

Safety Narrative Writing for PSURs and NDAs



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
- The primary challenge was Safety Narrative Writing for PSURs & NDAs
- All processing and reporting was done using ARISg
- A secondary driver was to improve turnaround times. 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 Safety Narrative Writing, supporting more than the 1500 narratives volumes/year

Process Improvements

- Accuracy of Narratives and QC are maintained at 100%
- Prepared safety narrative writing, quality check, training SOPs and delivery plan
- Created a training plan and quality check sheet based on initial training experience

Benefits

- Currently delivering more than 75 narratives/ week while the actual SLA is 25 drafted narratives/week
- 95% of narratives were delivered within 24 hours (minimum time taken was 2 hours for 1 pack) and the remaining 5% within 48 hours of receipt

Delivered more than 1500 drafted narratives and 2000 QC narratives last year.

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

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