



**HEALTH CANADA
EXPERT**

Pharmaceutical Engineering, Validation, cGMP Compliance Audit & Design Review
Biotechnology | Med. Dev. | NHP | Nutraceuticals | Cosmetics | Cannabis | Aquaponics

① cGMP Facilities Design & Compliance Audit & Review (ISO14644, ASME-BPE, ISPE)

- ✓ Sanitary Process Equipment & Clean Utilities Design (URS, P&ID, DDE).
- ✓ Cleanrooms Layout & HVAC Design & Functional Analysis.
- ✓ Aseptic & Injectable facilities design.
- ✓ High potent facilities design.
- ✓ Biological, Vaccine Biosimilar containment facilities design (BSL1-3).
- ✓ Explosion Proof facilities design (ATEX, NFPA).
- ✓ Risk analysis assessment & mitigation.

② Process, Facilities Engineering, Construction & Project Management (EPCMV)

- ✓ PM : Delivery, Installation, Commissioning (FAT, SAT), Start-Up.
- ✓ Troubleshooting, Engineering & PLC Control Tests.
- ✓ On-Site Building, Works follow-up & Benchmark.
- ✓ Traceability Matrix & Change Control Management.
- ✓ Quality Assurance & Supplier's Audit.
- ✓ "Site Master File" (SMF) & cGMP training.

③ Validation and Quality

- ✓ Validation Master Plan.
- ✓ Continued Process & Cleaning Validation (FDA, EMEA).
- ✓ IT & BMS Validation (GAMP).
- ✓ Processes, Cleaning, Sterilisation Validation.
- ✓ SOP, batches release.
- ✓ Change controls, CAPA, RAPA, GAPA.

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PBE, YOUR c-GMP ENGINEERING, VALIDATION & REGULATORY COMPLIANCE PARTNER

We save lives and the planet



**EXPERT
SANTÉ CANADA
HEALTH CANADA
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Clients trust PBE Expert in GMP Compliance

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PBE, VOTRE PARTENAIRE EN INGÉNIERIE, VALIDATION & CONFORMITÉ RÉGLEMENTAIRE

Nous sauvons des vies et la planète