

## Aslam Lukde

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### Professional Summary

Senior Pharmacovigilance professional with 10+ years of experience across ICSR processing, regulatory compliance, audit readiness, and team leadership. Strong exposure to SQL- and Python-based analytics for PV workflow checks, quality reporting, adverse event summaries, and performance analytics. Adept at translating PV domain knowledge into data-driven insights.

### Core Skills

Pharmacovigilance: ICSR Processing, Adverse Events, SAE, MedDRA Coding, E2B, Literature Screening, Signal Detection (Supportive Analytics), PSUR, RMP, CAPA, RCA, EMA/FDA, ICH-GCP, QC, QA

Tools: Argus Safety, SQL Server, Microsoft Excel

Data & Analytics: SQL, Python (Pandas, NumPy), Data Validation, AE Summaries, KPI Reporting, Matplotlib, Seaborn

### Professional Experience

#### Team Manager – Pharmacovigilance | MedVigil Clinical Research

Oct 2017 – Sep 2024 | Mumbai, India

- Led end-to-end ICSR operations for EU and US markets
- Managed and mentored a team of 25+ PV professionals
- Developed Python-based scripts (demonstrated) for workflow checks, quality summaries, AE summaries, and employee utilization charts
- Built KPI and management reports using SQL and Excel
- Achieved zero major audit findings (EMA, HPRA)

#### Drug Safety Specialist | Cognizant Technology Solutions

May 2014 – Oct 2017 | Mumbai, India

- Processed ICSR from clinical trials, spontaneous and literature sources
- Performed MedDRA coding and narrative writing
- Conducted quality reviews and supported workflow improvements

### Education

Bachelor of Pharmacy (B.Pharm), 2012