

Scaling Up for Safety

How to Gain Efficiencies without Sacrificing Quality

Challenge

Staff and manage a complete pharmacovigilance operation in a developing region in only six months — while meeting productivity, compliance and cost-saving targets.

Solution

Quintiles harnessed its pharmacovigilance experience and extensive staffing capabilities to aggressively recruit and develop a world-class workforce that can handle a high volume of cases.

Results

The customer exceeded its goals for quality, productivity and profitability, achieving a cost-per-case reduction of more than 50%. Today, this flexible, scalable operation processes nearly 100,000 cases per year.

Today, many biopharmaceutical companies are increasingly relying on outsourcing to save money, especially in countries with low labor costs. But safety operations, from clinical through post-marketing, require a higher level of expertise than many commonly outsourced functions, making it particularly challenging for biopharmaceutical companies to realize savings without putting quality and compliance at risk.

That was the challenge facing one of the world's largest pharmaceutical companies when it sought a Functional Service Provider (FSP), commissioning Quintiles to create and manage a pharmacovigilance center of excellence in India.

Challenge: Gear up Safety Center in a Developing Region in Six Months

Outsourcing pharmacovigilance is still relatively new to the industry; even more so to India. A major biopharmaceutical company's previous staffing partner, a BPO, had drastically underestimated the logistical challenge of finding qualified staff.

As such, the customer needed an ally who could integrate a center with its existing global operations in only six months and handle unexpected or sudden increases in case volumes. The right provider would bring not only the heavy-duty technical and organizational know-how required for any significant outsourcing initiative, but also a specialized understanding of pharmacovigilance requirements.

Quintiles' directive was clear: Staff and manage a pharmacovigilance center of excellence in a developing region — while meeting productivity, quality and compliance targets, and lowering the cost per case.

Solution: Accelerated Problem-Solving Informed by Expertise

The first step was to work with the customer as an ally to develop a detailed transition and project management plan. Building around a series of project milestones, Quintiles established 43 key performance indicators (KPIs) on which the project's success would be measured. Real-time monitoring using the Quintiles dashboard was set in place to help managers improve performance, along with a newly established governance structure for escalation issues and to make the entire process more efficient.

In six months, Quintiles staffed the center with fully-trained employees in a region where there were few with pharmacovigilance experience. In the two years since opening, the center has not missed a single safety or performance goal.

Subject matter experts and trainers provided oversight in specific therapeutic areas. An extensive training program using Quintiles' deep experience in pharmacovigilance ensured that new recruits had the safety-specific skills and knowledge needed to deliver the desired results for the customer.

Quintiles used its previous experience setting up a data management center for the company as a staffing model — first identifying 175 recruits despite the lack of pharmacovigilance experience among thousands of applicants.

Quintiles exceeded expectations in part because the phased recruitment plan was strategically designed to deliver the right balance of skilled veterans and teachable talent at the right time. Coupled with our deep therapeutic resources and unparalleled expertise in meeting regulatory requirements for pharmacovigilance, Quintiles also had the crucial ability to provide rapid and thorough training.

Results: Lower Costs, Increased Efficiency, Quality Operations

Quintiles met all major milestones on time and on budget, staffing the center of excellence with skilled, trained workers in only six months.

Process improvements led to higher-than-expected productivity-per-employee, allowing the center to keep staff levels at 175 employees versus the 203 the customer had originally anticipated. Even with a smaller workforce, the center proved highly productive from the start, rapidly scaling up to efficiently process 67,000 cases the first year. That number leapt to nearly 100,000 the second — 35% of all safety cases by volume for the customer.

In measures of productivity, the center did not miss a single performance goal in two years, completing 98.5% of cases in the agreed time. When it came to quality, 90% of the center's helpdesk tickets met peer review. As the customer gained confidence, it sent the center more complex cases. The center now operates as an integral part of the customer's global workflow.

The customer significantly exceeded its targets for the project, quickly expanding the number and variety of products handled in India during the relationship. Through process re-engineering, Quintiles was able to decrease the cost-per-case by more than 50% in the first year, even as volume increased.

Today this company's Bangalore-based center of excellence is able to quickly scale up or down to meet constantly changing business demands, providing a flexible, metrics-driven solution to match staffing needs and budget pressures.

Just as important, Quintiles has now established a presence in the region for accreditation and training, as well as a good management core and a succession pipeline to fuel regional development.

Big Goals, Big Results

Pharmacovigilance isn't like many other operations that are commonly outsourced. It takes a workforce with highly specialized skills and capabilities to deliver the value and reliability that pharmaceutical companies are looking for.

Here are some of the benefits we delivered for this major pharmacovigilance outsourcing initiative:

- > *Cost-per-case reduction of more than 50% in year 1*
- > *100% compliance with CAPA process*
- > *Scalable organizational design to meet rapidly changing needs*
- > *Handle 35% of all customer's safety cases by volume*
- > *Higher-than-expected productivity resulting in reduced FTE needs*
- > *Expanded number and types of products handled during the relationship*
- > *An operation with the ability to process 100,000 cases of variable complexity per year, in addition to the 30,000 medical reviews and 20,000 literature reviews to date*

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