SOPHIA BROWN

Drug Safety Associate

support@qwikresume.com (123) 456 7899 Los Angeles

www.qwikresume.com

PROFESSIONAL SUMMARY

Dedicated Drug Safety Associate with two years of experience in pharmacovigilance, adept at managing adverse event reports from initial receipt to completion. Proven ability to maintain regulatory compliance and ensure data integrity within safety databases. Committed to enhancing patient safety through meticulous data analysis and effective communication with healthcare professionals.

WORK EXPERIENCE

Drug Safety Associate

Apr / 2024-Ongoing

Pineapple Enterprises

Santa Monica, CA

1. Conduct thorough review of adverse event reports for accuracy and completeness.
2. Coordinate and perform adverse event SAEAE triage, ensuring accurate data entry and quality review of cases.
3. Participate in the triage process for incoming documents, facilitating timely medical evaluation of adverse event information.
4. Ensure compliance with regulatory requirements in drug safety reporting.
5. Submit CIOMS and MedWatch forms for serious cases to regulatory authorities including the FDA and EU.
6. Assist in the preparation and review of regulatory reports, requesting follow-up information from consumers and healthcare professionals.
7. Maintain up-to-date knowledge of SOPs and current FDA regulations to ensure compliance.

Drug Safety Associate

Apr / 2023-Apr / 2024

Lakeside Apparel Co

Chicago, IL

1. Conduct data entry of post-marketed serious and non-serious individual case safety reports, ensuring compliance with Client standard operating procedures.
2. Utilize both ARGUS and ArisG systems for various projects, enhancing data management efficiency.
3. Identify and prioritize cases from workflow, determining appropriate submission timelines and criteria.
4. Review data entries for completeness and accuracy, making necessary adjustments to maintain data integrity.
5. Code suspect and concomitant drugs using Company Drug Dictionary and WHO Drug Dictionary.
6. Assess seriousness criteria of events, ensuring appropriate classification in line with established guidelines.

EDUCATION

Master of Pharmacy

Apr / 2022-Apr / 2023

University of California

Chicago, IL

Focused on pharmacovigilance and regulatory affairs.

SKILLS

Adverse Event Reporting 7

Regulatory Compliance 7

Data Analysis 8

Clinical Trials 10

ACHIEVEMENTS

- Achieved a 95% accuracy rate in data entry for adverse event reports, improving overall reporting compliance.
- Successfully streamlined the submission process for CIOMS and MedWatch forms, reducing submission time by 20%.
- Contributed to training new team members on ArisG and ARGUS systems, enhancing team efficiency.