform the company's governance and compliance framework: It needed to

be standardized, with system-driven processes and future readiness.

We deployed a dedicated team of compliance specialists and regulatory affairs consultants to address the client's resource constraints. We also implemented targeted technology interventions and knowledge support to improve project reporting to stakeholders through tools such as a real-time project information dashboard.

## IMPACT

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### A future-ready company

By implementing a best-in-class CMC compliance system, the company can not only sustain compliance, it can generate greater patient and business value by focusing on transformation opportunities across the value chain. The CMC process is faster and more efficient, so processes are completed right the first time and cycle and wait times are reduced.

With improved visibility and reporting across more than 1,300 consumer health product licenses and 40 manufacturing sites, the company has better global compliance controls. This reduced the risk of non-compliance findings during health authority inspections, and minimized the possibility of costly damage to the company's reputation.

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#### About Genpact

Genpact (NYSE: G) is a global professional services firm that makes business transformation real. We drive digital-led innovation and digitally-enabled intelligent operations for our clients, guided by our experience running thousands of processes primarily for Global Fortune 500 companies. We think with design, dream in digital, and solve problems with data and analytics. Combining our expertise in end-to-end operations and our AI-based platform, Genpact Cora, we focus on the details - all 87,000+ of us. From New York to New Delhi and more than 25 countries in between, we connect every dot, reimagine every process, and reinvent companies' ways of working. We know that reimagining each step from start to finish creates better business outcomes. Whatever it is, we'll be there with you - accelerating digital transformation to create bold, lasting results - because [transformation happens here](#). Get to know us at [Genpact.com](#) and on [LinkedIn](#), [Twitter](#), [YouTube](#), and [Facebook](#).

For additional information, visit <https://www.genpact.com/risk-compliance/regulatory-affairs>

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