Marin Lolić

Date of birth: 12/09/1996

Nationality: Croatian

Gender: Male

CONTACT

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ABOUT ME

Experienced Pharmacovigilance Specialist with a strong background in regulatory submissions, adverse event management, and compliance within clinical trials and post-market surveillance. Proficient in using Argus Safety, Safety Easy and Veeva Vault databases to manage expedited and non-expedited individual case safety reports (ICSRs) and aggregate safety reporting. Expertise in creating Line Listings (LLs), managing Periodic Safety Reports (PSUR/DSUR), and performing gateway-to-gateway submissions. Skilled in ICSR reconciliation, data migration, and ensuring regulatory reporting compliance with health authorities, ethics committees, and safety partners.

WORK EXPERIENCE

Arriello s.r.o. Remote, Croatia

Global Drug Safety Specialist

07/07/2024 – Current

- Manage ICSR processes in Veeva Safety Database, ensuring compliance with expedited and periodic safety reporting.
- Create Line Listings (LLs) for monthly and ad-hoc client reports, including aggregate and DSUR reports.
- Perform ICSR reconciliation with clients and safety partners to ensure data integrity and regulatory compliance.
- Conduct testing of gateway submissions to health authorities and perform data migration testing for new product types and territories.
- Collaborate on CAPA management related to submissions and data discrepancies.
- Ensure compliance with global regulatory requirements for adverse event submissions and maintain oversight on compliance timelines.

Primevigilance d.o.o. Zagreb Zagreb, Croatia

Pharmacovigilance (PV) officer, Team leader

01/05/2023 – 06/07/2024

- Led a team responsible for ICSR management in Argus, ensuring timely and accurate safety data entries.
- Managed adverse event submissions to health authorities, ethics committees, and safety partners, including gateway-to-gateway testing.
- Supported ICSR reconciliation and performed quality checks on submitted data to ensure regulatory compliance.
- Conducted testing for new E2B profiles and involved in data migration for new products entering new territories.
- Generated custom reports for Periodic Safety Reports (PSUR/DSUR) and assisted in setting up periodic reporting requirements.
- Coordinated safety management plans and ensured compliance with both local and international regulations.

Primevigilance d.o.o. Zagreb Zagreb, Croatia

Senior PV Associate

01/05/2022 – 01/05/2023

- Performed triage, data entry, MedDRA coding, and narrative writing for post-marketing and clinical trial ICSRs in accordance with GVP and client-specific requirements.
- Managed case processing workflows, including follow-up activities and timely submission of ICSRs to regulatory authorities (e.g. EMA, MHRA, FDA).
- Supported line listing generation and reconciliation activities for regulatory reporting and safety surveillance purposes.
- Conducted QC checks of pharmacovigilance documents and case data in safety databases (e.g. Argus).

- Contributed to TMF management by uploading, reviewing, and performing quality control of essential pharmacovigilance documents.
- Collaborated with cross-functional teams to ensure compliance with global PV regulations and internal quality standards.

Primevigilance d.o.o. Zagreb Zagreb, Croatia

PV Associate

01/11/2020 – 01/05/2022

- Processed and managed clinical safety data entries in various databases (ArisG, Argus), ensuring compliance with SOPs.
- Participated in database UAT and contributed to improving overall workflow efficiency.
- Contributed to regulatory submissions, supporting ongoing amendments, notifications, and safety reporting to local Regulatory Authorities and Ethics Committees.

EDUCATION AND TRAINING

01/10/2015 – 01/10/2018 Split, Croatia

Bachelor degree in Biology and Chemistry University of Split, Faculty of Science Split

01/10/2018 – 01/10/2020 Rijeka, Croatia

Master degree in Drug reaserch and development University of Rijeka, Department for biotechnology

01/10/2022 – CURRENT Split, Croatia

Master Degree in Management Faculty of Economics, Business and Tourism

LANGUAGE SKILLS

MOTHER TONGUE(S): Croatian

Other language(s):

English

Listening C1
Spoken production C1
Reading C1
Spoken interaction C1
Writing C1

German

Listening A2
Spoken production A2
Reading A2
Spoken interaction A2
Writing A2

Levels: A1 and A2: Basic user; B1 and B2: Independent user; C1 and C2: Proficient user

SKILLS

Microsoft Office package: Microsoft Word, Excel, PowerPoint, Access | Argus Database | MedDRA Coding | Veeva EDC | Clinical Data Management | eCRF Design and Management | veeva vault | MediData Rave (EDC) | Data Validation and Quality Control | Database Management Systems (e.g., ArisG, ARGUS) | Study Documentation and SOP Development | Project Leadership and Team Coordination | Veeva Vault | CSR Reconciliation

DRIVING LICENCE

Driving Licence: AM

Driving Licence: B

HONOURS AND AWARDS

01/10/2018 University of Split

Dean award for success

01/09/2015 Croatian ministry for science, education and sport

National scholarship

National scholarships for academic years from 2015. until 2020.

SKILLS

Key Skills and Expertise

Regulatory Submissions Management: Successfully managed submissions to Regulatory Authorities and Ethics Committees, ensuring timely approvals and adherence to country-specific regulations.
Clinical Trial Start-Up Processes: Supported clinical trial start-up activities, including document submission and compliance with regulatory timelines.
Competent Authority Submissions: Coordinated submissions to Competent Authorities, ensuring compliance with local and international guidelines for clinical trials.
Trial Master File (TMF) Management: Managed the collection, review, and maintenance of essential documents within the TMF, ensuring inspection readiness and compliance with company SOPs.
ICH GCP Compliance: Ensured that all clinical trial processes and documentation were conducted in compliance with ICH GCP and local regulatory requirements.
Project Management Support: Provided project management support by participating in budget discussions, tracking progress, and ensuring adherence to project milestones.

ACHIEVEMENTS

Professional Achievements

- Successfully managed multiple clinical trial submissions and site activations, consistently meeting regulatory requirements and internal timelines.
- Built and maintained strong relationships with clinical trial sites and stakeholders, facilitating smooth communication and efficient problem-solving.
- Achieved high performance indicators (KPIs) across start-up activities, demonstrating reliability in submissions, documentation quality, and project coordination.
- Ensured full compliance with ICH GCP guidelines and local regulatory requirements during clinical trial start-up processes.

RECOMMENDATIONS

Ijeoma Tiggs Director of ICSR, Primevigilance USA

I had the opportunity to collaborate with Ijeoma Tiggs on several pharmacovigilance projects during my time at PrimeVigilance. She consistently demonstrated a high level of professionalism, attention to detail, and a proactive approach to team coordination and client communication. I greatly appreciated her clear guidance and collaborative spirit throughout our work together. Ijeoma has kindly agreed to be listed as a reference for any future opportunities.

Email ijeoma.tiggs@primevigilance.com

Marina Živković PV officer, ICSR team leader at Primevigilance Serbia

I worked closely with Marina Živković for an extended period at PrimeVigilance, where she served as an ICSR Team Leader. Marina consistently demonstrated exceptional leadership, in-depth pharmacovigilance knowledge, and a collaborative spirit. Her guidance and reliability were key to the team's success, and she was always approachable and supportive. It was a pleasure working with her, and I truly value the professional relationship we built.

Email marina.zivkovic@primevigilance.com

Ivica Ljubenkov Mentor during my Bachelor's thesis in Biology and Chemistry

I collaborated with Prof. Ljubenkov during my Bachelor's thesis at the Faculty of Science, University of Split. He provided expert mentorship and scientific guidance throughout the research and writing process. His support significantly contributed to the successful completion of my thesis project.

Email ivica.ljubenkov@pmfst.hr

Sandra Kraljevic Pavelic Mentor during my Master's degree thesis in Biotechnology

I collaborated with Sandra Kraljević Pavelić during my Master's thesis at the Department of Biotechnology, University of Rijeka. As my supervisor, she provided excellent academic guidance, critical feedback, and continuous support throughout the research and writing process. Her mentorship was instrumental in the successful completion of my thesis work.

Email sandrakp@biotech.uniri.hr