Cristina Épure, Bsc, ERT

Toxicology Program Manager, Bsc, ERT

Executive Summary:

Bachelor's Degree in microbiology & Immunology-Highly experienced in Quality Assurance, Industrial Hygiene and risk assessment, medical information, and cleaning validation– more than 9 years in the pharmaceutical industry and medical devices.

Education:

05/2010 **University de Montréal B.Sc.**, Microbiology & Immunology

Work History:

07/2022- Present **Toxicology Program Manager,** Affygility Solutions

01/2020-07/2022 **Associate Toxicologist,** Affygility Solutions

09/2019 – 12/2019 **Team Lead,** Amaris Inc., Senior Quality Consultant, Delta Pharma Inc. – Montreal, QC

- Collaborated in the approval and closure of note to files and minor deviations
- Attended investigations meetings as the Senior quality consultant
- Contributed to keeping up to date deviations management procedures
- Redaction of standard operational procedures (SOPs) and Work Instructions (WIs)
- Ensured problem documentation and verification of corrective actions
- Collaborated with cross-functional teams to track CAPAs.
- Collaborated with production personnel in the process of effective investigations.
- Evaluated investigations and CAPA's to identify areas of opportunity for improvement.

03/2018 – 05/2019 **Team Lead,** Amaris Inc., Quality Consultant, Zimmer CAS – Montreal, QC

- Participated in the development of risk analysis.

- Reviewed and identified the IQ, OQ, PQ, process validation documents of Zimmer CAS suppliers.
- Managed, tracked, and trended all supplier's cleanroom monitoring data.
- Coordinated onsite visits with suppliers to assess the quality documents.
- Wrote and executed protocols and test reports.
- Ensured problem documentation and verification of corrective actions.
- Ensured Traceability between the requirements and design results.
- Written summary documents for product verification and validation.
- Promoted verification and validation practices at the forefront of the industry to achieve reliability and quality of product above standards, allowing the enterprise has to maintain its reputation and remain the reference in the industry.
- Stayed on the lookout for advanced technology in the field.

05/2016 – 03/2018 **Associate, Industrial Hygiene and Toxicology,** Pharmascience – Montreal, QC

- Established the control-banding comprehensive occupational health program at Pharmascience (in collaboration with EHS, Production and Engineering teams).
- Implemented the Hazard communication system, safety measure presentation revision, training, and communication plan.
- Provided toxicological Data and ADE determination for Cleaning validation team.
- MSDS (Material Safety Data Sheet) Redaction • Part of the Health Risk assessment team to conduct risk assessments for Pharmascience, Pendopharm, and third-party raw materials, finished products, packaging materials.
- Reviewed or edited scientific content of documents to support internal clients.
- Provided safety related information as needed on products in development or handled by PMS personnel.

- Wrote and reviewed SOPs and WIs (work instructions) relevant to Safety and Communication process for safe planification, manipulation, storage, and transportation of Pharmascience and Pendopharm products.
- Developed and conducted air sampling campaigns in order to evaluate employee exposure to occupational hazards.
- Industrial Hygiene Project Management.
- Good knowledge of HC GMP, EMA/ ICH guidelines and RiskMapp.

05/2015 – 05/2016 **Specialist, Cleaning Validation,** Pharmascience – Montreal, QC

- Developed Cleaning Validation protocols and reports according to the appropriate SOPs.
- Performed Cleaning Validation assessments for each product and corresponding equipment train including determination of Acceptance Criteria.
- Executed Clean and Dirty Hold Time studies for process equipment.
- Analyzed data associated with validation reports.
- Determined product contact surfaces areas and swab points for process equipment.
- Maintained the cleaning validation matrix as projects transition from development to commercial scale batches.
- Investigated Out-of Specification results and determined necessary CAPA.

04/2013 – 04/2015 **Associate, Medical Information and Drug Safety,** Pharmascience – Montreal, QC

- Participated in the establishment of the control-banding comprehensive occupational health program at Pharmascience (in collaboration with EHS, Production and Engineering teams).
- Participated in the Hazard communication system establishment, safety measure presentation revision, training, and communication plan.
- Provided toxicological Data and ADE determination for Cleaning validation team.
- MSDS (Material Safety Data Sheet) Preparation.

- Part of the Health Risk assessment team to conduct risk assessments for Pharmascience, Pendopharm, and third-party raw materials, finished products, packaging materials.
- Reviewed scientific content of documents to support internal clients.
- Collaborated in writing and reviewing Standard operating procedures (SOPs) and WIs (work instructions) relevant to Safety and Communication process for safe planification, manipulation, storage, and transportation of Pharmascience and Pendopharm products.

06/2011 – 03/2013 **Associate, Medical Information and Product Complaints,** Pharmascience – Montreal, QC

Medical Information Queries

- First points of contact with clients therefore evaluate calls and use scientific competences to comprehend queries and requirements for response.
- Searched various medical and scientific literature/tools at disposition in order to retrieve information.
- Understood, evaluated, and assessed validity and value of query information retrieved and summarizes this according to requestor's need.
- Responded to and recorded external/internal medical information/ pharmacovigilance (PV) queries and their follow-ups in the Medical & Scientific electronic database.
- Summarized and communicated information to clients (verbally or in written) with a customer focused approach.

Customer complaints

- Utilized scientific competencies to evaluate quality complaint and determine relevant/necessary questions.
- Collected documents and records customer complaints linked to the quality of a product in Medical Information electronic database.
- Submitted credit requests when applicable to Credit department.
- Followed up complaint investigations with customers and appropriate departments.
- Recorded follow-ups in Medical Information electronic database.

- Analyzed final investigation reports issued by QA to ensure that conclusion of report and any corrective actions respond to the subject of the complaint and are appropriate.
- Used scientific expertise to assess the consequence of complaints and gave visibility concerning potential corporate impact to appropriate departments.
- Ensured that all activities are in line with regulatory authority guidelines and for audit purposes maintained hard copy of all documentation and communications up to date for each complaint files.
- Managed multiple priorities and skill sets while using scientific knowledge to prioritize tasks.
- Accountable to ensure that processes and course of actions related to a complaint are followed and each complaint has an appropriate and timely solution.

08/2010 – 05/2011 **Laboratory Technician**, GSK (GlaxoSmithkline) – Laval, QC

Alternative Vaccine Delivery Group

- Elisa Tests in the department of research in Immunology.
- Analysis of the results.
- Good knowledge of GLPs.
- Microsoft Office.
- Microtome trained.
- Softmax pro 4.8
- GraphPad (Prism).
- H&E Staininig.

06/2009 – 08/2010 **Laboratory Technician,** Pharmaprix – Montreal, QC

- Used LabExpert as a program to register prescriptions.
- Prepared prescriptions/medications for patients.
- Used and maintained laboratory equipment.
- Prepared magisterial.
- Prepared equipment orders and all necessary products for laboratory to be operational.

- Following the pharmacist directives and under his supervision done all necessary follow ups with patients.

05/2008 – 05/2009 **Experience Related to my University Degree**

Microbiology Laboratory Stagier.

As part of the initiation to research course being a laboratory analyst. Performed antibacterial analysis from biguanides tested from different bacterial souches. (Mg 1655 of E. coli, Pseudomonas Aeruginosa, Bacillus subtilis.) This analysis permits mainly to test biguanides resistance and sensibility. This research was conducted under the supervision of Professor Szatmari at Montreal University.

Tasks:

- Gelose, bacterial souches preparations.
- Keeping up to date results obtained from research project.
- Preparing electrophoresis gel.
- Presenting all research project results obtained in front of Dr. George Szatmari team on a weekly basis.

Training and Courses:

- ISO 13485: 2016 Lead Team Auditor Certified
- Completed Affygility Potent Compounds course
- ERT Certified

Highlights:

- Ability to quickly learn new concepts, applications and processes and transfer this knowledge to others.
- Strong organizational and administrative skills; ability to set priorities, detail oriented, excellent written and oral communication skills.
- Able to work independently or as a team player.
- Solicits knowledge, expertise and learn by listening to others.

Languages:

- Fluent in English, French, and Romanian

The Society of Toxicology

presents this

Certificate of Associate Membership

to

Cristina Epure

who is hereby entitled to all of the rights and privileges of membership
as provided in the Bylaws of this Association.

Committed to Creating a Safer and Healthier World by Advancing the Science and Increasing the Impact of Toxicology.

President

Executive Director

August 20, 2020
Join Date

SOT | Society of Toxicology

EUROTOX

This is to Certify that

CRISTINA EPURE

may use the title

ERT

EUROPEAN REGISTERED TOXICOLOGIST

whilst registered with the

PORTUGUESE

Register of Toxicology

Signature

May 15, 2023

Date

EUROTOX
Basle, SWITZERLAND