

Drug Safety and Pharmacovigilance case processing



Customer

One of the world's largest pharmaceutical companies. The company sells its products in more than 130 countries.

Business Challenge

- The customer was looking to consolidate operations, improve productivity and gain cost and process efficiencies
- This included outsourcing of three distinct services: Full assessment of non-serious adverse event (AE) reports; serious and non-serious litigation adverse event processing and data entry
- All processing and reporting was done using ARISg
- A secondary driver was to continue regulatory compliance with increased product pipeline

Mahindra Satyam's Solution

- Mahindra Satyam BPO established an offshore delivery platform customized to the customer's needs.
- Process and knowledge transition was successfully executed by Mahindra Satyam transition team within eight weeks.
- The application was scaled up and went live with AE Product litigation case processing, supporting more than the 9000 AE case volumes/year

Benefits

- Mahindra Satyam BPO delivering services consistent with internal service levels prior to outsourcing
- Currently processing ~1000 cases per month. Volume expected to ramp up to 1500 cases per month
- Quality is currently maintained at 99.8% with 100% TAT
- Developed quality verification plan and sheet for cases processed in addition to training plan and SOPs

Offshore operations currently consist of 21 healthcare professionals, team leads and managers.

At Mahindra Satyam BPO's Life Sciences practice, we offer high end, value added services like Research & Development, Manufacturing and Sales & Marketing.

R&D: CDM, Clinical Trial Site Setup, Safety Narrative Writing, Medical Writing, AE Management, Regulatory Filings, Litigation Case Processing.

Manufacturing: Material Management, Manufacturing Ops Support, Engineering Services, Supply Chain Management, Packaging Services, Distribution, Logistics

Sales & Marketing: Promotional Artwork, 2D & 3D Animation, Visualization, Medical Affairs Support, Sales Force Support, Content & Portal Management, eLearning

For further information please write to Connect@mahindrasatyambpo.com and rfi@mahindrasatyam.com.