

Pharmacovigilance System (PV) Post Merger Integration

A top 10 pharmaceutical company acquired a global biotech company and needed to integrate the two PV systems while ensuring business continuity and maintaining patient safety standards throughout the integration.

Challenge

In order to fully integrate the two PV systems and meet required timelines, the following key items were assessed and an appropriate integration plan was created and executed.

- All safety information handling activities within 21 affiliate offices required transfer to acquirer
- Two global safety databases were used and maintained in parallel while preparations for seamless integration were developed
- Individual case safety report backlog was inventoried and processed in parallel to integration planning activities
- Legacy company safety data sources, including 55 market research / patient support programs were identified and catalogued, transitioned, and remediated
- All legacy company inspection CAPA required review, action, and closure with sufficient documentation to support post-integration inspection readiness

Collaborative Approach

SSI Strategy partnered with the client R&D integration team and PV leaders to develop and execute a detailed plan that incorporated all facets of the PV system in addition to impacted functions outside of PV. The integration was successfully completed ahead of schedule with the following steps being taken:

- ✓ Performed comprehensive risk assessment and implemented successful mitigation plans
- ✓ Created a governance structure that included an escalation and approval process
- ✓ Assessed both PV systems and identified 7 key work streams requiring strong project management as well as representation from both companies
- ✓ Determined key milestones and ensured on time submission of all regulatory filings
- ✓ Created an effective plan for CAPA review, action, closure, and documentation
- ✓ Collaborated with the overarching integration team to identify key interdependencies, ensure clear lines of communication and minimize risk
- ✓ Developed a PV integration “toolkit” to ensure the use of best practices and assist in future integrations

Impact

The project resulted in the successful completion of the integration of the acquired PV system into the acquirer’s existing system. The activities were completed on time and without any incidences of discontinuity or compliance gaps. Post integration, the client is fully prepared from an inspection readiness standpoint regarding the integration and is assured that all integrated data and processes align with the parent company’s compliance standards.

Looking to the future, our client has an enhanced understanding of the contribution that early planning and incorporation of risk management principles has in ensuring the success of critical safety projects.

About SSI Strategy

SSI Strategy is a boutique management consultancy focused on Pharmacovigilance and Medical Affairs. We combine business acumen and consulting discipline to develop solutions for life science companies.

Contact:

Dr. Greg Fiore - President
Greg.fiore@ssistrategy.com
212.691.2000