

# Valérie Paquet, M.Sc., ERT

Toxicologist, Pharmacologist

## Executive Summary:

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Master's degree in pharmacology & Toxicology – highly experienced in occupational toxicology, performed the OEL/ADE/PDE derivation of more than 500 APIs, industrial hygiene, and risk assessment – more than 13 years in the pharmaceutical industry – experience in quality assurance, pharmacovigilance, medical information, and clinical research – passionate by drug discovery and medical advance technologies.

## Licenses and Certificates:

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- European Registered Toxicologist (ERT)
- Full member Society of Toxicology (SOT)

## Education:

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| 11/2014     | <b>Attendance to the SafeBridge Potent Compound Safety Boos Camp I&amp;II</b> – New Jersey, US  |
| 2002 - 2004 | <b>Master's degree in Experimental Health Science, Pharmacology-Toxicology</b> , INRS-Institut Armand-Frappier – Montreal, QC, Canada |
| 1995 – 1998 | <b>B. Sc., Biochemistry</b> , Université du Québec à Montréal, QC, Canada   |

## Work History:

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| 10/2020 – 07/2022 | <b>Senior Toxicologist</b> , Affygility Solutions  |
| 10/2019 – 10/2020 | <b>Associate Toxicologist</b> , Affygility Solutions <ul style="list-style-type: none"><li>• Perform Toxicological Evaluations of API including the determination of OEL and ADE/PDE</li><li>• Occupational Health Classification of API</li></ul>   |
| 03/2018 – 10/2019 | <b>Toxicologist</b> , Continuous Improvement Team, Cambrex – Mirabel, Canada <ul style="list-style-type: none"><li>• Develop an Industrial Hygiene Program - Participate in authorities audits related to the industrial hygiene and the prevention of cross-contamination</li><li>• Perform Toxicological Evaluations of API including the determination of OEL and ADE/PDE - Control-banding classification of new molecules in the pipeline</li><li>• Perform a corporate risk management plan for the prevention of cross-contamination and follow-up of the actions to be implemented</li></ul> |

- Writes and updates safety data sheets (SDS) for finished products
- Perform Health Risk Assessment for products manufactured and/or packaged by Cambrex for which a contamination may affect the product safety
- Perform the investigation following the observation of a deviation or a non-conformity event
- Lead actions plans to follow the investigation for continuous improvement of production activities
- Implement CAPA following the investigation

08/2017 – 03/2018

**Specialist Investigation**, Production Support, Pharmascience Inc. – Montreal, Canada  
(on half-time duty with toxicologist position)

- Perform the investigation following the observation of a deviation or a non-conformity event
- Lead actions plans following the investigation for continuous improvement of production activities
- Implement CAPA following the investigation
- Participate in authorities audits related to production supports and industrial hygiene

01/2015 – 03/2018

**Toxicologist**, Industrial Hygiene Team, Pharmascience Inc. – Montreal, Canada

- Develop an industrial hygiene program
- Perform Toxicological Evaluation of API including the determination of OEL and ADE/PDE
- Lead discussions regarding containment requirements for pharmaceutical product manipulation, including Active Pharmaceutical Ingredients (API's)
- Lead round table discussions when potent API products are introduced
- Collect data and issue recommendations on pharmaceutical and chemical product handling
- Efficiently communicate results concerning exposure levels, risks, and appropriate control measures
- Develop creative state-of-the-art approaches to assess and implement industrial hygiene and occupational health & safety solutions
- Develop corporate standards, policies, or procedures, where applicable, within the industrial hygiene field of expertise, in compliance with current regulations

- Identify methods to reduce risks at source. Develop and implement corrective measures to control risks to employee health; provide appropriate training
- Ensure regulatory compliance within the IH field of expertise and maintain relevant records and documentation
- Assess the relevance or adequacy of individual protection equipment or dust reduction and containment measures
- Responsible for safety measures (drug manipulation/handling document)
- Control-banding classification of new molecules in the pipeline
- Writes and updates safety data sheets (SDS) for finished products
- Support, when required, the process of Health Risk Assessment for products manufactured and/or packaged and/or distributed by PMS

06/2013 – 01/2015

**Lead Specialist, Drug Hazards Unit, Medical and Scientific Information & Drug Safety, Pharmacia Inc. – Montreal, Canada**

**Control-Banding Project**

- Establishment of the control-banding comprehensive occupational health program at PMS
- Hazard communication system establishment, safety measure presentation revision, training, and communication plan
- Control-Banding Classification and assessment of airborne acceptable concentrations (OEL) for PMS manufactured and packaged products
- Banding categorization of every raw material

**Supervision of the Drug Safety Assessment Associate/Specialist**

- Including interview, training, and supervision

**Toxicological Evaluation and ADE determination for Cleaning Validation**

- Following standard operating procedure and cleaning validation matrix; provide ADE and physico-chemical parameters

**Safety Measures**

- Performs safety evaluations for products to be evaluated at the Portfolio meetings
- Support to the Drug Safety Associate/Specialist in the creation and updates of Safety Measures (SM) for products handled at PMS, PendoPharm and third party according to business needs

- Provides safety related information as needed on products in development or handled by PMS personnel

#### **SDS (Safety Data Sheet)**

- Support to the Drug Safety Associate in the creation, request and updates of Safety Data Sheets (SDS) that are required by law for finished products (PMS, PendoPharm and third party) according to business needs. Adoption of GHS
- General administrator of the MSDS Online database (raw materials): document reception, request, and updates and, employee access management

#### **Medical Health Risk assessments**

- Part of the Health Risk Assessment team to conduct risk assessment for PMS, PendoPharm and third-party raw materials, finished products, packaging materials

#### **Technical document preparation/reviews**

- Reviews or edits scientific content of documents to support internal clients
- Collaborates in writing and reviewing SOPs and WIs relevant to Safety, Health & Safety and Communication Process for safe planning, manipulation, storage, and transportation of PMS and Pendopharm products

06/2010 – 06/2013

**Drug Safety & Medical Information Associate/Specialist, Pharmascience Inc. – Montreal, Canada**

- First point of contact with clients therefore evaluates calls and use scientific competences to comprehend queries and requirements for response
- Searches various medical and scientific literature / tools at disposition in order to retrieve information
- Understand evaluate and assess validity and value of query information retrieved and summarizes this according to requestor's need
- Responds to and records external/internal medical information queries and their follow-ups in the Medical & Scientific Information electronic database
- Summarize and communicates information to clients (verbally or in written) with a customer focused approach
- Creates and updates Safety Measures (SM) for products handled at Pharmascience, PendoPharm and third party.
- Performs safety evaluations for products to be include in pipeline

- Provides safety related information as needed on products in development or handled by PMS personnel
- Creates/request and updates Safety Data Sheets (SDS) that are required by law for finished products (Pharmascience, PendoPharm and third party)
- Prepares SDS for products not required by law on request and manage SDS internal database
- Conducts Medical Health Risk Assessment
- Reviews or edits scientific content of documents to support internal clients (marketing, regulatory affairs...)
- Creates/updates standard letters, product information sheets and other scientific documents for Medical Information as needed
- Collaborates in writing and reviewing SOPs

09/2008 – 06/2010

**Clinical Trial Assistant, Quintiles Canada Inc**

- Maintain clinical tracking systems
- Assist in the preparation and distribution of clinical documentation and reports such as correspondence, status reports
- Serve as a central contact with the sites
- Assist with distribution of Clinical Trial Supplies and maintenance of tracking information
- Assist with management of Case Report Forms (CRFs) and clinical data flow
- Assist with filing and other activities as directed by CRA and agreed by the CTL/PM

04/2008 – 09/2008

**Quality Assurance Specialist, GlaxoSmithKline Canada – QC, Canada**

- Responsible for assuring the quality of manufactured products in compliance with all applicable regulations and guidelines
- Responsible to maintain the quality system by reviewing and investigate deviation to procedure
- Review of master production documents

01/2006 – 12/2006

**Drug Safety Assistant, Novartis Canada – QC, Canada**

- Handle, review, report and process all serious and non-serious adverse events and maintain SAE information in the database
- Handle, review, report and process all serious adverse events from foreign post-marketed products
- Code SAE designation according to Med DRA

- Communicate details of any serious adverse events that are reported
- Summarize reports for submission letters to Regulatory Agencies
- Request, track and process follow-up information and queries with the reporter to capture additional relevant data and changes requested by the medical advisor

2005 – 2006

**Stage** in the clinical research laboratory, Dr Jean-Pierre Hallé, Maisonneuve-Rosemont Hospital – QC, Canada

- Receive patients, prepare cases, complete clinical records and data entry (CRF), filing, preparing mailings laboratories, responding to queries, order the materials, screening of patients, phones recruitment.

1998 - 2000

**Clinical Research Assistant** in the Laboratory of Hereditary Breast and Ovarian Cancers, CRCHUL, Laval University – QC, Canada

- Receive Patients
- Establish contacts with various hospitals
- Obtaining the consent of the patient in accordance with the various ethical committees
- Complete clinical records (CRF)
- Analyze pathology reports
- Coordinate and manage the laboratory analysis and the monitoring of patients
- Establish a computerized database allowing coordination and the proper functioning of the project

1998

**Stage** in the Laboratory of Hereditary Breast and Ovarian Cancers, CRCHUL, Laval University – QC, Canada

## Strengths:

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- Sociable and strong presenter
- Multi-skilled
- Attention to details
- Good team spirit and aptitude to work in groups
- Can easily adapt to changing situations and environments
- Strong learning capabilities
- Good sense of organization

**Skills:**

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Strong knowledge of:

- French (Bilingual French/ English)
- MS Software (Word, Excel, Access, Power Point, Outlook), Internet

**Awards and Honors:**

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|-------------------|--|
| 11/2003           | Recipient of student travel award from the Society of Environmental Toxicology and Chemistry                                     |
| 09/2003 – 09/2005 | Recipient of scholarship from the Armand-Frappier Foundation   |
| 06/2013           | Recipient of Scientific Affairs Honors for Outstanding Result  |
| 06/2014           | Recipient of Scientific Affairs Honors for Out of the Box Thinking   |
| 06/2016           | Part of the final Nominees (10/1500 employees) for the Trophy Torch Bearer for the employee representing the best the PMS values |