Renata Valentim

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SUMMARY

Pharmacovigilance professional with experience in patient safety strategy, compliance oversight, and risk management in clinical studies and post-marketing. Skilled in cross-functional collaboration with medical, regulatory, and access teams to implement safety strategies aligned with business priorities. Experienced in safety data analysis, PV process optimization, and communication with global stakeholders. Strong background in training, mentoring, and influencing decision-making through data-driven insights. Knowledge in analytics tools (Excel, Power BI, Python, SQL).

KEY SKILLS

- Patient Safety Strategy
- Cross-functional Collaboration
- Regulatory Compliance & Risk Management
- Stakeholder Engagement & Negotiation
- Digital Health & Data Insights
- Leadership & Mentoring
- Safety Communication & Decision-Making

PROFESSIONAL EXPERIENCE

Sr. Drug Safety Associate | ICON PLC, São Paulo, Brazil | Jun/2021 – Current
Responsibilities:

- Leadership in the management of clinical studies, participating in internal meetings and with sponsors to set up and perform continuous monitoring of clinical studies
- Responsible for submitting adverse events (SUSAR/SAE) and periodic reports to investigators, ethics committees and regulatory authorities.
- Screening and distributing notifications and tasks, ensuring deadlines and regulatory compliance.
- Generating monthly metrics reports for sponsors, evidencing compliance with deadlines and justifying any deviations.
- Reviewing corrective and preventive action plans (CAPA), promoting continuous improvement of pharmacovigilance processes.
- Preparing and presenting materials for internal and external audits, including inspections by regulatory authorities.
- Managing and reviewing the Trial Master File (TMF), ensuring traceability and document integrity of clinical studies.
- Continuously reviewing budgets to ensure correct pricing of services provided, identifying the need for adjustments and requesting change orders for financial adequacy as studies evolve.
- Continuous monitoring of regulatory changes that impact pharmacovigilance locally and globally, ensuring the effective assessment and implementation of new requirements to ensure compliance in pre-marketing processes.
- Mentoring and developing new analysts, guiding them in pharmacovigilance activities and improving their soft skills, especially in relationships with sponsors and stakeholders.
- Participation in the training team for new employees after the acquisition of another company, helping to develop the system guide, preparing and presenting training sessions, and answering questions, acting as a

mentor and buddy for colleagues.

Associate Product Surveillance Analyst | Allergan, São Paulo, Brazil | Nov/2017 – May/2021
Responsibilities:

- Processing adverse events and technical complaints of medical devices marketed in Latin America, ensuring compliance with local and international regulations.
- Support in submitting reports to regulatory authorities in Latin America, ensuring that all regulatory obligations are met within the established deadlines.
- Follow-up in Portuguese, Spanish and English with reporters by telephone and email.
- Organization of calibration meetings with local and global teams, promoting the alignment of technovigilance practices and increasing the efficiency of operations.
- Integration and training of new employees, ensuring compliance with internal standards and procedures, in addition to contributing to team development.
- Participation in product warranty processes, collaborating with risk management and product monitoring to ensure compliance with regulatory requirements.

Junior Pharmacovigilance Analyst | Captativa, São Paulo, Brazil | May/2016 – Oct/2017
Responsibilities:

- Processing of adverse events from spontaneous reports and post-marketing studies

Pharmacovigilance Intern | Sanofi, São Paulo, Brazil | Jan/2015 – Apr/2016
Responsibilities:

- Processing of adverse events reported through the customer service system, ensuring compliance with local and international regulatory guidelines.
- Submission of adverse event reports of drugs and medical devices to local regulatory authorities, meeting established deadlines and requirements.
- Follow-up in Portuguese with patients and healthcare professionals by phone and email

EDUCATION

- **Bachelor's degree in pharmacy** | UNIFESP, Diadema, São Paulo, Brazil; Feb/2010 – Jul/2016
- **MBA in Data Science and Analytics** | USP ESALQ, Brazil; Apr/2024 – Nov/2025

COURSES

- **Excel, SQL and PowerBI** | Conquer, Brazil; completed in 2023
- **Pharmacoeconomics** | Racine Institute, Brazil; completed in 2023
- **Clinical Research** | Invitare Clinical Research, Brazil; completed in 2021

LANGUAGES

- **Portuguese:** Native
- **English:** Fluent
- **Spanish:** Advanced