

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 cost-savings targets.

Solution

We combined safety experience with extensive staffing capabilities to aggressively recruit and develop a world-class workforce in a matter of months.

Results

This pharma company met and exceeded their goals for profitability from the start, achieving a price-per-case reduction of more than 35%. Today, this scalable operation has already processed nearly 100,000 cases, 30,000 medical reviews and 20,000 literature reviews.

Today, many biopharmaceutical companies are increasingly relying on outsourcing to gain cost savings, 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 cost benefits 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) to create and manage a pharmacovigilance center of excellence in India.

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

The company had already engaged a leading global consulting firm to establish and manage the center, but when it became clear that the firm had underestimated the staffing and process components required for the initiative to succeed, the pharma company turned to Quintiles.

The company needed an ally that could rapidly staff the center of excellence and establish the capacity to scale appropriately as its needs changed — all while generating significant cost savings. 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.

Solution: Accelerated Problem-Solving Informed by Expertise

Good planning, common goals and transparency were key to the project's success. Our first step was to work closely with the customer to develop a detailed transition and project management plan. Building around a series of project milestones, we designed a plan to meet 41 key performance indicators (KPIs) on which the project's success would be judged. We established a clear governance structure with an issue escalation process to maximize efficiency. We brought in subject matter experts to support every team, even providing oversight in specific therapeutic areas.

The first six months were critical — that was the amount of time we had to staff the center with qualified, fully trained employees in a region where there were few with pharmacovigilance experience. We executed a phased recruitment plan designed to deliver the right balance of skilled veterans and teachable talent at the right time.

For this project, our established presence in India was also a key factor contributing to the project's success. We had already set up a separate data management center of excellence for the company and were able to use it as a model.

When it comes to staffing specialized operations, it's important to bring the right knowledge and experience from the start — in order to anticipate and efficiently address problems that can arise.

The first six months of this project were critical — that was the amount of time we had to staff the center with qualified, fully trained employees in a region where there were few with pharmacovigilance experience. Quintiles executed a phased recruitment plan designed to deliver the right balance of skilled veterans and teachable talent at the right time. We focused on hospital employees to find candidates with comparable skill sets, who could be trained for the specifics of the job. By the end of the entire recruitment process, we had screened 3,600 applicants and narrowed the list down to 175 new recruits.

To ensure that new recruits had the safety-specific skills and knowledge needed to deliver the desired results for the customer, we built an extensive training program using our deep experience in pharmacovigilance. A global learning management system gave the team access to classes taught by Quintiles experts in pharmacovigilance. The tailored curriculum also delivered key knowledge on systems and specific therapeutic areas.

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. With our process improvements, we achieved higher than expected productivity-per-employee, allowing us to keep staff levels at 175 employees versus the 203 the customer had originally anticipated.

As a result, our customer is significantly exceeding its targets for the project. For instance, through process re-engineering and labor arbitrage, Quintiles was able to achieve a price-per-case decrease for the customer of more than 35% in only six months, even as volume doubled in that time. To date, the center has processed nearly 100,000 cases, 30,000 medical reviews and 20,000 literature reviews.

Just as important, today this company's Bangalore-based center of excellence is able to quickly scale to meet constantly changing business demands, providing a flexible and efficient solution to match their needs and budget pressures as they evolve.

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:

- > *Price-per-case reduction of more than 35%*
- > *Scalable organization design to meet rapidly changing needs*
- > *Higher-than-expected productivity resulting in reduced FTE needs*
- > *An operation that has processed nearly 100,000 cases, 30,000 medical reviews and 20,000 literature reviews to date*

Contact Us:

In the US: +1 877 988 2100

In Europe: +44 (0) 1344 708000

In other areas: +1 919 998 2000

On the web: www.quintiles.com/safety

Email: safety@quintiles.com

