



EXPERT
SANTÉ CANADA
MAPAQ

Quality Assurance 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

Quality Assurance Module

For internal auditor



Trainings Summary

BPF-01 Introduction to good manufacturing practices

BPF-02 Normalized procedures redaction

BPF-03 In-process controls

BPF-04 Documentation of manufacturing

BPF-05 Control and quality insurance

BPF-08 GMP application to quality control laboratories



Trainings Summary

BPF-09 Mastering change

BPF-10 Deviations and their management

BPF-10a OOS (Out Of Specifications) and OOT (Out Of Trend)
management

BPF-11 e-BPF and cGMP : differences and similarities

BPF-12 Metrology

BPF-13 ISO 15378 Standard- GMPs applied to packaging items



Trainings Summary

BPF-14 Clinical batches

BPL-01 Introduction to Good Laboratory Practices (Microbiology laboratory)

INM-01 Introduction to Good Manufacturing Practices for medical devices

PAI-01 « Pre-approval inspection » preparation for the FDA

PAI-02 Preparation for an FDA inspection: inspection by system



Trainings Summary

VAL-01 Validation Master Plan (VMP)

VAL-02 Validation : General concepts

VAL-03 Validation : From theory to practice

VAL-04 Validation protocol drafting

VAL-05 Validation : sterilization processes

VAL-06 Validation : manufacturing processes



Trainings Summary

VAL-07 Validation: Aseptic filtration processes

VAL-08 Validation : Cleaning processes

VAL-09 Validation and engineering

VAL-11 Analytical validation

VAL-12 Criticality analysis and risk analysis

VAL-13 Qualification of laboratory devices



Trainings Summary

BPF-01 Introduction to good manufacturing practices

VAL-14 Sampling techniques in validation

VAL-15 AIS compliance

ING-30 Basic elements of a purified water system

ING-40 Ventilation systems in the pharmaceutical environment

AUD-01 Internal and external audits



CLIENT

Needs
Questions
Follow-Up



CLIENT - Needs

Which trainings are you interested in?



CLIENT - QUESTIONS

Which training courses would you like a more explicit description of?

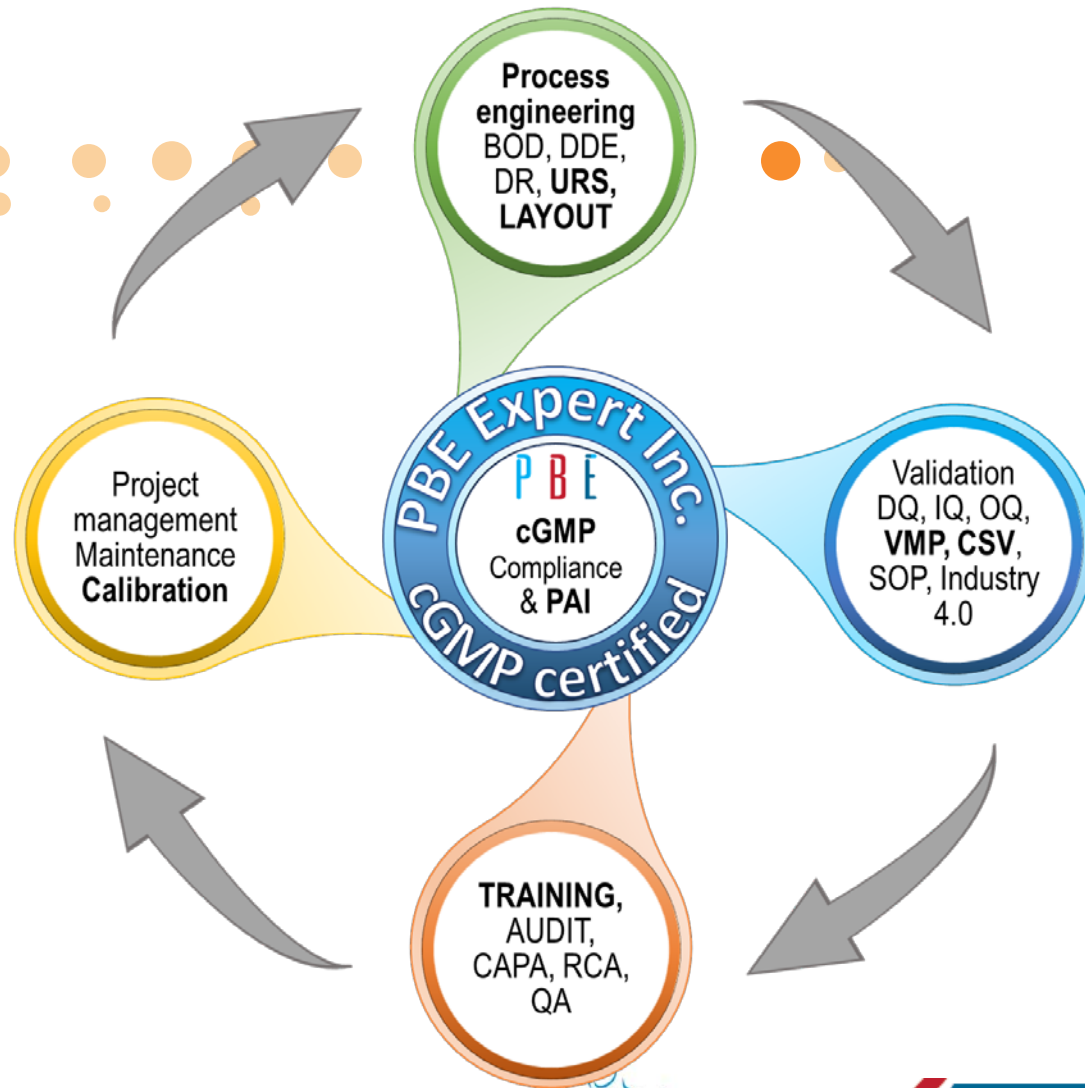
Other questions?



CLIENT – Follow-Up

What is the timeline / schedule for implementing the internal audit program?





Conclusion

