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ASIA EDITION

Pharmacovigilance: A strategic opportunity

06 September 2012 | Opinion | By BioSpectrum Bureau

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Guest Column

Ms Siew-Ping Goh, senior regional director and site head of lifecycle safety for Quintiles in Asia Pacific, leads more than 120 safety specialists across Singapore, Japan, India and China.

For many Asian pharmaceutical companies, pharmacovigilance is a critical component of any drug development program. As product safety continues to receive a high level of emphasis from regulators, developers and the public alike, the need to effectively meet regulatory requirements, manage risk and process safety reports remains a key point in pharmaceutical development in Asia.

However, a number of conflicting trends have emerged regarding pharmacovigilance strategy and operations among Asian firms in the recent years. Regulatory bodies across the region are intensifying safety regulations even as they are working to reduce approval times and accommodate the explosion of activities in the region.

As a result, companies are receiving a growing numbers of safety reports despite a trend towards decreasing staff in their pharmacovigilance operations. At the same time, many companies opt to retain in-house pharmacovigilance staff, while a

wide range of other pharmaceutical operations are increasingly becoming candidates for outsourcing and off-shoring. Together, these and other trends result in increased costs and slower processing times of pharmacovigilance operations.

Much like their counterparts in other parts of the world, many Asian pharmaceutical executives view pharmacovigilance primarily through the lens of cost, even as they recognize the value of carefully managing a product's safety profile. This perspective leaves companies struggling to achieve a balance between high productivity, short cycle-times and high quality.

For other components of the development process, the solution may well be found in outsourcing. Yet, due to the critical nature of analyzing and processing safety data, many companies are reluctant to turn to outsourcing as a solution.

The need for balance

To meet the requirements of a demanding and changing regulatory and development landscape, Asian pharmaceutical firms must view pharmacovigilance operations as more of a strategic opportunity and less of a mandated cost center. To accomplish this transition and effectively position themselves for the future, developers must identify a pathway that addresses both quality and productivity, while also minimizing risk, adapting to fluctuations in demand and creating strategic value by carefully managing the safety profile of products.

Of course, the challenges inherent in strategically positioning pharmacovigilance to create value are many. For one, language barriers and complex regulatory environments make Asia one of the most challenging markets for developers to achieve regulatory compliance. Within such a complex environment, managing data collection processes involving multiple non-clinical sites with non-physician medical reviewers proving to be a significant logistical and data collection challenge.

Further, lesser rates of electronic data capture and computer-based analysis than elsewhere around the globe force many companies to choose between devoting scarce resources away from strategic interactions with health authorities and developing innovative treatments and more towards day-to-day document and data management.

Perhaps most important need for Asian developers is to ensure the highest levels of quality around drug safety reporting and risk management, to both meet regulatory guidelines and to effectively shepherd drug development and commercialization. For example, many companies struggle with the ongoing potential for high levels of non-compliance risk from increasing numbers of case reports and changes in regulatory requirements. Developing timely and effective medical assessments, signal detection, medical review, case monitoring and other vital processes and analysis are critical components of successful pharmacovigilance.

As firms face the danger of non-compliance and can even place the status of their development and commercialization efforts in jeopardy from late or incorrect regulatory filings, many developers choose to place strict controls on all pharmacovigilance operations and mandate in-house capabilities whenever possible.

A mandate for quality

Yet, within the overall landscape of regulatory changes, clinical trial management and technology solutions, opportunities to develop more strategic pharmacovigilance processes exist. Today, many multinational pharma companies have developed partnerships with clinical research organizations (CROs) within Asia to help develop and manage pharmacovigilance operations and strategies.

Further, the use of both outsourcing and offshoring across a wide range of clinical trial activities beyond pharmacovigilance has grown considerably in recent years for both domestic and global developers. More promisingly, hurdles to processing documents and data across language barriers are falling, as an increasingly talented workforce and advanced expertise are being developed at a rapid pace across Asia.

For firms that place a premium on both quality and productivity, finding a CRO to serve as a strategic partner can be difficult. For many developers, the bulk of work currently being outsourced to outside providers is centered primarily or exclusively around lower-level data entry and site management tasks. For maximum success, however, a pharmacovigilance services provider must be able to successfully manage complex data collection processes inherent in large studies involving multiple non-clinical sites, possess a deep understanding of regional regulatory requirements and offer the highest possible levels of data management quality and language capabilities.

Further, service providers must be able to ramp up resources quickly to accommodate a developer's work flow needs, be able to demonstrate productivity and efficiency gains on a year-over-year basis and provide a transparent platform that allows

insight and control as needed to all phases of pharmacovigilance operations.

Opportunity for strategic value

In order to truly become a strategic partner with pharmaceutical developers in turning pharmacovigilance operations and processes from a cost center to a strategic advantage, a CRO must first and foremost be able to ensure that quality and compliance don't suffer as a result of transferring of pharmacovigilance work away from a developer's in-house staff.

Recently, Quintiles launched a Center of Excellence in Dalian, China, to drive productivity, lower costs for pharmacovigilance and back office support for pharmaceutical firms in Asian geographies. With a highly trained staff and wide range of expertise in case processing and handling, the Dalian location can lower pharmacovigilance costs by as much as half.

Quintiles stands uniquely qualified to provide Asian firms the support and cost savings they need to move pharmacovigilance processes from regulatory mandate to strategic advantage. Designed to work with the highest quality standards, the Dalian center builds on Quintiles' experience in project management, quality assurance and clinical trial experience, along with a management and technical staff who have built credibility with investigators and regulatory authorities across the region.

For firms able to identify the right partnership, the opportunity exists to help differentiate their products from the competition by increasing its value through lower costs and streamlined development processes. In fully capturing a product's safety profile without committing a wealth of resources or diverting focus from other critical processes, pharmaceutical firms across Asia can transform their pharmacovigilance efforts from a costly, mandated process to a strategic asset that creates value and helps deliver innovative products to patients with fewer hurdles, higher quality and increased safety.

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