Riajul Islam

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SUMMARY

With 10 years of pharmacovigilance experience, I ensure accurate safety data reporting through effective quality systems, clinical analysis, and process improvements. I am committed to regulatory compliance and have a solid understanding of industry standards. My track record shows I can drive efficiency, productivity, and growth, earning me a reputation as a trusted professional.

SKILLS

Drug Safety Reporting: ICSR case processing (e.g. Literature and Clinical Trials), Literature monitoring, Quality review, Updating QMS, drafting SOP and WI, Aggregate reporting (PSUR and PBRER).

Pharmacovigilance Operation: Team management, Operational oversight, Quality assurance (QA), CAPA and deviation management, Communication and Collaboration, Performance management, providing technical expertise, and conducted Audit. Ensure appropriate Follow-up is obtained and prioritize work to ensure internal and regulatory timelines are met.

EXPERIENCE

QINECSA SOLUTIONS — **MYSORE, INDIA**
Drug Safety Scientist — Apr 2021 to Mar 2024

- Developed a comprehensive quality management plan to ensure compliance with regulatory guidelines, resulting in a 95% reduction in compliance issues.
- Implemented a new process workflow to minimize errors and enhance overall quality, reducing error rates by 80% and increasing productivity by 25%.
- Conducted training and quality meetings with clients, resulting in a 90% client satisfaction rate and a 40% reduction in client complaints.
- Proposed a new improvement plan, which led to a 30% increase in quality management process efficiency and a 20% reduction in costs.
- Prepared training and audit plans (internal & external), ensuring that 100% of employees were trained and equipped to follow quality processes, and the system was evaluated for effectiveness 4 times a year.
- Expand regulatory expertise on case collection and expedited reporting with regulatory agencies (e.g., FDA and EMA)

COGNIZANT TECHNOLOGY SOLUTION — **KOLKATA, INDIA**
Data Analyst — Mar 2016 to Apr 2022

- Processed 200 literature cases and implemented quality control measures, resulting in a 95% accuracy rate for case processing. Literature monitoring.
- Drafted 10 aggregate reports (e.g., PBRER), ensuring compliance with regulatory guidelines and enhancing the overall quality of reporting.
- Integrated the PV trace application, enhancing functionality by 25% and improving data accuracy by 20%.
- Process adverse events and other safety information from various sources (e.g., Clinical Trials, Patient Support Programs, Market Research, literature, spontaneous reports, etc.).

- Review individual reports to find missing information, determine if follow-up is needed to clarify the seriousness, expectedness, and cause of the event, and complete the case.

QUINTILES INDIA PVT. LTD (NOW IQVIA) **BENGALURU, INDIA**
Assocs. Operations Specialist Sep 2015 to Feb 2016

- Triaged and processed 250 solicited, spontaneous, and clinical trial cases in a month, ensuring accurate and timely reporting of adverse events.
- Coordinated with cross-functional teams, including medical affairs, data management, and clinical operations, to ensure timely and accurate reporting of adverse events.
- Complete or verify MedDRA coding

SCIFORMIX TECHNOLOGIES PVT. LTD. (NOW FORTREA) **PUNE, INDIA**
Jr. Safety Data Analyst Apr 2014 to Aug 2015

- Monitored the safety of pharmaceutical drugs once they were on the market, reviewing and evaluating adverse event reports (AERs) to determine if they meet regulatory reporting requirements.
- Conducted manual coding of 200 adverse events weekly using the MedDRA dictionary, ensuring precise and consistent coding of labs, historical conditions, and products during ICSR processing

HEMOGENOMICS PVT. LTD **BENGALURU, INDIA**
Quality Assurance Executive Aug 2012 to Apr 2014

- QA documentation (draft SOP, deviation, RCA-CAPA, Shipment tracking, and Change control)
- Completed Novartis Audit without any critical error and Vendor management.

EDUCATION

M-Pharm - (Clinical pharmacy) **BHUBANESHWAR, INDIA**
Utkal University Aug 2009 to Jul 2011

B-Pharm **BHUBANESHWAR, INDIA**
I.G.I.P.S, BPUT University Aug 2005 to Jul 2009

CERTIFICATIONS

- Industry Program in Pharma Regulatory Affairs: Jun 2021 from Bioinformatics Institute of India
- Post Graduate Diploma in Clinical Research & Pharmacovigilance: Jul 2011 from Syncorp Clincare Technologies Pvt. Ltd

ADDITIONAL INFORMATION

- Received awards like ‘Unicorn’, ‘Spotlight’, and ‘Certificate of Appreciation’ for high-quality performance, demonstrating exceptional dedication and passion for delivering outstanding results from 2016 to 2021 from Cognizant technology solutions.

- Earned ‘Employee of the Month’ (QA) for dedication, passion, and exemplary performance, showcasing a strong commitment to quality and excellence in 2013 from Hemogenomics Pvt. Ltd.