Curriculum Vitae

Personal information

Lina Masioniene

Work experience

Sep 2024 - present and

Nov 2021 - Dec 2023

Chief specialist, Pharmacovigilance and poison information division, the State Medicines Control Agency (SMCA) under the Ministry of Health, Lithuania

Agency's lead and coordinator for EU Joint Action JA12 SAFE-CT project „Safety assessment cooperation and facilitated conduct of clinical trials";

Consulted on the safety reporting in clinical trials and post-marketing for external stakeholders in accordance with European Union regulations, directives and national requirements;

Agency's representative and assessor for EMA's Clinical Trials Coordination Group (CTCG) for the assessment of safety information in clinical trials for the investigational medicinal products such as Suspected Unexpected Serious Adverse Reactions (SUSARs) reports, Development Safety Update Reports (DSURs) and other safety related information with regards to the implementation of the new clinical trials regulation in EU (CTR EU No 536/2014);

Submitted Serious Individual Case Safety Reports (ICSRs) into EudraVigilance (EVWEB) safety database received from health care professionals and consumers, and assessed causality;

Agency's expert for the training of Rwanda's FDA pharmacovigilance staff for the clinical and post-marketing surveillance improvement in Rwanda as part of European Commission twinning fiche project: „Strengthening Rwanda's FDA regulatory functions related to medicinal products including vaccines".

Jan 2024 - Aug 2024

Pharmacovigilance Scientist, Uppsala Monitoring Centre, WHO Collaborating Centre, Sweden

Performed clinical assessment of case series related to potential signals, including causality assessment and review of the scientific literature;

Critically reviewed the signal assessments performed by the team members;

Disseminated of the findings, including publishing in the WHO Pharmaceuticals Newsletter and peer reviewed scientific journals as well as presenting at scientific conferences;

Shared expertise in collaborations with other sections and departments within UMC, such as Education & Training and Research;

Worked closely with WHO's Pharmacovigilance team and provided support to the WHO advisory committees on the safety of medicinal products and vaccines.

Oct 2019 - Jul 2021

Pharmacovigilance Specialist (QPPV office), Biomapas, Service provider for Clinical Trials, Regulatory Affairs and Pharmacovigilance, Lithuania

Global weekly literature review of case reports for assigned active substances published in Pubmed, Reactions weekly, Embase and other scientific sources, monitoring for the safety issues and assessing reportability;

Entered and processed SUSARs in clinical trials from the source documents into ARGUS safety database for the clinical research organization which included MedDRA coding and assessment of seriousness, expectedness and causality;

Issued post-marketing regulatory documents such as PSURs, RMPs, aRMMs and medical communication documents such as brochures for HCPs and patients;

Entered spontaneous and literature ICSRs into the company's Veeva Vault safety database and submitted ICSRs to EudraVigilance database (EVWEB), registered new organizations into EudraVigilance system, submitted new SmPC data for authorized medicinal products to extended EudraVigilance medicinal product dictionary (XEVMDP), Article 57 database;

Wrote Business Continuity and pharmacovigilance SOPs for the company and clients;

Participated in pharmacovigilance audits and summarized findings.

Jan 2007 - Sep 2019

Adverse Reaction Information Specialist, Canada Vigilance program, Health Products Surveillance and Epidemiology Bureau, Marketed Health Products Directorate, Health Canada, Ottawa, Canada

Conducted pharmacovigilance activities in accordance with the appropriate procedures and relevant guidance documents within established timelines for pharmaceuticals, biologics, cells, tissues and organs, and blood and blood components;

Assessed adverse drug reaction reports received from marketing authorization holders, health care professionals and consumers using the methods and techniques related to the adverse drug reaction information analysis;

Processed ICSRs received from manufacturers, health professionals and consumers into Canada Vigilance ARISg database including MedDRA coding of the main components of the report, assessed seriousness, expectedness and causality;

Weekly monitored the safety information of the medicinal products for the signal detection purpose including the retrieval of aggregated safety information from Canada Vigilance database, WHO VigiBase and VigiLyze signal detection and management system;

Specialized in the signal detection, investigation and analysis for Biotech immunosuppressants and blood fractionated products and monitored for the signal identification the assigned Designated Medical Events and presented potential signals in the signal evaluation meetings to medical reviewers;

Canada Vigilance lead of cells, tissues and organs project, and blood and blood components project in coordination and processing of adverse reactions received from Canadian transplant and blood establishments; managed issues and inquiries with inspectors and evaluators in requesting additional information from establishments. Three recognition awards received for managing projects;

Contributed to Health Canada's Human Cells, Tissues and Organs for Transplantation Adverse Reaction Reporting Form and Guidance Document for Cell, Tissue and Organ Establishments - Safety of Human Cells, Tissues and Organs for Transplantation.

Dec 2005 - Jan 2007

Regulatory Project Officer, Biotherapeutics and Quality Regulatory Affairs Division, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Canada

Screened and assessed New Drug Submissions (NDS), Supplemental NDSs, Notifiable Changes, Clinical Trial Applications, Priority Review Requests;

Reviewed and issued screening reports for the clinical documentation such as Investigator’s brochures, non-clinical and clinical overviews;

Regulatory project management: coordinated the submission projects for biologics within the strict review timelines; a liaison between the sponsor, quality and clinical review team;

Issued the submission related regulatory documents according to the established review timelines and procedures;

Communicated and counseled the sponsors on Health Canada’s guidelines and regulations.

Sep 2004 - Dec 2005

Associate I, Drug Safety, Apotex Inc., Toronto, Canada

Processed and evaluated adverse drug reaction reports for Apotex products in clinical trials, post marketing and literature;

Interacted with health professionals, consumers and affiliate offices during investigation of case reports;

Entered adverse drug reaction reports into the global safety database Oracle - AERS using MedDRA coding terminology;

Prepared and submitted expedited adverse drug reaction reports in CIOMS and MedWatch forms to Health Canada, FDA, EMEA and the rest of the world.

Jul 2003 - Feb 2005

Coordinator Regulatory Affairs & Compliance, Regulatory Operations, Apo-Pharma Inc. (Apotex subsidiary), Toronto, Canada

Coordinated publishing of CTA/IND, NDS/NDA, MAA to Health Canada, EMEA and FDA, and other registration dossiers to the Ministries of Health of the rest of the world;

Compiled and assembled submissions in CTD and e - CTD format;

Maintained electronic and hard copy files database for all submissions and regulatory correspondences;

Prepared documents electronically in Word, WordPerfect, PowerPoint, AdobeAcrobat, Excel and Compose.

1999 - 2001

Regulatory Affairs/Medical Representative, Nycomed Osteuropa Marketing Service GmbH, Lithuania

Submitted adverse drug reaction reports to Lithuania‘s State Medicines Control Agency;

Collaborated with other European Union regulatory affairs managers from Austria, Denmark and Norway for the completion of adverse reaction reports;

As Medical Representative was responsible for detailing and sales of 14 pharmaceuticals and OTC products, managed 30 % territory of Lithuania;

Developed new contacts and conducted seminars and presentations to physicians and pharmacists, and organized educational events for consumers.

1997 - 2000

New Product Manager, Nortile, Pharmaceutical wholesale company, Lithuania

Primary company‘s contact with Canadian (Lab. Phoenix) and French (Lab. Medix, Lab. Gifrer - Barbezat, Lab. Fumouze) pharmaceutical companies;

Established new contacts which allowed registration of new products into Lithuanian market;

Developed new relationships which contributed to an increase in company sales;

Wrote marketing plans for the clients for brand and generic pharmaceuticals.

1995 - 1997

Scientific Administrator, Ministry of Health, The State Medicines Control Agency (SMCA), Lithuania

Primary liaison between the national agency and pharmaceutical companies;

Implemented European Union pharmaceutical registration procedures in Lithuania;

Conducted preliminary screening of submission documents for pharmaceuticals, biologics, diagnostics, food

supplements and medical cosmetics;

Advised pharmaceutical manufacturers on national registration requirements.

Education and training

Education:

2008 – 2011

Graduate Diploma in the Population Health Risk Assessment and Management, Ottawa and McGill Universities, Ottawa and Montreal, Canada

2002 - 2003

Graduate Certificate with Honours in the Regulatory Affairs Program, Humber College of Applied Arts and Technology, Toronto, Canada

1998

Clinical Pharmacist Certificate, Lithuanian University of Health Sciences, Lithuania

1989 - 1995

M. Sc. Pharmacy, Lithuanian University of Health Sciences, Lithuania

Professional training:

Medical Writer‘s Professional Development Programme of European Medical Writers Association, EMWA. Completed pharmacovigilance related courses and obtained eight credits.

Certified MedDRA Coder (CMC) (passed exam) in June 2021 at MedDRA MSSO. The certificate valid for 5 years.

Certificate of successful completion (passed theoretical and practical exams) of EudraVigilance course on electronic reporting of ICSRs: mandatory use of ISO/ICH E2B(R3) ICSR safety reporting in the EU, June 2021.

Certificates of accredited Good Clinical Practice E6 (R2) Basic courses completion (passed exams), ICH, Germany in 1999 and Biomapas, Lithuania in 2019;

Pharmacoepidemiology, epidemiology and biostatistics courses at University of Ottawa, McGill University and internal trainings at Health Canada, 2007-2019;

MedDRA Coding Conventions trainings by MSSO at Health Canada on the regular basis, from 2007 to 2019;

Certificate in pharmacovigilance, Kusuri Canada Corp., Ottawa, Canada, 2006.

Additional information

Publications

Projects

1. Agency's lead, coordinator and assessor of EU Joint Action JA12 SAFE-CT project „Safety assessment cooperation and facilitated conduct of clinical trials“.
2. Agency's expert for the training of Rwanda‘s FDA pharmacovigilance staff for the clinical and post-marketing surveillance improvement in Rwanda as part of European Commission twinning fiche project: „Strengthening Rwanda‘s FDA regulatory functions related to medicinal products including vaccines“.

Memberships

Former member of European Medical Writers Association, EMWA.

Other Relevant Information