Sarah Jenkins, PharmD

Senior Pharmacovigilance & Drug Safety Specialist

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Professional Profile

Dedicated Doctor of Pharmacy (PharmD) and Board Certified Pharmacotherapy Specialist with 8+ years of experience in pharmacovigilance and clinical safety operations. Proven track record in clinical trial and post-marketing safety reporting, complex MedDRA coding, safety narrative drafting, and FDA/EMA compliance. Extensive experience managing safety databases (Oracle Argus) and leading signal detection initiatives for oncology and immunology therapeutics.

Core Competencies

Systems & Databases: Oracle Argus, ArisG, MedDRA Browser, Veeva Vault, SAS
Regulatory Compliance: FDA 21 CFR Part 11, EMA GVP, ICH E2A/E2B(R3)/E2C, GCP
Medical Coding: MedDRA (LLT, PT, HLT, HLGT, SOC classification), WHO Drug Dictionary (WHO-DD)
Processes & Deliverables: ICSR processing, Signal Detection, Narrative Writing, DSUR/PSUR, Risk Management Plans (RMP)

Professional Experience

Senior Drug Safety Specialist 2023 – Present
Nexa Pharmaceuticals Boston, MA

- Lead the triage, assessment, and medical review of serious adverse events (SAEs) and adverse events of special interest (AESIs) for phase II/III clinical trials in oncology.
- Perform high-quality MedDRA coding for adverse events, medical history, and concomitant medications, ensuring accuracy and alignment with ICH guidelines.
- Author and review safety narratives for development safety update reports (DSURs) and periodic safety update reports (PSURs) submitted to the FDA and EMA.
- Serve as the safety database administrator for Oracle Argus, managing user access rights, custom queries, and standardizing data entry workflows to reduce processing errors by 18%.
- Collaborate with cross-functional clinical study teams to execute signal detection activities, identifying potential safety signals and drafting risk management plans (RMPs).

Pharmacovigilance Associate 2020 – 2023
Synapse Therapeutics Cambridge, MA

- Processed and evaluated post-marketing adverse event reports, generating complete safety cases from initial receipt to final regulatory submission.
- Conducted duplicate search checks and medical reviews of individual case safety reports (ICSRs) in compliance with FDA 15-day alert reports.
- Drafted regulatory submissions for MedWatch Form 3500A and CIOMS I forms, maintaining a 100% on-time submission rate over a 3-year period.
- Assisted in the preparation of standard operating procedures (SOPs) for safety data migration during the integration of a new pharmacovigilance system.

Drug Safety Coordinator 2018 – 2020
Vertex Biotech Worcester, MA

- Monitored the department's incoming safety mailbox, triaging global adverse event reports and performing initial data entry of patient demographics.
- Maintained tracking logs for investigator notification letters and regulatory authority submissions.
- Conducted literature searches on PubMed to identify potential adverse events and safety signals associated with marketed products.

Education & Certifications

Doctor of Pharmacy (PharmD) 2012 – 2018
Meridian University of Health Sciences (Boston, MA)
Clinical Residency in Drug Safety & Pharmacovigilance

MedDRA Certified Coder MedDRA MSSO, 2019
Board Certified Pharmacotherapy Specialist (BCPS) 2018
Regulatory Affairs Certification (RAC) RAPS, 2021