Purushottam Gaykwad

Senior Drug Safety Associate

JOB OBJECTIVE

Targeting opportunities as a proactive healthcare expert, leveraging over 8 years of extensive experience in pharmacovigilance and drug safety operations to drive impactful results in the pharmaceutical sector.

CONTACT

ppgpatil007@gmail.com

9765908085

linkedin.com/in/purushottamgaykwad

EDUCATION

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

CORE COMPETENCIES

- Pharmacovigilance Operations
- Clinical Trial Safety Monitoring
- Risk Management Strategies
- Regulatory Compliance Frameworks
- Quality Assurance Protocols
- Adverse Event Reporting Standards
- Data Integrity and Validation
- Stakeholder Communication Strategies
- Process Improvement Methodologies
- Team Leadership and Development

TECHNICAL SKILLS

- Advanced proficiency in ARGUS Safety Database
- Expertise in MedDRA coding and medical terminology
- Comprehensive knowledge of pharmacovigilance regulations
- Proficient in data analysis and reporting tools

PROFILE SUMMARY

- Accumulated nearly 9 years of comprehensive experience in the pharmacovigilance domain, specializing in drug safety operations, case processing, and clinical research within the healthcare industry.
- Leading the role of Senior Drug Safety Associate at Qinesca, directing essential components of drug safety management while ensuring compliance with regulatory standards and project protocols.
- Leveraged comprehensive expertise in utilizing safety databases such as ARGUS and MedDRA, ensuring accurate case processing and data management in compliance with industry standards.
- Facilitated notable enhancements in team efficiency and compliance metrics through the development and execution of specialized training initiatives tailored to address identified performance gaps.
- Cultivated a supportive team atmosphere by exhibiting effective leadership skills and providing mentorship to junior associates in pharmacovigilance practices and case management.
- Played a pivotal role in a recent initiative aimed at optimizing the adverse event reporting workflow, resulting in enhanced operational efficiency and reduced processing times.
- Executed thorough quality checks and audits to uphold data integrity and ensure compliance with global pharmacovigilance guidelines and regulations.
- Exhibited exceptional analytical skills and attention to detail, enabling effective risk assessment and management in pharmacovigilance.
- Proficient in utilizing advanced data analysis tools to derive actionable insights, ensuring compliance with regulatory standards and enhancing overall drug safety operations.

WORK EXPERIENCE

Jan'2021 to Sep'2024: Senior Drug Safety Associate at Qinesca, Mysore, INDIA
Role:

- Orchestrating the workflow management process, ensuring optimal task prioritization and effective allocation of responsibilities among team members to enhance productivity.
- Addressing and resolving complex queries from stakeholders, maintaining a high level of service and ensuring timely responses to all inquiries.
- Steering overall productivity and quality of the team, ensuring strict compliance with regulatory standards and internal guidelines.
- Supporting both internal and external audits, providing necessary documentation and insights to demonstrate adherence to compliance requirements.
- Managing the influx of emails and escalations, ensuring that all ad-hoc requests are being managed effectively.
- Ensuring the prompt processing of incoming Adverse Events, aligning with Health Authorities' requirements and timelines.
- Conducting detailed monthly error analyses, identifying areas for improvement and recommending targeted refresher training sessions to enhance team performance.
- Leveraging proficiency in processing a diverse range of cases, including Literature, Clinical Study, Spontaneous, DEDP, Health Authority, and Legal Cases across all therapeutic areas.

- Skilled in quality assurance and compliance auditing
- Familiarity with Company Drug Dictionary (CDD)
- Competence in literature review and safety signal detection
- Mastery of Microsoft Office Suite for data management
- Experience with electronic case reporting systems

AWARDS & ACHIEVEMENTS

- Successfully led a project that improved the accuracy of case narratives, resulting in an increase in the quality of submissions to regulatory bodies.
- Spearheaded a project that streamlined the adverse event reporting process, resulting in a reduction of processing time, thereby enhancing overall operational efficiency.
- Developing and implementing a comprehensive risk management framework that is improving the identification and mitigation of potential safety issues, aligning with global pharmacovigilance standards.

Achievements:

- Spearheaded a project that improved the accuracy of case narratives, resulting in an increase in the quality of submissions to regulatory bodies.
- Successfully mentored a team of junior associates, leading to a measurable improvement in their case processing capabilities and overall performance metrics.
- Implemented a new quality check protocol that reduced data inconsistencies, while enhancing the reliability of case processing.
- Developed and executed a comprehensive training program for new hires, which decreased onboarding time and improved their initial performance ratings.

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.

PERSONAL DETAILS

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