SYNTEL
Consider IT Done®

Syntel's Factory Based Operational Model for Pharmacovigilance

Global Health Regulatory Agencies mandate all Pharmaceutical and Modern Drug Discovery companies to collect, process, and report adverse events. Organizations failing to achieve 100% compliance may face penalties or face drug withdrawal from the market.

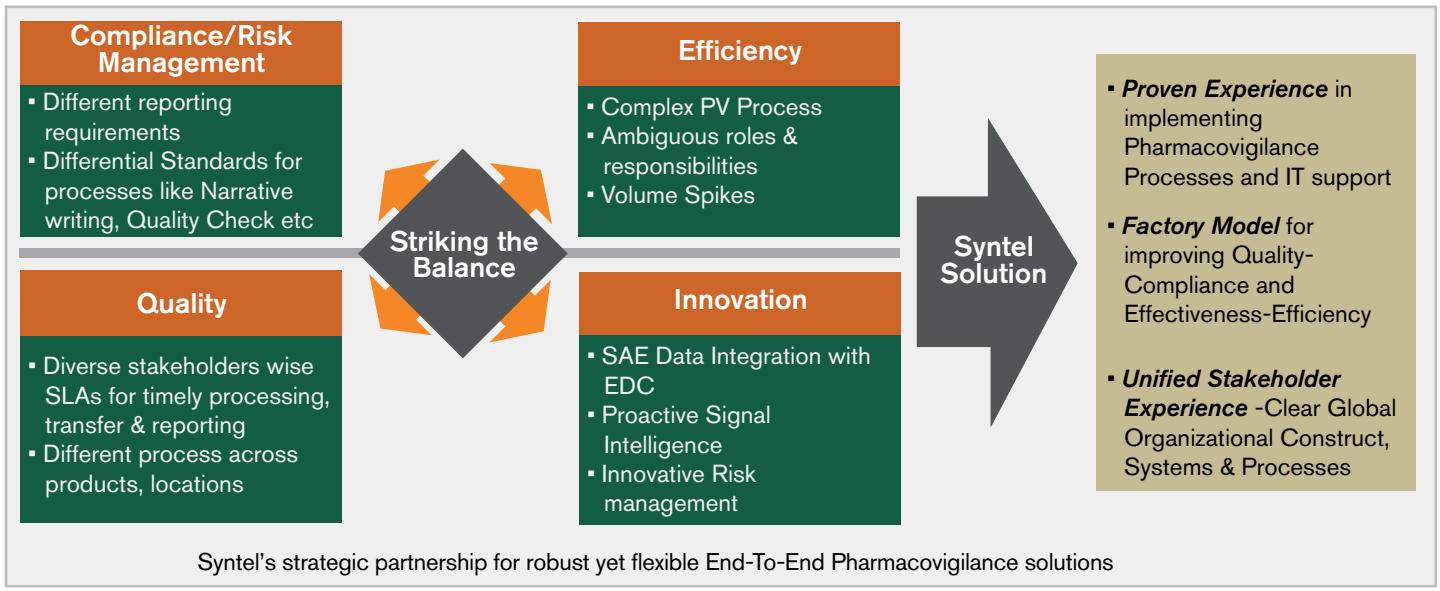
In the quest to discover and launch novel drug molecules and delivery systems, Pharmaceutical companies face a trade-off between Efficiency, Quality, Compliance, and Innovation. Resources with robust domain knowledge are not readily available. If internally sourced, the cost of maintaining niche resources & infrastructure is very high. Processing Adverse Event (AE) data adds to the cost pressure as case volume is variable and fluctuates as per various factors like age group, medical history, seasonal change etc.

WHY SYNTEL?

- A leading global IT and KPO service provider
- Established in 1980 (NASDAQ: SYNT)
- More than 24 offices in North America, Europe, and Asia
- Flexible onsite-offshore global delivery model
- Dedicated Centers of Excellence to help clients with expert advice and project guidance

Syntel's Solution

Syntel's Factory Based Operational Model for Pharmacovigilance enables organization to strike a balance between quality, effectiveness, compliance and efficiency. Syntel deploys a team of specialists handling distinct activities and following an assembly line. The Factory model offers high clarity on the task for each team member enabling a focused approach on the activity. This decreases turn-around time while achieving 100% regulatory compliance.



Syntel's strategic partnership for robust yet flexible End-To-End Pharmacovigilance solutions

Syntel offers a wide spectrum of IT and KPO support functions for Pharmacovigilance services. Syntel's services include 24x7 Support for crucial activities like Regulatory Submission to achieve 100% Regulatory Compliance for AE & Periodic reports. Syntel's teams have Multi-geographical presence thus enabling ready availability of robust domain knowledge resources.

KEY DIFFERENTIATORS

- **Unique Factory Based Operational Model** for striking balance between efficiency, compliance, quality & effectiveness
- **Experienced resources and ready infrastructure**
- **Diverse KPO Experience** in ICSR processing received from various sources viz. spontaneous, clinical trial, literature, solicited, social media etc. for drugs, OTCs & medical devices
- **Robust Experience on Safety Database** (Argus, AERS, ARISg) support: Implementation, data migration, customized solutions
- **Expert support on Regulatory submissions**
- **Business Excellence team** (LEAN, six sigma) for continuous PV process improvement
- **Audit Ready Pharmacovigilance Service platform** supported MHRA and FDA audits
- Healthy partnership with **a long-term value driven approach** to Pharmacovigilance

Business Benefits

- Efficient & hassle free PV Operations
- 100% Regulatory Compliance for AE & Periodic reports
- Reduced TAT of PV operations by 30-40%
- Decrease in TAT for Case Processing cycle (1 day for reportable Cases, 3 days for non-reportable cases)
- 20-30% reduction in cost of PV Operations
- Streamlined process leading to optimum productivity per associate
- Innovative tools like Report Submission Management Tool, PSUR Line Listing Generation & Workflow Tool etc. leading to 20% cost savings
- Customizable and Re-usable methodology for any of the Pharmacovigilance services.
- Lesser dependence on in-house specialists

Delivering excellence in Pharmacovigilance Service Area

Client

One of the top 20 global Bio-Pharmaceutical Organizations based out of Japan

Challenges

- Managing end-to-end AE reports received from USA, Japan & Europe
- Managing 40,000 cases yearly with operational efficiency and Japanese language support
- Migrating legacy PV data

Syntel's Solution

- A team of 20 skilled HCPs deployed ramped up to 35+ FTEs in less than 3 months
- A dedicated team for managing migration of legacy AE data
- The unique operational Factory Model for E2E global case Management (case routing)
- One Team approach for standardization of PV activities across geographies while catering to specific local regulatory requirements
- Provide 24 x 7 Global Support for PV activities

Business Benefits

- Reduce effort by 20% through operational efficiency
- Developed client specific process training with 15% reduction in process sign-off time
- Efficient migration of 50,000 legacy cases
- Resource optimization leading to 20% effort reduction
- Successful regulatory audits

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For more information, visit Syntel online at **www.syntelinc.com**
or call us at **US/+1 (248) 619-3503, UK/+44 (0) 207-636-3587**