Marie-Josée Moore, RN, BSc.
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PROFILE

A highly motivated team player, result-oriented and dedicated healthcare professional with over 25 years' experience in the pharmaceutical industry (Pharmacovigilance, Medical Information, Regulatory Affairs/Compliance and Sales), complimented by 3 years as a Registered Nurse. Committed to build outstanding customer relationships and focused on delivering results. Energetic, very well organized and bilingual (French / English).

EMPLOYMENT HISTORY

Milestone Pharmaceuticals (Montreal, Quebec) — May 2022 – Present

Director Pharmacovigilance Operations

- Manage Global PV strategy and activities
- Lead/ensure compliance with regulatory requirements and GVP
- Keep abreast of latest and upcoming safety related regulatory requirements
- Lead preparation and coordination of PV inspections
- Provide input/support at key Committees
- Ensure safety issues monitoring/tracking and maintain appropriate documentation of AEs
- Ensure Follow ups are performed adequately to obtain additional information
- Supervise/manage AEs global database
- Supervise and ensure compliance of expedited and periodic safety reports generation and submission to regulatory authorities and Central Ethics Committees
- Ensure that AEs are coded adequately using MedDRA dictionary by establising coding conventions
- Provide regular updates on PV and related projects/activities
- Ensure that literature review is performed
- Present AE process as needed
- Supervise/participate in developing/implementing PV procedures
- Ensure training PV procedures within the Company is up to date
- Supervise PV global communication and reconciliation tools
- Supervise implementation of SDEAs
- Participate in developing/implementing procedures required to ensure efficient department operations
- Manage budget related to PV activities
- Respect company policies/procedures

Astellas Pharma Canada Inc. (Markham, Ontario)

Senior Affiliate PV Manager — **Apr. 2020 – Jan. 2022**
Affiliate PV Manager — **Apr. 2017 – Mar. 2020**
Associate Manager, PV & GCP Compliance — **Jan. 2016 – Mar. 2017**
Project Leader, PV & GCP Compliance — **Oct. 2012 – Dec. 2015**

- Responsible for leading & directing all aspects of compliance related to PV
- Act as Drug Safety Officer, overseeing compliance of the PV activities
- Develop innovative approaches for managing risk areas through auditing, metrics management, quality initiatives and facilitated remedial solutions
- Maintain an efficient vigilance system in compliance with Health Canada (HC) regulations/ guidelines
- Manage HC's Post-Market Reporting Compliance Inspections & served as an inspection's coordinator

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- Lead Astellas Pharma Canada's (APCA) Inspection Readiness Programs
- Prepare/maintain safety data exchange agreements & internal Work Instructions with Global PV & business partners
- Ensure Annual Summary Reports, RMPs and other related reports are prepare and submit on time
- Track documentations
- Coordinate responses to questions from HC/ Healthcare professionals regarding adverse event cases
- Plan/conduct internal/external process/system audits to: 1) assess compliance with requirements & Astellas standards, 2) ensure & improve quality
- Communicate findings to audit stakeholders to ensure understanding & collaborate with auditees to develop corrective actions to address root causes
- Prepare/implement Working Practice Guidelines to comply with HC requirements & Astellas standards for PV compliance
- Keep abreast of necessary HC regulations, ICH Guidelines & requirements and make necessary updates in our documents after evaluating their impacts
- Interact with Global and external service providers on PV compliance matters. Respond to queries/request from internal/Global stakeholders
- Provide required PV training to relevant groups (new hires)

UCB Pharma (Oakville, Ontario)

2010 – 2012

Drug Safety Manager

- Implemented the Drug Safety Manager position at UCB by bringing the safety reporting activities to Canada from Global by submitting CIOMS directly to HC
- Developed SOPs and processes for collecting, documenting, processing and reporting of Adverse Events (AE) for UCB product
    - Continuously monitor, direct & track the flow of local/global safety cases for all UCB drugs
    - Requested additional information & conducted appropriate follow-ups
    - Maintained/supervised appropriate documentation progress of all cases
    - Assured quality control
    - Ensured clearly outlined of clinical trial reporting requirements in local/global trials as required (Phase IV)
    - Reviewed literature & publications regularly for adverse experiences
    - Kept current on pertinent regulatory safety publications & requirements. Inform and educate other members of the group
    - Periodically, conducted training lectures on safety topics and PV
    - Acted as deputy Local Safety Officer (LSO)
    - Ensured compliance with regulatory reporting of adverse events
- Key interface for PV activities with other stakeholder groups & departments
    - Reviewed third party contracts related to PV/Safety Data Exchange Agreements
    - Represented drug safety on cross-departmental teams
- Actively involved in internal/external PV audits
- Provided 24/7 safety coverage
- Provided project management support for new & ongoing tactics related to PV
    - Implemented transition of reporting responsibilities, by UCB Canada to HC
    - Ensured smooth & timely transition from US Clinical Safety & PV
- Assisted Medical Director in the development of Medical Affairs deliverables related to Medical Information and PV

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LEO Pharma (Markham, Ontario) **2008 - 2010**

Medical Information and Pharmacovigilance Specialist

- Reported all adverse events (AEs) to the appropriate Canadian Regulatory Authorities, study investigator/coordinator & Central Pharmacovigilance (PV) according to regulations & SOPs
- Processed AE information from clinical trials & spontaneous reports Prepared/filed Safety Updates
- Participated in project teams as PV resources and contact person
- Prepared and conducted PV training to Clinical Site Managers
- Provided prompt and accurate information (French/English) to request for Medical Information (MI) from internal/external customers
- Maintained a database of the MI requests & responses
- Maintained references & other MI resources
- Prepared and conducted training for Sales & Marketing on Leo products & PV
- Reviewed promotional material – Prepared and Review MI/PV SOPs

Wyeth Pharmaceuticals (Markham, Ontario)

Pharmacovigilance Associate **2005 - 2008**

- Responsible for collecting, processing and reporting Canadian and International (AEs) to HC & to Wyeth Global Safety in compliance with local/global regulatory requirements/procedures. Generated CIOMS Forms using MedDRA convention coding
- Processed SAE reports from clinical studies
- Maintained accurate and retrievable AE report filing system in a secure environment
- Participated in departmental procedures and initiatives to improve process/efficiencies
- Maintained current knowledge of global drug safety regulations
- Liaised with associated groups (clinical, project management, regulatory affairs) in PV related issues
- Reviewed specific Canadian literature for AEs
- Generated & distributed reports for performance management
- Obtained further details from AE reporters in order to be compliant with Wyeth/HC guidelines
- Handled AE inquiries from internal/external customers
- Ensured compliance with HC/Wyeth procedures
- Developed AE training program (French/English) & provided AE training for all newly hired employees.
- Participated in AE refresher training for all employees
- Reviewed AE training material for other Wyeth locations (Brandon, Montreal)
- Developed/maintained local SOPs/SPIs on AE related issues

Apotex Inc. (Toronto, Ontario)

Drug Information Associate **2003 - 2005**

- Provided responses to all requests for drug /disease information in a courteous, timely manner by providing information that was balanced, accurate, clinically relevant thorough, referenced and clear in an appropriate format for external health professionals as well as internal customers
- Entered all requests for DI in the IRMS system ensuring date entry was complete/accurate, reflecting the approach taken to answer the question. Updated IRMS database as required
- Classified/prioritized DI requests, using Medline & other databases/Internet to retrieve information

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- Reviewed promotional materials, visual aids & galleys for CPS monographs & various Compendia in a timely manner. Contributed to various projects as assigned including scientific writing of: Health Hazard Assessments and preparation of DI Bulletins for Sales and Marketing
- Collected initial information relative to Adverse Events, then forwarded the relevant information to Drug Safety to ensure compliance with Federal Drug Safety Regulations
- Coordinated the Special Access Program by confirming/ preparing all requests for the product as authorized by HC & handled product complaints for all Apotex portfolios

Pfizer Canada **(formerly Pharmacia, Mississauga, Ontario)**

Associate Regulatory Affairs/Compliance **1997 - 2003**

- Assessed, organized, filed and followed through to approval various types of submissions (eg. SNDSs, X-Ref., NDSs, NCs, Internal submissions)
- Established appropriate level of change for CMC changes made to our products and ensured that the product monographs were compliant with those changes
- Reviewed labeling to ensure regulatory compliance
- Extensive experience with ATIs, DMFs and DIN Notifications
- Participated in self-inspections of our Distribution Centres to comply with Health Canada GMP Guidelines
- Prepared & conducted French GMP training for Montreal Distribution Centre employees to introduce them to the principles of GMP & to ensure compliance with regulations

Drug Information Specialist **1995 - 1997**

- Initiated the DI Specialist position
- Provided timely/accurate information on marketed products to internal/external customers
- Provided information on research topics using several databases
- Reported adverse events for marketed products to the medical group
- Reviewed promotional materials

Syncare Pharmaceuticals Inc. (Mississauga, Ontario)

Sales Representative **1993 - 1995**

- Strategic sales planning/management of generic drug sales within Québec
- Identified, analyzed and capitalized on market opportunities/trends
- Set sales objectives
- Developed/managed key accounts customers with monthly visits of key pharmacists
- Customer service, authorized returned goods & shipped merchandise

Tandem Computers Canada Ltd (Markham, Ontario)

National Dispatcher/Customer Service Representative **1991 - 1993**

- All duties related to a customer service representative

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Hôpital de l'Enfant-Jésus (Québec, Québec)

Registered Nurse **1988 - 1991**

- All duties related to a hospital caregiver

EDUCATION

Certificate Safety & PV Program	DIA	2016
BSc.	University of Montreal (Québec)	1991
RN	Collège F-X Garneau (Québec)	1987
Specialization in Cardiology	Collège Ste-Foy (Québec)	1987

TRAININGS/ MEMBERSHIPS

Board of Director PV Network
Registered Nurse with College of Nurses of Ontario
Member of the Drug Information Association