Easing regulatory pressures for a global pharma

A major firm transforms post-approval maintenance for scale, insights, and growth

WHO WE WORKED WITH
A global pharmaceutical major with presence in over 100 markets.

WHAT THE COMPANY NEEDED
A more efficient approach to managing regulatory workload pressures, enhanced capabilities to innovate, and the agility to scale operations.

HOW WE HELPED
We took a two-pronged, holistic approach: First, we helped transform existing business processes, then we used digital technology to drive innovation.

WHAT THE COMPANY GOT
We helped the firm increase efficiencies by providing scalable resources and a fresh approach to innovation - and that led to cost savings. Based on our insights, the company was able to enhance processes, improve overall performance, and reinvigorate its regulatory team.
Accelerate growth. Foster innovation. And scale for agility

Life sciences companies around the world face an uphill battle with increasing work volumes, as legal requirements around drug approvals continue to evolve. To secure these all-important approvals, companies must be flexible enough to rapidly deploy significant resources. After drugs have been approved, maintaining licenses remains a challenge for many companies, forcing too many people to spend too much time on repetitive tasks, and hampering their ability to add value and contribute to growth.

In that context, our client began looking for a partner to lead a dramatic shift. The firm wanted to apply advanced thinking, new technology tools, and innovative design to transform all of these processes – and put growth at the forefront.

Plus, in looking for a partner, the client had other criteria in mind. We had to be able share risk while still maintaining our commitment to quality and compliance. At Genpact, we pride ourselves on our ability to increase visibility into operations, heighten spend intelligence, improve benchmarking, evangelize best practices, and ensure quality while driving compliance. By meeting these requirements, we felt confident we could scale operations for the client in a way that made processes far more agile.

SOLUTION

Bring every process up to speed – and turbocharge innovation

Here’s how our two-pronged approach worked:

Process

- Established centers of excellence (CoE) for submission management, authoring, translation management, publishing, and regional support for submission management and translations
- Introduced management and strategy policies for post-approval maintenance submissions
- As the company underwent digital transformation, we delivered effective operations and continuous improvement in outcomes with end-to-end process oversight
- Our master black belt Lean Six Sigma team drove process re-engineering

Innovation

- Set up a collaborative innovation team to foster fresh thinking and improve overall productivity in day-to-day operations
- Helped governance and operational teams develop an innovation platform that eased and quickened the route between ideas and implementation
- Identified and deployed digital technologies that increased automation and transformed workflows, improving quality and leading to faster delivery

IMPACT

Right-sized resources. Innovative operations. And a fresh perspective.

Here’s what the company gained by partnering with Genpact:

- Scalable regulatory resources thanks to a dedicated global team of some 150 regulatory professionals, all of them cross-trained and capable of flexing to meet the client’s requirements
- Real performance insights made possible by analytics and executive-level dashboards across the processes
- Improved compliance and cycle time due to visibility of workflow and targeted continuous improvements, together with the standardization of key processes and communications
- Efficiency savings of more than 20% over a five-year period, plus more than 40 ideas implemented in the first 12 months
- Innovations in client operations aligned with Genpact Cora RegAssure – our regulatory product lifecycle management solution - including more than 10 high-impact joint innovation projects
• **Elimination of siloed processes** between submission coordinators, CMC, and publishing, enabling better control of the end to end processes

• **Automation in planning and reporting**, which resulted in a 5% productivity improvement in the renewals process in the first nine months alone

By partnering with Genpact, the company was able to embed new skills and drive behaviors that will allow it to flourish - and maintain compliance of existing products, while focusing on bringing new products to market even faster. That benefits the enterprise. It also benefits their patients.
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.

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

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