ASLAM LUKDE

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PROFESSIONAL SUMMARY

Senior Pharmacovigilance Professional with 10+ years of experience in ICSR processing, safety data management, regulatory compliance (EMA/FDA), and team leadership. Expertise in Argus Safety, MedDRA, SQL-based analytics, and process optimization. Proven ability in audit readiness, training, and operational excellence.

CORE COMPETENCIES

- Pharmacovigilance: ICSR Processing, Adverse Event Reporting, Regulatory Submissions (EMA/FDA), Literature Screening
- Tools & Standards: Argus Safety, MedDRA, E2B, ICH-GCP
- Data & Analytics: SQL, SQL Server, Data Warehousing, Python (Pandas, NumPy)
- Visualization & Tech: Matplotlib, Plotly, Flask, HTML, Bootstrap
- Leadership: Team Management, KPI Reporting, Audit Readiness, Training & Mentorship

PROFESSIONAL EXPERIENCE

Team Manager | MedVigil Clinical Research | Mumbai | Oct 2017 – Sep 2024

- Led a team of 25+ pharmacovigilance professionals managing end-to-end ICSR processing
- Organize, manage and maintain a highly compliant Pharmacovigilance (PV) system
- Ensure PV business continuity and after hours availability
- Lead and coordinate internal and external PV audits and inspections
- Ensure internal regulatory/PV processes and procedures are well documented and support compliant regulatory/PV activities
- Reduced case turnaround time by 25% through workflow optimization
- Achieved zero major findings in EMA and HPRA audits
- Developed SOPs, training manuals, and quality dashboards
- Coordinated cross-functional activities with QA, medical, and IT teams

Drug Safety Specialist | Cognizant Technology Solutions | Mumbai | May 2014 – Oct 2017

- Processed and reviewed ICSRs in compliance with global regulatory requirements
- Conducted quality checks and ensured data accuracy in Argus Safety
- Performed MedDRA coding and quality reviews
- Collaborated with medical reviewers for case assessments and follow-ups
- Generated periodic safety reports and supported regulatory submissions
- Mentored new hires and supported international teams

Business Manager | Prudence Healthcare Pvt. Ltd | Mumbai | Nov 2013 – Mar 2014

- Oversaw sales operations and team performance in the pharmaceutical division
- Developed and managed pharmaceutical sales strategies and CME activities

Nutrition Executive | Vintage Biological Pvt. Ltd | Mumbai | Oct 2012 – Mar 2013

- Managed key accounts and sales for clinical nutrition products
- Conducted market research and competitor analysis

- Organized training sessions for healthcare professionals
- Promoted clinical nutrition products to healthcare professionals

CERTIFICATIONS & PROJECTS

SQL for Data Analysis & Warehousing (Udemy)

SQL Skills & Achievements

- Proficient in writing complex SQL queries for data extraction, transformation, and reporting
- Experience in building and optimizing SQL Data Warehouses for large datasets
- Skilled in ETL processes and data pipeline development
- Conducted Exploratory Data Analysis (EDA) using SQL on real-world datasets

Key Projects

SQL Data Extraction & Reporting:

- Developed complex SQL queries for data extraction, transformation, and reporting
- Built an enterprise-level SQL Data Warehouse, optimizing ETL processes
- Conducted Exploratory Data Analysis (EDA) on real-world datasets for actionable insights

Data Science & Python Expertise

- Data Cleaning & EDA: 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 with an emphasis on reproducible and interpretable analytics.

- Data Visualization & Pattern Interpretation: Experienced in translating complex datasets into interpretable visual insights using Matplotlib and Plotly. Skilled in distribution analysis, pattern comparison, and symptom–outcome association mapping to validate data behavior and clinical relevance.

- 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 structured safety summaries and regulatory-aligned signal evaluation using descriptive statistics and visualization.

EDUCATION

Bachelor of Pharmacy – 2012