Integrated Drug Safety Business and Technology Solution Delivers Operational Efficiency to a Leading Global Generic Pharma Company

Client

A leading generic and branded specialty pharmaceutical medicines company with more than 200 global prescriptions drug product applications needed to rethink their safety technology and operations strategy and practices

Client Situation

The client had its pharmacovigilance operations split between two separate service providers. One provider supported their case processing activities, database hosting and aggregate reporting requirements, while the other managed their medical information and contact center operations. The complex and inefficient nature of the arrangement led the client to rethink their need for a more seamless and integrated approach.

Some of the major challenges the company faced when developing their path forward included:

1. Growth and Future of Database Solution: The client’s service provider was using a validated but home grown application to store their safety data. While the solution worked adequately for their short-term objectives it did not support their long-term vision. They needed to find a future proof, robust and scalable solution that would serve them well in the ever changing global safety environment.

2. Robust Electronic Submission Capability: At the time, the client’s application provided electronic submission but not ‘database to database’ submission. They needed to make this
Process more efficient both in terms of time and effort to do the submission. This required a partner who could enable direct electronic submission to the FDA or regulators database i.e. the provision for a true ‘database-to-database’ submission to the FDA (AS2 submissions).

3. Integrated Service and Technology Solution: The fragmented nature of the vendor’s engagement model was leading to operational inefficiencies, cost escalations and loss of valuable time. The client needed a single vendor end-to-end solution that would meet all of their needs as opposed to managing two separate service providers.

4. Cost and Time Efficiencies: The price and time required to manage multiple service providers was cost and time prohibitive so the client had to take into consideration the inherent efficiencies that a single vendor could provide.

Solution and Differentiators

The direct consequence of the disparate vendor arrangements prompted the client to consider another vendor who could seamlessly implement and manage an end-to-end solution. Sciformix was among a handful of service providers with an Argus hosting solution as well as the capability for electronic AS2 submissions to the FDA. Incidentally, Sciformix had already planned to move to the latest version of Argus while other vendors and pharma companies continued to work with the older version. This proactive strategy resonated well with the client and supported their need for scalability.

In terms of an end-to-end safety solution, Sciformix’s capabilities included the expertise of medical information, a contact center, case processing, aggregate reporting, signal management and risk management. This was apparent during the client’s due diligence when reviewing Sciformix’s processes, pharmacovigilance capabilities, panel discussions and mock calls. The client was extremely satisfied with the level of knowledge and subject matter expertise that the Sciformix staff displayed. The off-shore model was also cost-effective, alleviating the need for on-site IT related infrastructure and headcount costs. Implementation and transition from the previous database was successful due to Sciformix’s detailed and rigorous project planning and program management, and focus on quality and process monitoring.

For life science companies, the highly regulated nature of their business warrants the need to continuously look at opportunities to improve their technology capabilities, processes and cost effectiveness. Sitting idle is not an option especially when meeting submission deadlines is critical. Being forward thinking and looking to create a scalable environment are key business imperatives.

Since the partnership was forged in 2009, the client has been compliant with global regulatory requirements. Their safety database has also been transitioned to the Sciformix Safety Cloud, using Argus and the team is proactively working on R3 recommendations and implementations.
Achievements and Benefits

Achievements:

- Within 6 months of the engagement, established AS2 submission gateway with FDA
- 99.90% regulatory compliance for past 6 years, with current compliance at 99.98%
- 99% quality metric for critical fields for past 6 years
- 99% database and application up-time year over year
- 100% compliance with timelines for all dictionary upgrades, patch implementations and service desk availability as per SLAs
- 99% TAT compliance for service desk tickets as per SLAs
- 24 hours TAT for MIS listings and database reports and 48 hour TAT for customized line listings

- Support all regulatory inspections in real time with no critical findings from any agencies

Client Benefits:

- Scalable, in-house, cloud based safety database
- Cost savings via a single vendor strategy
- Operational cost advantage employing an off-shore model and ongoing process improvement initiatives
- Future proof technology infrastructure by transitioning to the Sciformix Safety Cloud, using Argus and working on R3 recommendations