

PBE – Your partner in cGMP Compliance, Validation, Quality Assurance, Process & Facility Engineering

PROFESSIONAL EXPERIENCE

Process and chemical engineer with a Bachelor degree from Sherbrooke University and Master level courses in Engineering, concentration in International project management and global engineering. Mrs Lestage has more than 15 years experience in engineering, **QPIC**, research and development, batch release, SOP, validation of cleaning and processes & technical transfers (cGMP, CFR-21 part 210).

Furthermore, Marie-Eve’s various documents have successfully passed a general inspection without any observations from the FDA or Health Canada. Her experiences in Quality include the releases of numerous lots, CAPAs and SOPs redaction and revision, FDA and Health Canada audits, and numerous answers to inspections observations. She is a **Lean Six Sigma Green Belt**.

EMPLOYMENT HISTORY

2018 to date	Director of Projects, PBE, Laval, QC
2016 to 2018	Engineering consultant, Independant, Chateauguay, QC
2013 to 2015	Senior Process and Technical Transfert Engineer, Level II, Confab, St-Hubert, QC
2005 to 2012	Senior Validation and Technical Transfert Engineer, Valeant, Ville St-Laurent, QC
2004 to 2008	Microsoft Access Programmer, Ramonage Express/Men in Black, St-Edouard, QC
2003	Junior Process Engineer, Thona Canada ULC, Magog, QC
2001 to 2002	Junior Quality Engineer, H Power Enterprise Canada ULC, Magog, QC
2000	Microsoft Access Programmer – Research Assistant, Sherbooke University, QC
1999 to 2000	Chemical Engineer Internship, SNC-Lavalin Environment, Longueuil, QC
1998	Chemical Engineer Internship, Ultramar Refinery, St-Romuald, QC

**MARIE-EVE LESTAGE,
SENIOR PROCESS, TRANSFERT, QA, VALIDATION & PROJECT MANAGER**

MAIN PROJECTS

2018 to date **Director of Projects**
PBE, PHARMA BIO EXPERT INC., LAVAL, CANADA

- **LALCO**
 - Batch release services.
 - Quality assurance services.
 - SOP development.
 - Audit and cGMP compliance support for related Health Canada inspection.

2016 to 2018 **Engineering Consultant**

Multiple suppliers and third party manufacturing searches for different confidential clients.
Training

2013 to 2015 **Confab**

REDACTION AND REVISION OF TRANSFERT DOCUMENT: raw material and finished product specifications, Master Batch Records, Packaging Batch Records, transfert protocols, transfert reports, GAP Analysis.

REVISION OF VALIDATION DOCUMENTS: process, packaging and cleaning validation protocols and reports.

PROJECT MANAGEMENT: Raw material and packaging selection, project management plans, RACI, Gantt charts, meetings, internal and external communication, DMADV.

TRANSFERT PROJECT EXECUTION: Laboratory, pilot and full scale production, Manufacturing and Packaging followup of Validation and

QUALITY ASSURANCE: CAPA, Complaint analysis, Statistical Process Control, GAP Analysis, narcotics and controlled substances management as alternate.

SANDOZ, CANADA

Transfert project management for Anagrelide, vast cost reduction analysis project for all their products, adaptation of process for serialisation of batches filling of suppositories.

VALEANT, CANADA

Transfert Project Management for Zostrix and Zostrix HP, Canadian formulas.

MEAD JOHNSON, CANADA

Transfert Project Management for the packaging of Fer-in-Sol, Poly-vi-Sol and Tri-vi-Sol, for the Canadian, American and Mexican Markets. Cost reduction initiative for Expecta manufacturing process.

PRESTIUM PHARMA, USA

Transfert Project management for Vusion topical ointment manufacturing and packaging processes.

RENAISSANCE PHARMA, USA

Technical support in the transfert of production and packaging of Denavir ointment and mesalamine suppositories.

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YASOO, USA

AquADEKs chewable tablets formulation adjustments as per client requests before production.

WATSON, USA

Transfert project management for Diclofenac Sodium Topical Solution manufacturing and packaging processes.

2005 to 2012

Valeant Canada

REDACTION AND REVISION OF TRANSFERT DOCUMENTATION: raw material and finished product specifications, Master Batch Records, Packaging Batch Records, transfert protocols, transfert reports, standard operating procedure.

REVISION AND REDACTION OF VALIDATION DOCUMENTATION: equipment, process, packaging and cleaning validation protocols and reports.

PROJECT MANAGEMENT: plans, RACI, Gantt charts, meetings, internal and external communication.

QUALITY ASSURANCE AND CONTROL: CAPA, Complaint analysis, Statistical Process Control, release of validation and investigated batches, analysis of validation samples in quality control laboratory, redaction and revision of standard operating procedure and laboratory analysis methods.

REGULATORY AUDITS: War room personnel, technical representative for quick answer of high level managers in the meeting room, postaudit technical remediation of observations.

Daily production meeting with high level managers, regular production troubleshooter and technical investigator.

MANAGEMENT: Replacment Technical Service Manager, Replacement Technical Transfer Manager following successful training, technical transfer cost and feasibility evaluation for submission, narcotics and controlled substances.

LEAN SIX SIGMA: Green Belt training and certification, 5S projects, DMAIC, Value Stream Mapping, 5 Whys, Statistical analysis and fitting tools, Business process mapping, Cause and effect diagram, Control Charts, Design of Experiment, Pareto analysis, Process capability.

2004 - 2008

Ramonage Express and Ramonage Men in Black, St-Edouard-de-Napierville

MICROSOFT ACCESS PROGRAMMER

Database management system programmation for clients. Data entry and retrieval forms and query code.

2003

Thona Canada ULC, Magog

JUNIOR PROCESS ENGINEER

Research and Development of rubber formulations for automotive industry. Floor troubleshooter, daily production meeting.

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2001 - 2002 *H Power Enterprises of Canada, St-Laurent*

JUNIOR QUALITY ENGINEER

Research and Development of fuel cells residential co-generation units. Startup and testing before shipment. Training of personnel, technicians, engineers, managers and clients on operation of the units.

2000 *Sherbrooke University, Sherbrooke*

MICROSOFT ACCESS PROGRAMMER – RESEARCH ASSISTANT

UV rays fabric whitening simulation program, including a graphic representation of the intensity of the color in real elapsed time.

1999 - 2000 *SNC-Lavalin Environment, Longueuil*

CHEMICAL ENGINEERING INTERNSHIP

Sampling of Air and Noise.

1998 *Ultramar Refinery, Saint-Romuald*

CHEMICAL ENGINEERING INTERNSHIP

Supervision of a sampling project by a consulting firm of on-site chimneys.
Monthly, quaterly and yearly reports of waste water quality to Canadian government.
Yearly reports of air contamination to Canadian government.
Weekly sampling of washing towers and waste water and effluent.
Followup of laboratory testing and results.
Followup on groundwater quality.
Management of decontamination of soil after leaks in tank park.
Management of transportation of waste refractory bricks to Texas recycling facility.
Train engineers on Excel.

**MARIE-EVE LESTAGE,
SENIOR PROCESS, TRANSFERT, QA, VALIDATION & PROJECT MANAGER**

EDUCATION

2012 - 2014 *M. Eng., International project management and Global Engineering,*

ÉCOLE DE TECHNOLOGIE SUPÉRIEURE, MONTREAL, QC

2012 - 2014 *Short Program Second Cycle, Financial Engineering,*

ÉCOLE DE TECHNOLOGIE SUPÉRIEURE, MONTREAL, QC

2001 *B. Eng., Chemical Engineering,*

SHERBROOKE UNIVERSITY, SHERBROOKE, QC

1997 *Nature Sciences,*

COLLÈGE ANDRÉ GRASSET, MONTREAL, QC

ADDITIONAL TRAINING

Computer skills:

Microsoft Office: Word, Excel, Power Point, Visio, Project and Visual Basic

Chrome, Microsoft Internet Explorer, Puffin, Safari

Microsoft Windows, IOS

AutoCAD, SketchUp

Polymath, LabView, DasyLab, Coumpound, Simulink, Minitab, MathCad, Hysys, JD Edwards, DÉFI

Knowledge of Industry standards:

ISO 9001 / 14001, QS 9000 and TS 16949

GMP / GLP

SPC

FDA and Health Canada Norms

Controlled Drugs and Substances Act

Benzodiazepines and Other Targetted Substances Regulations

Narcotic Control Regulations

Precursor Control Regulations

Training courses:

2018 First Aid in the workplace, Groupe de Santé Langevin for CNESST

2017 Forensic Engineering, Level 3 engineering, The Open University

2015 Quality by Design

2014 Technological transfert

**MARIE-EVE LESTAGE,
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- 2009 Technological Transfert Substitute Manager
- 2006 Green Belt Training and Certification, Valeant Canada
- 1997 ASP Construction, Health and Safety on construction sites, CSST

PROFESSIONAL ASSOCIATIONS

- 1998 to 2017 : Ordre des ingénieurs du Québec (P.Eng.Quebec)
- 2018 to renew

LANGUAGES

- French, English

NATIONALITY

- Canadian

