Aslam Lukde

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Professional Summary

Senior Pharmacovigilance professional with 10+ years of experience in ICSR processing, regulatory compliance, audit readiness, and team leadership. Strong hands-on exposure to Python- and SQL-based analytics for pharmacovigilance workflow checks, adverse event summaries, quality metrics, and operational dashboards. Proficient in applying descriptive statistics, data visualization, and exploratory analysis to support PV decision-making. Highly motivated self-learner with the ability to invest focused effort to deliver data-driven results.

Core Skills

Pharmacovigilance & Regulatory:

ICSR Processing, Adverse Events (AE/SAE), MedDRA Coding, E2B Reporting, Literature Screening, PSUR, RMP, CAPA, RCA, Audit Readiness, QC/QA, EMA, FDA, ICH-GCP

Tools & Systems:

Argus Safety, SQL Server, Microsoft Excel

Data Analytics & Programming:

Python (Pandas, NumPy), Statistical Analysis (Descriptive statistics, trend analysis, basic regression models), Data Visualization (Matplotlib, Plotly), Web Scraping (Python), HTML, Website Development(Flask), Bootstrap, SQL (Data querying, aggregation, validation)

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 ensuring EMA and FDA compliance
- Managed and mentored a team of 25+ pharmacovigilance professionals
- Developed Python-based analytics scripts for workflow checks, AE summaries, KPI dashboards, and quality metrics
- Applied Pandas and NumPy for data cleaning, validation, and descriptive analysis of PV datasets
- Built management-ready visualizations using Matplotlib and Plotly
- Applied basic statistical and regression techniques for exploratory and trend analysis
- Leveraged SQL for querying large safety datasets and operational reporting
- Achieved zero major findings in EMA and HPRA regulatory audits

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

Data Science & Python Expertise

Python for Data Science & Exploratory Analysis
Hands-on experience using Python (Pandas, NumPy) for data cleaning, validation, transformation, and exploratory data analysis on large healthcare and pharmacovigilance datasets. Proficient in deriving descriptive statistics, identifying patterns, detecting anomalies, and performing feature-level analysis to support evidence-based insights. Strong focus on reproducible, transparent, and interpretable analysis rather than black-box modeling.

Data Visualization & Pattern Interpretation
Experienced in translating complex datasets into interpretable visual insights using Matplotlib and Plotly. Skilled in feature importance analysis, distribution-based comparisons, and symptom–outcome association mapping to evaluate model behavior and data structure. Emphasis on visualization-led validation, stability analysis, and alignment of data-driven patterns with established clinical knowledge.

FDA Signal Detection & Pharmacovigilance Analytics
Applied Python- and SQL-based analytics to support FDA-oriented pharmacovigilance activities, including adverse event aggregation, trend monitoring, and exploratory signal detection. Experienced in preparing structured safety summaries, identifying symptom–event associations, and supporting signal review through descriptive statistics and visual analysis. Strong understanding of the role of data analytics in regulatory-compliant signal evaluation rather than automated clinical decision-making.