



EXPERT
SANTÉ CANADA
MAPAQ



Engineering & Validation Training Program

PBE, Pharma Bio Expert Inc

PBE-Expert Inc – CANADA

PBE is a Training Company with Agreement CPMT #0059104

P B E
EXPERT

PBE, Training Company Agreement CPMT #0059104

Commission
des partenaires
du marché du travail
Québec

CERTIFICAT D'AGRÈMENT

Loi favorisant le développement et la reconnaissance
des compétences de la main-d'œuvre

Titulaire : PBE, PHARMA BIO EXPERT INC.

Numéro d'agrément : 0059104

NEQ : 1168916956

Date de délivrance : 6 février 2018

Catégorie d'agrément : Organisme formateur

Date d'échéance : 5 février 2020

CHAMPS PROFESSIONNELS

01 Administration et commerce
03 Alimentation, hôtellerie et tourisme
06 Chimie et biologie

Par : *Isabelle Benfleur*

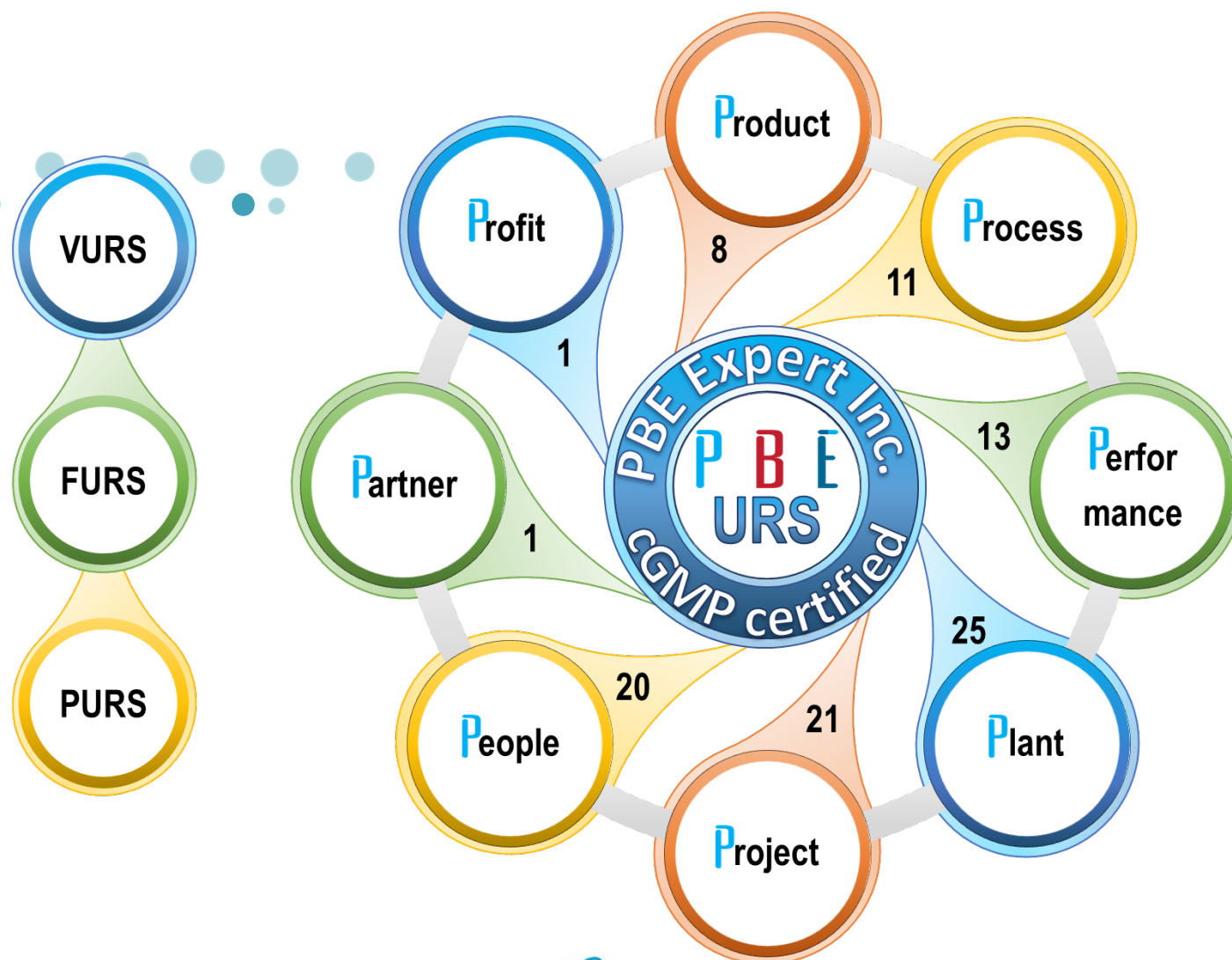
Le 7 février 2018

La délivrance du certificat est valide en fonction des documents soumis à la
Commission des partenaires du marché du travail.

Ministère du Travail, de l'Emploi et de la Solidarité sociale

10-6282 (06-2003)
ENT-0031 (12-2016)





Program

- PBE, Pharma Bio Expert services
- PBE Training Program
- CLIENT Needs
- Questions and Follow Up



Training Program

Engineering module For internal auditors



Trainings Summary

ING-01 cGMP applications, from sanitary conception to pharmaceutical installations qualification « Compliance, Quality, Safety, QBD, Risk Analysis »

ING-02 Integrated pharmaceutical project management.
Design documents development : URS, SDS, Risk Analysis
RAA, QA Sheets (FAQ)

ING-03 Risk Management, from design to pharmaceutical units qualification, according to FDA, ICH Q9, ASTM 2500, ISPE vol5, FMEA / AMDEC.



Trainings Summary

ING-04 Clean Utilities, from sanitary conception(ICH Q9 / Production, Storage, Distribution), Commissioning, to Qualification. Case Study: Purified Water

ING-05 Design of pharmaceutical compressed air systems.

ING-06 Cleaning Process Development (CIP, COP).



Trainings Summary

ING-07 Sterilization Processes Development (SIP, SOP).

ING-08 Contaminant origin in ZAC and air & surface decontamination technologies. Dressing and behaviour in ZAC.

ING-09 GMP application to Bioprocess design (Vaccines).

ING-10 Design, Commissioning to Qualification of pharmaceutical installations of ZAC, HVAC, AHU, & FFU. Clean Room design. Implementation and monitoring of HVAC system maintenance.



Trainings Summary

ING-11 Case Study n°1: ZAC, pharmaceutical air treatment systems for liquid and dry formulation (OSD) units.

ING-12 Case Study n°2: Systems (HVAC, CTA, FFU) for dry and highly active/toxic liquid form units (High Potent according to Safe Bridge standards 1 to 4).

ING-13 Case Study n°3: Systems (HVAC, CTA, FFU) in presence of flammable solvents (alcohol, acetone ...) and ATEX powders.



Trainings Summary

ING-14 Case Study n°4: Air Treatment Systems (HVAC, AHU, FFU) for aseptic installations for STERILE INJECTABLE products, RABS, Insulators.

ING-15 Case Study n°5: Systems (HVAC, AHU, FFU) for biological products (BSL2 and BSL3 / P2 & P3) involving biosecurity containment systems...

ING-16 GMP & GLP Compliance of Quality Control Laboratories (QCL).



Trainings Summary

ING-17 Annual product quality review : APR. Case Study : Deviation Management, investigative conduct, & CAPA.

ING-18 Cleaning Process Validation (CPV).

ING-19 New Process Validation (PV) approach applications following FDA 2011 / and EMA/ANSM 2014 guidelines.



Trainings Summary

ING-20 Warehouse, Cold Rooms, Freezers, Cold Chain: from design to Validation.

ING-21 Audit & Certification for food production and mineral water bottling units, HACCP, ISO-22000, ISO-9001

ING-22 Audit & Certification for medical devices (1 to 4) production and packaging (I & II) laboratories (ISO13485, FDA-CFR820).

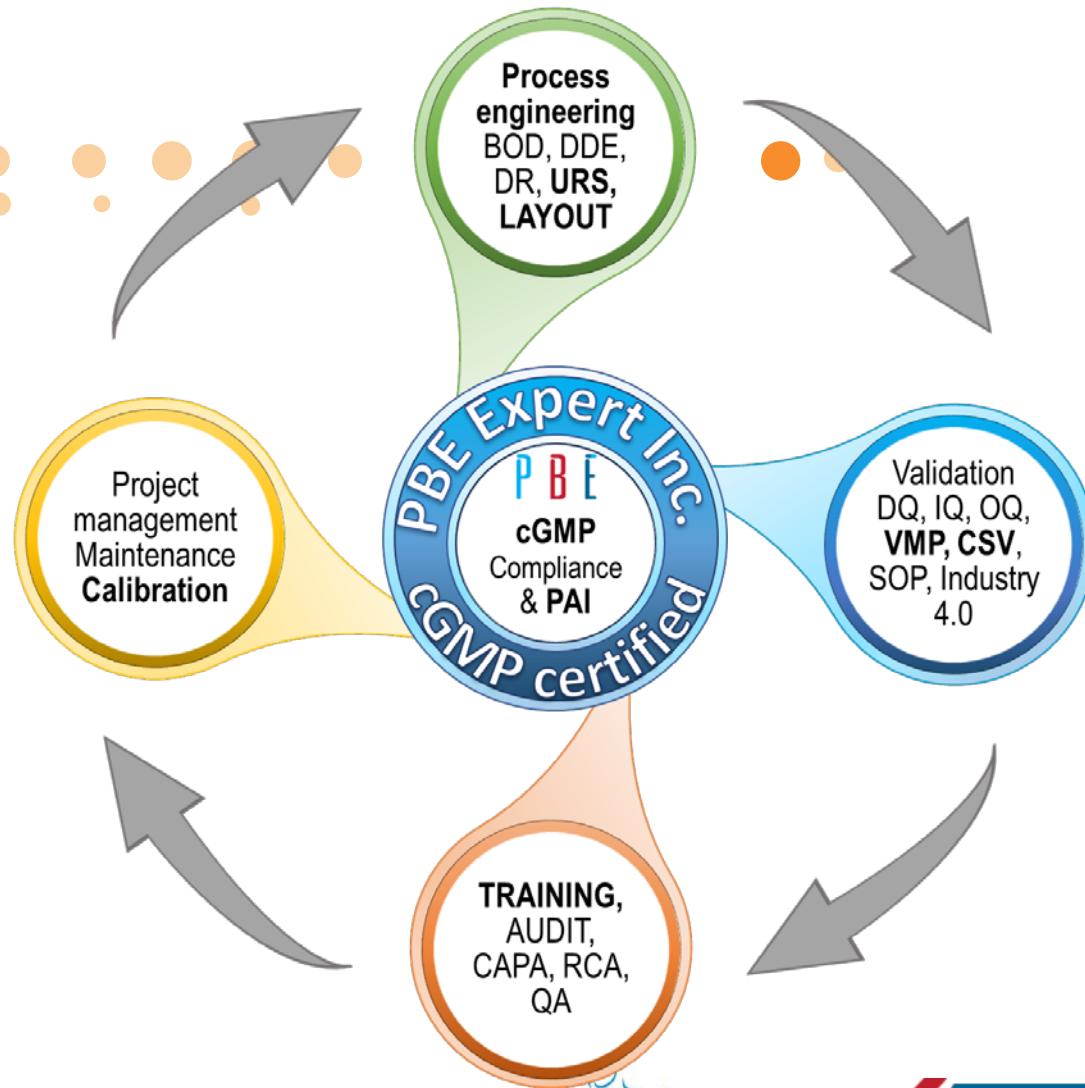


Trainings Summary

ING-23 Pre-Inspection (1 day of theory and 2 days of practice) & Compliance Audit for Quality Control Laboratories (QCL).

ING-24 Pre-Inspection (2 day of theory and 3 days of practice) & GMP compliance Audit of design and quality system of pharmaceutical production laboratories.





Conclusion

