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

**Aziz CHRAIBI, PhD., PEng.**
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PAI, c-GMP Compliance Design & Audit
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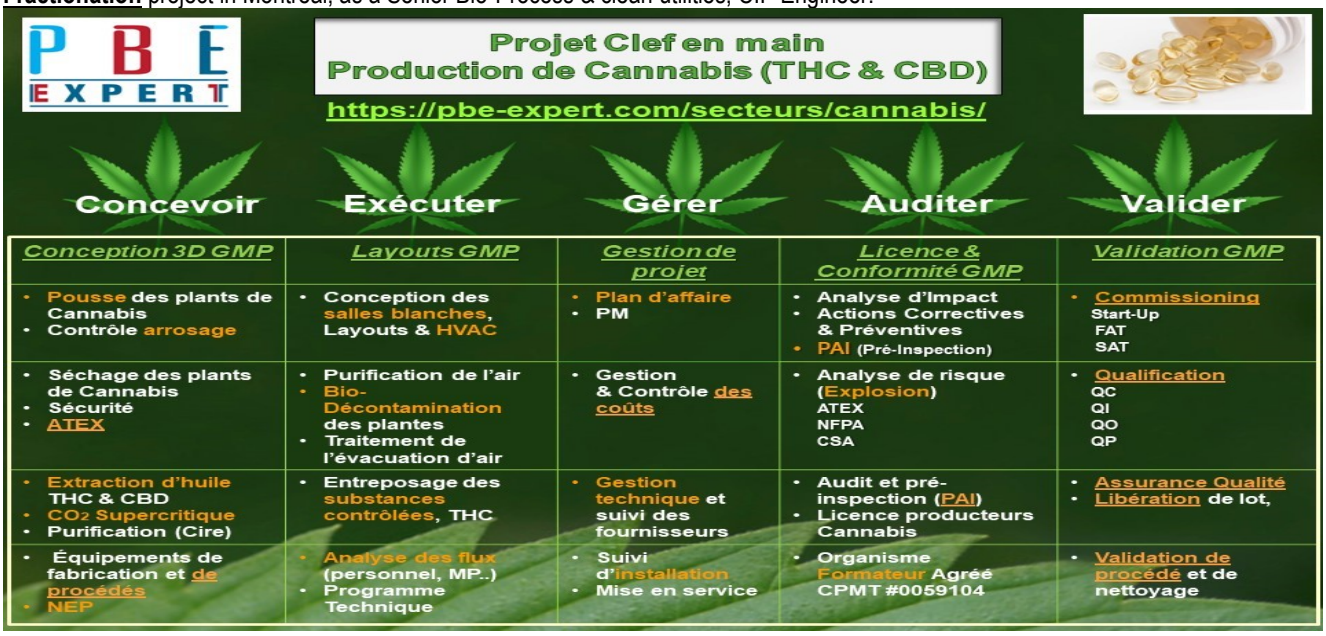
## PROFESSIONAL EXPERIENCE

Dr. Aziz Chraibi, is a professional chemical and process engineer, who has more than 25 years experience in consulting (**PBE**, **SNC Lavalin** Pharma & **Validapro** Inc.) involving in **EPCMV** projects related to **Cannabis**, **pharmaceutica**l, **biotechnology**, Blood **Plasma** fractionation, Morphine, API, Healthcare, Foods, cosmetics and Nutraceuticals cGMP facilities engineering design, procurement, installation, construction projects management, commissioning, validation, PAI, Audit, and maintenance as well. Since 2007, He was registered **as HEALTH CANADA EXPERT**. From 2018 He was registered as **MAPAQ EXPERT** (Food Inspection) and a **certified CPMT trainer** (**Agreement #0059104**) in Quebec.

He is skilled in the facility design involving clean rooms (ISO14644), pharmaceutical Facility systems (HVAC, HEPA filters, Bag In / Bag Out, access cards, doors electrical interlock), sanitary process equipment and clean utilities (PW, WFI, Pure Steam, Process Compressed Air, N2, …) and in **Cannabis** from Growth, **CBD & THC Extraction (Supercritical CO2 Technology and Supply)** till compounding in nutraceutical, pharmaceutical or foods final good forms **https://pbe-expert.com/en/sectors/cannabis-en/**, in compliance with the c-GMP regulations of Canadian and European, as well as US- FDA (21CFR parts 210, 211, 11), EMA, ICH, NFPA, ATEX, OSHA, HSE, ISO14644, ASME-BPE & USP797.

Accordingly, he oversaw many projects involving approximately 30 engineers and specialists, and he developed expertise in design and project management of over 50 biotech and pharmaceutical facilities (of 20 K$ until 30 M$ of capital cost), dedicated to aseptic fill and finish for sterile injectable and hazardous products, such as biological (BSL2, BSL3), high active and potent chemical products (level 3 and 4 according to Safe Bridge Standard), as well as API production involving flammable solvents (Class 1 & 2) and explosive dust accordingly with related standards, NFPA -30, NFC, CNPI-2010, ATEX, and applicable provincial HSE/OSHA codes as well.

He has experience in projects involving facility & construction project management, conceptual design, basic and detailed engineering, commissioning, benchmarking, FAT, installation, start-up, SAT, qualification, HSE issues management, risk assessment and mitigation measures by means of FMEA, ICH Q9 standards. In 2016, I was involved with **Bosch** company in **GreenCross Blood Plasma Fractionation** project in Montreal, as a Senior Bio-Process & clean utilities, CIP Engineer.



| https://pbe-expert.com/en/our-experts/azis-shraibi-en/ | |
|---|---|
| **Professional Experience** | **Expertise & Skills** |
| 2018: Directeur Engineering & Compliance, PBE CANNABIS Expert Inc. | Cannabis from Growth, CBD & THC Extraction (Supercritical CO2 Technology and Supply) till compounding in nutraceutical, pharmaceutical or foods final good forms : https://pbe-expert.com/en/sectors/cannabis-en/ |
| 2018: MAPAQ consultant qualified under measure 2 of the Levier program | Sanitary design. |
| 2018: Trainer approved by the CPMT (Approval #0059104). | Clean room design & HVAC. |
| 2013: President, PBE, Pharma Bio Expert Inc. | Integration of pharmaceutical systems. |
| 2012: Independent Consultant, Pharma Bio Expert. | Process engineering (ASME-BPE). |
| 2011: Project Director, Head of Engineering & Processes, SNC Lavalin Pharma. | Layouts development. |
| 2009: Assistant Director CRIP Biorefinery (École Polytechnique de Montréal). | Construction Project Management, Turnkey factories (EPCMV). |
| 2002: Member of the Ordre des Ingénieurs du Québec #125184. | GMP regulatory compliance audit. |
| 2001: Engineering Director Validapro Biosciences Inc. (Laval, Canada). | Commissioning, FAT, SAT. |
| 2000: Technical, Engineering, Maintenance, Production Director, Baltimar, Groupe Richbond. Morocco | HACCP, ISO-22000, GFSI, SQF certification. |
| 1997: Packaging, Flow, Quality systems, Laboratory Supervisor, Cosumar, ONA Group, Morocco | Pre-Approval Inspection (PAI). |
| 1991: Process Engineer, Cosumar, ONA Group, Morocco | Technology transfer & Training: Trainer Approved by CPMT#0059104. |

**2012-2018** **PBE,** Pharma Bio **Expert Inc. Montreal, Canada** (www.pbe-expert.com; www.pharmabioeng.com)
**Président, SME= Subject Matter Expert, EPM=Engineering Design & Project Management**

- Many assignments as a freelance consultant were conducted, involving GAP assessment and analysis, cGMP compliance & design review, conceptual design, basic (BOD) & detailed engineering design (DED), training, (invited speaker) for facilities, sanitary process equipment, clean utilities, and pharmaceutical and Facility systems:

- *Endoceutics, Aptalis (**EPCMV, SME**), Canada, 2016-17*
- *CUSUM Hospital, (**Audit, SME**), Canada, 2017*
- *Bosch, Pharmatech (**EPM, SME**), Canada, 2016*
- *Silicycle, (**Audit, SME**), Canada, 2017*
- *Prestige, Searchlight (**QA, SME**), Canada 2014-2015*
- *Laboratoires Confab, (**EPM, SME**), Canada, 2012-2013*
- *GASCO, (**Audit, SME**), Canada, 2013-2015*
- *Corealis Pharma, (**EPM, SME**), Canada, 2014-2015*
- *Prodoc, Laval, (**Audit SME**), Canada, 2014-2015*
- *Zenith Pharma, (**Audit, SME**), Morocco, 2014-2015*
- *Cooper Tunisie (**SME, Audit**), 2014, 2015Cooper Pharma, (**Audit, SME**), Morocco, 2014-2015*
- *Sothema, (**Audit, SME**), Morocco, 2014-2015*
- *Galenica, (**Audit, SME**), Morocco, 2013-2015*
- *Pharmagreb (**Audit, SME**), Tunisia 2015*
- *Teriak, (**EPM, SME**),Tunisia, 2013-2015*
- *Medicef, Hikma, (**EPM, SME**), Tunisia, 2014-2015*
- *Medis, (**Audit, SME**), Tunisia, 2014-2015*
- *Unimed, (**EPM, SME**), Tunisia, 2013-2015*
- *Pharmaderm, (**EPM, SME**), Tunisia, 2013-2015*

### ***Endoceutics, Montreal, Canada (2016-2017)*** — ***Sr. Process & Facility Engineer:***

- EPCMV Turnkey project of new vaginal ovules manufacturing facility & VMP.
- Process Skids design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system loop expansion design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573) URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- HVAC, BIBO systems design, detailed engineering, commissioning, FAT, SAT and validation.
- Layout design, detailed engineering, commissioning, FAT, SAT and validation.
- Differential Pressure Cascade and Cleanrooms classification, HVAC Zoning.
- Fat trap design, URS.
- Electrical & Mechanical Backup systems.
- Material, energy and waste balance and optimization.

### **GreenCross / BOSCH Blood Plasma Fractionation**, Montreal, Canada (2016-2017) ***Sr. Process & Facility Engineer***:

- Design Review and cGMP compliance design of process engineering of thawing & pool skids.
- Review and develop of updated technical specifications and drawings for:
- PLASMA THAWING SKIDs.
- CIP Skid.
- Clean Utilities production units & distribution of Pure Steam, Purified Water, WFI.
- Project meetings follow-up.
- FAT, SAT, IQ, OQ protocols development.
- Trace Matrix development.
- Process equipment and clean utilities
- Systems delivery, reception, onsite works supervision & PM.
- Installation follow up.
- SAT, IQ, Onsite execution.

### ***CUSUM Hospital, Montreal, Canada (2016-2017)*** — ***Sr. Process & Facility Engineer:***

- Purified water unit design review and gap analysis according to ASME-BPE & cGMP.
- Corrective actions proposal according to ASME-BPE & cGMP related to PW generation unit, PW Storage tank and PW Distribution Loop.

**2011-2012** **SNC-LAVALIN INC., Montreal (Québec) Canada** (www.snclavalin.com)

**Project Manager & Senior Biopharmaceutical Engineer, SNC-Lavalin Pharma**



- *Pillar5Pharma, Ottawa, Canada (2012)*
- *Sandoz, Boucherville, Qc, Canada, (2011-2012)*
- *Galderma, Baie d'Urfé, Canada (2011)*
- *Pfizer, Montréal, Qc, Canada (2011-2012)*
- *Novartis, USA, (2011-2012)*
- *Johnson & Johnson Inc., Canada (2011)*
- *Pharmascience, Montréal (Qc) Canada (2011)*
- *Laboratoires Confab, St-Hubert, Canada (2011)*
- *AstraZeneca, Montréal (Québec) Canada (2011)*
- *Piramal Healthcare, Laval (Qc) Canada (2011).*
- *Church & Dwight & Groupe Parima, Canada (2011-2012*

### ***Pillar5Pharma, Ottawa, Canada (2012)*** — ***Sr. Process & Facility Engineer:***

- Upgrading and regulatory compliance study, development of a (Layout) and economic evaluation the existing sterile large volume filling unit under (RABS).

### ***Sandoz, Boucherville, Canada, 2011-2012*** — ***Sr. Facility Engineer:***

- Management of several CAPA projects, HVAC system Design & Engineering, replacement of water chillers, installation of a ceiling above several conditioning rooms, improvement of the air quality at three warehouses and in a microbiology laboratory…

### ***Galderma Production Inc, Baie d'Urfé, Canada (2011)*** — ***Sr. Process Engineer:***

- Feasibility study to install a centralized detergent tank and cost estimate to move production from 77,000,000 to 14,000000 capsules/year.

### ***Pfizer, Montréal, Canada* (2011-2012)** — ***Sr. Facility Engineer:***

- Modification of mechanical & electrical B-17 warehouse systems. Detailed design engineering and technical specifications for HVAC system upgrade, mechanical engineering, fire protection, and electrical work of the warehouse. Assessment of the structural load of the slab to install a 'Racking System - Push-back'.

### ***Pharmascience, Montreal, Canada* (2011)** — ***Sr. Process Engineer:***

- Technical specifications of a sanitary heat exchanger for purified water.
- Optimization study of the pump pressure and flow rate of the purified water loop.

### ***Laboratoires Confab, St-Hubert, Canada* (2011)** — ***Sr. Process Engineer:***

- Plans and technical specifications for a CIP cleaning system in a place dedicated to the washing of three production and storage tanks (PFD, P&ID, technical specifications, SDS).

### ***AstraZeneca, Montreal, Canada* (2011)** — ***Sr. Process Engineer:***

- Technical and economic study of the installation of a cage washer.

### ***Piramal Healthcare, Laval, Canada (2011)*** — ***Sr. Process & Facility Engineer:***

- Improvement study of a line of encapsulation of sterile products.

### ***Church & Dwight Canada & Groupe Parima, Montréal, Canada, 2011 & 2012*** — ***PM:***

- Regulatory compliance study (NFPA30, CNPI-1995, CSAC22.10-10, HSE, RRQ,c.S-2.1,r.19.01, CCQ-c.V) for the use of flammable alcohol at the production level.

**2009-2011** **École Polytechnique de Montréal., Montreal, Canada** (www.biorefinery.ws)
**Deputy Director, CRIP Biorefinery Center**

**2001-2008** **VALIDAPRO BIOSCIENCES INC., Laval (Quebec) Canada** (www.validapro.com)

### Director, Facility Systems and Process Engineering

- Supervision of 6 to 15 engineers and management of more than 30 Biopharmaceutical projects from $20K to $30K (Lists of projects provided below);

### *Fruits & Passion, Québec, Canada, 2008*

- Develop URS, plans and specifications for an HVAC system, A USP purified water unit and mixing tanks for the manufacture of cosmetics.

### *Laboratoires Renaudin, France, 2008*

Design a new construction plan & URS compliant with GMP/EMA regulatory requirements for the preparation and filling of sterile products.

### *Aguettant, Lyon, France, 2008*

- Regulatory compliance audit, sanitary design study and review of technical specifications for the PW and WFI high volume production plant.

### *Becton Dickinson, France & Hongrie, 2007-2008*

Design a sterile production unit of a highly toxic OSD formulation (level 3).

### *Ipsen Beaufour, Dreux, France, 2005-2007*

- Design two production Facility dedicated to High Potent OEL3 sterile injectables (according to Safebridge) in an aseptic environment (ISO 5 A) and High Potent OEL5 (OSD) tablets (according to SafeBridge).
- EPCMV Turnkey project of the new facility & VMP.
- Process, production equipment and Isolators design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system (generation, Storage, Distribution loops) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573) URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- HVAC, BIBO systems design, detailed engineering, commissioning, FAT, SAT and validation.
- Layout design, detailed engineering, commissioning, FAT, SAT and validation.
- Differential Pressure Cascade and Cleanrooms classification, HVAC Zoning.
- Electrical & Mechanical Backup systems.
- Material, energy and waste balance and optimization.

### *DBI, Idron, France, 2006-2007*

- Technical feasibility and economic studies of a new 'CMO' pharmaceutical production unit dedicated to highly toxic and BSL2 products.

### *Cephalon, France, 2007*

- Review the design, plans and specifications, URS of a lyophilizer. Design a sterile tablet formulation packaging line, tender analysis and recommendation.

### *Pierre Fabre, Aignan, France, 2007*

- Design a new sterile production Facility of Nicogel in accordance with GMP (EMA) and (FDA) for the preparation and filling of products as well as tablets (OSD).

### *Bausch Lomb, France, 2007*

- Develop URS, plans and specifications for a new USP purified water system as well as the risk analysis study according to FMEA.

### *Prodoc, Laval, Canada, 2006-2007*

- Design, consult with suppliers, monitor the installation and qualification of a pharmaceutical compressed air system. 75 HP compresssor, according to ISO 8573-2-2-2.
- Validation of clean compressed air.
- Design of a new printing equipment, layout, cleanroom, MAL, PAL, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.

### *Biovex (CMO), Montréal, Canada, 2005*

- Design the layout to produce a BSL2 / P2 / ISO8 vaccine for a CMO.

### *Merial, Toulouse, France, 2005*

- Design a new Humid granulation unit for products using flammable and ATEX explosive solvents.
- Develop URS and risk analysis according to FMEA.
- Detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.

### *Laborium Inc. (CMO), Montreal, Canada, 2004-2007*

- Design layout and BOD to produce BSL2 / P2 / ISO8 vaccines for a CMO.

### *Biosyntech, Laval, Canada, 2004-2007*

- Review of regulatory compliance design for aseptic sterile injectable products.

### *Pfizer Global Manufacturing, Amboise, France, 2005*

- Study the design review and its qualification (DQ) for two new (two-door) autoclaves installed in the wash and aseptic production area respectively.

### *Laboratoire Denis Giroux, St-Hyacinthe, Québec, Canada, 2005*

- Design sterile injectables, BSL2 products, highly toxic, oncological, hormone and topical products preparation rooms.
- Facility, cleanrooms, PAL, MAL, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT & validation.
- Isolators, RABS, Biological cabinets, Laminar air flow, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- HVAC design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.

### *Axcan Pharma Inc., Mont-Saint Hilaire, Québec, Canada, 2004-2005*

- Design of the revamping of existing Facility to produce Biskalcitrate products. The factory is located in Germany (CMP group).
- EPCMV Turnkey project of the new facility & VMP.
- Process, production equipment and Isolators design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system (generation, Storage, Distribution loops) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573) URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- HVAC, BIBO systems design, detailed engineering, commissioning, FAT, SAT and validation.
- Layout design, detailed engineering, commissioning, FAT, SAT and validation.
- Differential Pressure Cascade and Cleanrooms classification, HVAC Zoning.
- Electrical & Mechanical Backup systems. Material, energy and waste balance and optimization.

### *McGill University, Bio Safety Level 2 Laboratory, Montreal, Québec, Canada, 2005*

- Design the layout for premises classified BSL2 / ISO7 to produce pancreatic cells.
- Installation of critical equipment: formulation, filling, biological hoods, autoclave, washing machine,
- Revision and approval of drawings and specifications for HVAC systems and clean room panels.
- Revision and approval of drawings and specifications for the purified water system.
- Revision and approval of drawings and specifications for production equipment, autoclave, washing machine, biological cabinets, *filling machine.*

### *Ferring, Suisse, Lausanne, 2003 - 2004*

- EPCMV Turnkey project of the new facility & VMP.
- Process, production equipment and Isolators design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system (generation, Storage, Distribution loops) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573), Vacuum system, deduster, Liquid Nitrogen unit, black steam URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- Material, energy and waste balance and optimization.

### *OM Pharma, Geneva, Suisse, 2001-2004*

- Turnkey project to produce BSL2 / ISO7 vaccines.
- Downstream & Upstream processes skids design EPCMV Turnkey project of the new facility & VMP.

- Process, production equipment design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system (generation, Storage, Distribution loops) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573) URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- HVAC, BIBO systems design, detailed engineering, commissioning, FAT, SAT and validation.
- Layout design, detailed engineering, commissioning, FAT, SAT and validation.
- Differential Pressure Cascade and Cleanrooms classification, HVAC Zoning.
- BSL2 Effluent waste Kill unit (ACTINI) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Electrical & Mechanical Backup systems.
- Material, energy and waste balance and optimization.

### ◆ *Mayne Pharma, Montreal, Québec, Canada, 2003-2004*

- Optimize the warehouse's PFD & Design and identify the critical parameter (URS) of a freezer at (-20°C).

### ◆ *Steris, Québec, Canada, 2003*

- Design the layout plan of BSL2 / ISO8 classified premises for testing on washing machines with on-site decontamination.
- Process, production equipment design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system (generation, Storage, Distribution loops) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573) URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- HVAC, BIBO systems design, detailed engineering, commissioning, FAT, SAT and validation.
- Layout design, detailed engineering, commissioning, FAT, SAT and validation.
- Differential Pressure Cascade and Cleanrooms classification, HVAC Zoning.
- BSL2 Effluent waste Kill unit (Steris) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Electrical & Mechanical Backup systems.
- Material, energy and waste balance and optimization.

### ◆ *Labopharm, Laval, Québec, Canada, 2003*

- Process, production equipment design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- CIP Skid design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- USP Purified water system (generation, Storage, Distribution loops) design, URS, detailed engineering, FDS, Functional Analysis, commissioning, FAT, SAT and validation.
- Process Compressed Air System (ISO-8573) URS, design, detailed engineering, commissioning, FAT, SAT and validation.
- HVAC systems design, detailed engineering, commissioning, FAT, SAT and validation.
- Layout design, detailed engineering, commissioning, FAT, SAT and validation.
- Differential Pressure Cascade and Cleanrooms classification, HVAC Zoning.
- Electrical & Mechanical Backup systems.
- Material, energy and waste balance and optimization.

### *Neurochem, Montréal, Québec, Canada, 2003*

- Develop the equipment, systems and utilities matrix for the new clinical research & Layout, flows, utilities and systems optimization center.

### *LAAS- CNRS, France, 2003*

- Develop the preliminary engineering study (BOD) for the realization of phase 2 of the project to build a research center on electronic boards.

### *Duchesnay, Laval, Québec, Canada, 2003*

- Develop the preliminary & detailed engineering study for the construction of a new Facility to produce Diclectin tablets by dry granulation.

### *HMR, Montreal, Québec, Canada, 2003*

- Develop the preliminary conceptual study for the construction of the BL3/ISO8 laboratory of the new Maisonneuve Rosemont Hospital.

### *Biocean, Sherbrooke, Québec, Canada, 2003*

- Regulatory compliance review of the new Facility construction project for collagen production in accordance with Canadian and US GMP.

**2000** **BALTIMAR – RICHBOND GROUP, Casablanca, Morocco (3) Best sugar refineries**
**Fish oil refining, shortening & chocolate manufacturing and packaging plants**
**Production, Engineering & Maintenance, Director,** reported to Richbond Group President

**1991-2000** **COSUMAR, O.N.A. GROUP, Casablanca, Morocco**
**Department Head, Production, Maintenance, Engineering, Project management, Packaging, & Quality Control,** reported to Site General Manager

## EDUCATION

1990 **PhD** in Process Engineering, Energy concentration, **CNR**S Font Romeu, Science Faculty, Perpignan University, France. *(Thesis submitted for the **1990 National Scientific Research Center: CNRS best thesis award**).*

1986 **Master's** & **Bachelor's** degrees in Chemical Engineering, Process Engineering concentration, École Nationale Supérieure des Ingénieurs de Génie Chimique de Toulouse, **ENSIACET**, & **INPT**, France.

## PROFESSIONAL AFFILIATIONS

- 2002 to date: Ordre des ingénieurs du Québec (Quebec Professional Engineers).
- 2017 to date: ISPE.

**Languages** **French, English, Spanish**

**Nationality** **Canadian**