



## MEMORANDUM

Projet :  
Nom :  
Objet :  
Date : 2020-02-03

### PBE Expert Inc

PBE-Expert Inc. is a leading Consulting Canadian company in manufacturing industries, compliant with FDA / Health Canada, Europe EU-GMP/cGMP requirements applied to Pharmaceutical, Biotechnology, Nutraceutical, cannabis and Foods industries.

PBE-Expert Inc. involves skilled resources such as Health Canada & MAPAQ Experts, having more than 25 years of experience in process engineering, with +300 projects meeting the cGMP of FDA, EMA & Health Canada and the standards, ASME-BPE, ISO-14644, ISO13485, FDA-820 and others with the most recent completed projects are the following: Endoceutics Canada project (Vaginal ovules, 2017), GreenCross / Bosch Canada (Blood Plasma Fractioning, 2016-2017), WFI and POU Qualification, Vetoquinol, Liberté, Nuvac, Biena, Trans Herb, etc.

We provide at least the following services:

- ✓ Pharmaceutical Facilities Design
- ✓ Clean Utilities and Pharmaceutical systems
- ✓ Process Engineering 'ASME-BPE'
- ✓ Layouts development and Technical Specifications
- ✓ cGMP Compliance Audit PAI & training
- ✓ C&Q Validation & Maintenance, including Validation Master Plan, Qualifications SOP, Risk Analysis Assessment, Redaction of protocols, execution of qualification protocols, Final report, Development of critical parameters and process, Cleaning Validation, Process Validation, Sterilization cycles Validation.
- ✓ Quality Assurance and Regulatory affairs

**PBE**, Your cGMP Process & Facilities Engineering Partner  
**PBE**: Process, Building & Engineering



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### Our Experts:

Our experts are specialised in different fields. Please find our skilled team resources resumes:

- Engineering and Validation Director: **François Goupil, PEng**, Process and chemical engineer with a Bachelor from University Laval in Quebec City. Mr Goupil has more than 25 years experience in engineering, automation, validation of manufacturing equipment, clean utilities, pharmaceutical systems and computer systems (cGMP, GAMP5, CFR-21 part 210, 211, 11). Furthermore, Francois CSV validation documents have successfully passed a general inspection without any observations from the FDA. Specific software or system: Network Infrastructure, JD Edwards ERP, Empower chromatographic data, building monitoring system, data historian, Siemens PLC.
- Engineering and GMP Compliance Director: **Aziz Chraibi, PhD, PEng, PBE's Managing Director**. Dr. Chraibi has more than 25 years experience in process, Layout and facility engineering as well as in validation. In 2007, He is **Health Canada Expert** & in 2018 registered a **MAPAQ Expert**. He designed and led successfully many pharmaceutical & Cannabis projects from the design, construction, validation till Pre-Approval Inspection: Endoceutics, Greencross/Bosch, Ipsen, OM Pharma, Pharmascience, Aguetant, Pfizer, Steris, Merial, Cephalon, Sandoz, Galderma, Merial, Biocean, Laboratoire Giroux, BD, Zenith Pharma, Axcan, Aptalis, Biosyntech, Confab, Galenica, Pharmaderm, Lise-Watier, Fruit & Passion.
- Validation Director: **Annick Patenaude** has several years of expertise in qualification/validation. She worked as a qualification/validation specialist in the pharmaceutical industry where she took up many challenges including the qualification of equipment and systems, process validation, corrective actions management, procedures and activities coordination. She was nominated as Quality Systems Associate and qualified responsible person for controlled substances at Confab. At Sterigen (sterile facility), she was in charge of the validation and metrology department. At PBE Expert, she was responsible for process and cleaning validation and equipment qualification. She was involved in the design, URS (production and process equipment) for medical cannabis as well as in the Licensing process from Health Canada & EU-GMP.
- Validation Manager: **Liliana Arias Giraldo** Liliana has more than 10 years of experience in pharmaceutical Validation field, manufacturing equipment, sterilization and packaging. She has a very good knowledge of Canadian (BFP) and American (FDA) regulations for equipment validation. Liliana has excellent analytical skills and good command of the office suite (Excel, Word, Power Point, low data, etc.). In addition, she has extensive experience in project planning. In addition to having very good communication skills, she also has skills to prioritize, to demonstrate a good autonomy, a sense of organization and a team spirit.
- Validation and Process Specialist: **Charlene Wang** has a bachelor's degree from Polytechnic University in chemical engineering.