**MEERA MENON L**

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## OBJECTIVE

Highly motivated and detail-oriented Drug Safety Executive with 4.4 years of experience in case processing, seeking to leverage expertise in Pharmacovigilance and Regulatory activities to contribute to the success of a leading pharmaceutical service provider. I aim to expand my knowledge, work collaboratively in a team, and bring innovation to benefit the organization.

## CORE COMPETENCIES

- Pharmacovigilance activity: Proficient in Individual Case Safety Report (ICSR) management,case triage, processing, narrative reporting requirements and tracking of safety information.
- Monitor, assess and report adverse drug reaction other safety information from various sources such as Clinical trial, post marketing surveillance etc and performing literature screening for ICSR.
- Regulatory Safety Reporting Activities: Familiarity with different scientific committees in EU, varioustypes of Marketing Authorization in EU and US, safety label updates, referral procedures in EU, and different types of safety labels.
- Aggregate Reporting: Basic knowledge of PSUR/PBRER, PADER, and DSUR.

## ACADEMIC DETAILS

- B. Pharm, St. Joseph College of Pharmacy (2015-2019)

## PROFESSIONAL EXPERIENCE

**PV Scientist II Mentor, Tata Consultancy Service (Feb/2022-Present)**

- Mentors junior team members to enhance their proficiency and ensure compliance.
- Provide guidance, advice and support to the Mentees and assist them to achieve the expected goals and objective.
- Commits to meeting with mentees on regular basis, teaching convention related to the project and review the ICSRs and providing feedbacks.
- Provide encouragement and assist the mentee in identifying professional development.
- Maintaining proper data of mentoring and discussing weekly.

**PV Scientist I, Tata Consultancy Service (Nov/2021-Feb/2022)**

- Performs day-to-day PV activities, assists in ICSR processing according to standard operating procedures and project safety plan as required.
- Perform Pharmacovigilance activities such as data entry, coding and assessment of adverse events, case review, follow-up, tracking of reports, and regulatory reporting activities.
- Intake of cases from investigative sites, triages and evaluate ICSR data to establish an accurate clinical assessment of the case and process information on reported adverse drug and device experiences, including accurate data entry in the safety database with minimal supervision.
- Regulatory reporting of cases from different sources including Clinical study, post marketing surveillance, non-interventional study and spontaneous report (e.g. MedWatch, CIOMS I).
- Collection of Adverse Events (AEs) from all sources, tracking of cases through case processing activities, and coordinating workflow activities to promote accurate reporting and efficient time management.
- Independently draw up a draft narrative based on the description of the case provided by the reporter using the standard narrative construction guide; use the basic grammar rules to improve the content of the narrative. To determine what information should be included in the narrative and to provide a concise description of the event's character and course, apply judgment.
- Identification and management of duplicate ICSRs to ensure data accuracy and completeness.
- Enter data into Safety databases (Knowledge in Arisg, LSMV).
- Perform quality review of ICSRs to uphold stringent standards.
- Expertise in processing clinical cases with SUSARs.
- Identifies information to be queried and follows up until information is obtained.
- Review for safety drug coding, maintenance of drug dictionary, MedDRA coding as required.
- Possess specialized knowledge in handling device-related cases, FDA Malfunction cases and pregnancy cases, ensuring comprehensive and compliant reporting.
- Perform SAE reconciliation of clinical cases to identify any discrepancy and take necessary action.

**Drug Safety Associate, Wissen InfoTech Pvt Ltd (IQVIA RDS Pvt Ltd) (Feb/2021-Nov/2021)**

- Handled ICSR Case Processing of Astrazeneca COVID-19 VACCINE (AZD1222 Project).
- Performed Drug Safety data management processes such as Case intake, Case Entry, Duplicate Search, evaluate ICSR data for completeness, Regulatory submission, Listedness Assessments for AEs, MedDRA coding, WHO coding, Causality assessment and Narrative writing, reporting requirements and case follow-up according to applicable regulations, SOPs, and project-specific safety plans.
- Verification, analysis and preparation of reports on various adverse drug reactions. Review of source documents. Checking cases on the safety database for accuracy in key fields and making amendments if necessary.

- Hands-on experience in Sapphire and Argus Database.
- Also served as Subject Matter Expert (SME) on Pharmacovigilance Workflow-Data Entry under which performed various SME activities such as quality control check of processed ICSRs reports and providing feedback on errors to the teammates; Handling query mails to Log team, conducting Reiteration sessions for the team, CAPA Implementation.
- Independently assess expectedness, seriousness and causality in accordance with regulatory guidelines and product reference safety information.

**Production Executive, Capsulation & Pharmaceutical Pvt Ltd (Dec/2019-Jan/2021)**

- Oversaw all aspects of production operations, including planning, scheduling, and execution to ensure timely and efficient manufacturing processes.
- Managed the procurement and dispensing of raw materials required for production, ensuring adequate inventory levels and adherence to quality standards.
- Enforced adherence to Standard Operating Procedures (SOPs) to maintain consistency, quality, and regulatory compliance throughout the production process.
- Batch Manufacturing Record Documentation: Documented batch manufacturing records meticulously, recording all relevant data and ensuring accuracy and completeness for regulatory purposes.
- Supervised blistering and packing activities to ensure proper handling, labeling, and packaging of pharmaceutical products in compliance with regulatory requirements and industry standards.

## SKILLS

- Pharmacovigilance
- Clinical Research
- Regulatory Activities
- Aggregate Reporting

## LANGUAGES KNOWN

English, Hindi, Tamil, Malayalam