Purushottam Gaykwad

Senior Drug Safety Associate

JOB OBJECTIVE

Targeting opportunities as a proactive healthcare expert, leveraging over 8 years of extensive experience in multiple pharmacovigilance areas such as Aggregate reports, Signal detection, Case processing of E2B & non E2B, training management and maintaining client relationships

CONTACT

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EDUCATION

- B.Pharma - Pharmacy, Sudhakar Rao Naik Institute of Pharmacy, Pusad, 2015

CORE COMPETENCIES

- Drafting of aggregate reports (PBRER)
- Identification of risk
- Development of search strategy
- Signal detection and validation
- Case processing of E2B & non E2B (Literature, Spontaneous, Clinical Trials)
- Literature search and review
- Maintaining client relationships
- Training management
- Argus Safety Database, Saphire Database
- Proficient with Microsoft Office Suite (Outlook, Word, Excel).

TECHNICAL SKILLS

- Integrated analyses of safety data in support of aggregate reports (e.g. Aggregate reports PSURs/PBRERs).
- Strong verbal, written and interpersonal communication skills.

PROFILE SUMMARY

- Accumulated nearly 9 years of comprehensive experience in the pharmacovigilance domain, have mastered multiple such as Aggregate reports, Signal detection, Case processing of E2B & non E2B, training management and maintaining client relationships.
- Analyzes, reviews, and interprets safety data, both non-clinical and clinical and any other relevant sources
- Authoring and review of Aggregate reports (PSURs/PBRERs) for submission to local and other Health Authorities`
- Performing literature search and presentation of relevant articles for the aggregate reports.
- Management and reconciliation of relevant process trackers
- Exposure in handling regulatory agency/ Pharmacovigilance Risk Assessment Committee (PRAC) inquiries.
- Providing reliable support for high priority Ad-hoc activities
- Interacting with appropriate client personnel to resolve issues related to the Aggregate reports as per clients' policies
- Ensuring that deliverables to the clients comply with the relevant regulatory requirements and are sent to the client within agreed timelines
- Contributes to safety and pharmacovigilance training programs
- Collaborates with Regulatory Affairs to ensure appropriate reporting of pharmacovigilance and drug safety information to regulatory agencies and prescriber community

WORK EXPERIENCE

Jan'2021 to Sept'2024: Senior Drug Safety Associate at Qinesca, Pune, INDIA
Role:

- Draft aggregate reports (PBRER) within the allocated timelines.
- Stakeholder identification and confirmation
- Arrangement of kick-off meetings.
- Clinical trial information requests.
- Formulating strategy for safety issues and response to health authority requests and integrating benefit-risk evaluation
- Identify risk, develop search strategy and get endorsed by MR.
- Request data required to draft different sections of PBRER and review for accuracy.
- Evaluation of line listings and compile non-safety sections of PBRER with respective stakeholder's input.
- Responsible for global and local Literature screening.
- Review and finalize literature to be included in PBRER and get endorsed by MR.
- Comment resolution of MR review and quality review and finalize the report.
- Worked on signal detection and validation.

- Strong organization and prioritization skills able to multitask.
- Flexibility to adapt and meet fluctuating business priorities.
- Able to occasionally work extended and/or flexible schedule to meet client requirements.
- Ability to build relationships, collaborate and influence across disciplines within company and with outside stakeholders.
- Excellent verbal, written and presentation skills.

Jan'2020 to Jan'2021: Junior Data Analyst at Cognizant Technology Solutions India Private Limited
Role:

- Managed end-to-end case processing, ensuring compliance with regulatory requirements.
- Trained and mentored new team members, enhancing their case processing skills.

Dec'2018 to Oct'2019: Pharmacovigilance Associate at Apcer Life Sciences
Role:

- Steered case processing, ensuring adherence to quality standards and regulatory requirements.
- Conducted thorough evaluations of cases, contributing to the efficient processing of high volumes

Dec'2015 to Dec'2018: Drug Safety Specialist at Tata Consultancy Services
Role:

- Managed various case types, ensuring compliance with established protocols and guidelines.
- Executed end-to-end case processing, including coding of adverse events and medical histories.
- Responsible for collating error trends and taking refresher session for the team.

PERSONAL DETAILS

Address	:	Pune, India
Languages Known	:	English, Hindi, Marathi
Date of Birth	:	05 August 1992