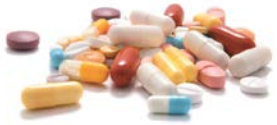


EXPERT
SANTÉ CANADA
MAPAQ

AUDIT & PAI
Quality Control Laboratory - QCL

PBE, Pharma Bio Expert Inc

PBE-Expert Inc – CANADA

Training Company Agreement CPMT #0059104

PBE, Training Company Agreement **CPMT** #0059104

Commission des partenaires du marché du travail
Québec

CERTIFICAT D'AGRÉMENT

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

Titulaire : PBE, PHARMA BIO EXPERT INC.

Numéro d'agrément : 0059104

NEQ : 1168916956

Catégorie d'agrément : Organisme formateur

Date de délivrance : 6 février 2018
Date d'échéance : 5 février 2020

CHAMPS PROFESSIONNELS

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

Par : Isabelle Bergeron

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

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

Program

Assignment n.1- Review of critical procedures

Assignment n.2- Conduct of on-site audits

Assignment n.3- Development of an action plan to correct observations according to their criticality

Assignment n.4- Follow-up after implementation of corrective actions

Assignment n.5- Coaching through preparation, conduct of and response to FDA inspection

Assignment n.6- Self-inspection and continuous control (Capability)

Assignment #1

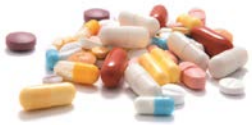
Objectives of assignment #1

1. GMP training applied to QCL.
2. Evaluation of level….
3. PAI / FDA prerequisites ….
4. Review and corrections of ….
5. Implementation of new….
6. SOP / ….
7. SOP / Preparation …
8. SOP for ….
9. Preliminary audit and state …..

Assignment #2

Objectives of assignment #2

1. Review of quality system: …
2. Formation … (theoretical and practical).
3. Realization of a « …. » :
   a. Review and Update…..
   b. Develop a plan ….
   c. Draft a ….
4. Assessment of the relevance….
5. Coaching through management…
6. Review and approval ….

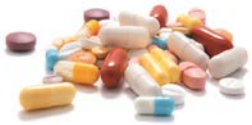


Assignment #3

Objectives of assignment #3

Development of **corrective actions** :

- ✓....
- ✓....
- ✓....
- ✓....



Assignment #4

Objectives of assignment #4

End of work **inspection** (if applicable):

- ✓ R….
- ✓ Q….
- ✓ R….
- ✓ F….
- ✓ C….

Assignment #5

Objectives of assignment #5

Preparation … :

- o Plans ….
- o Organization ….

Participation ….

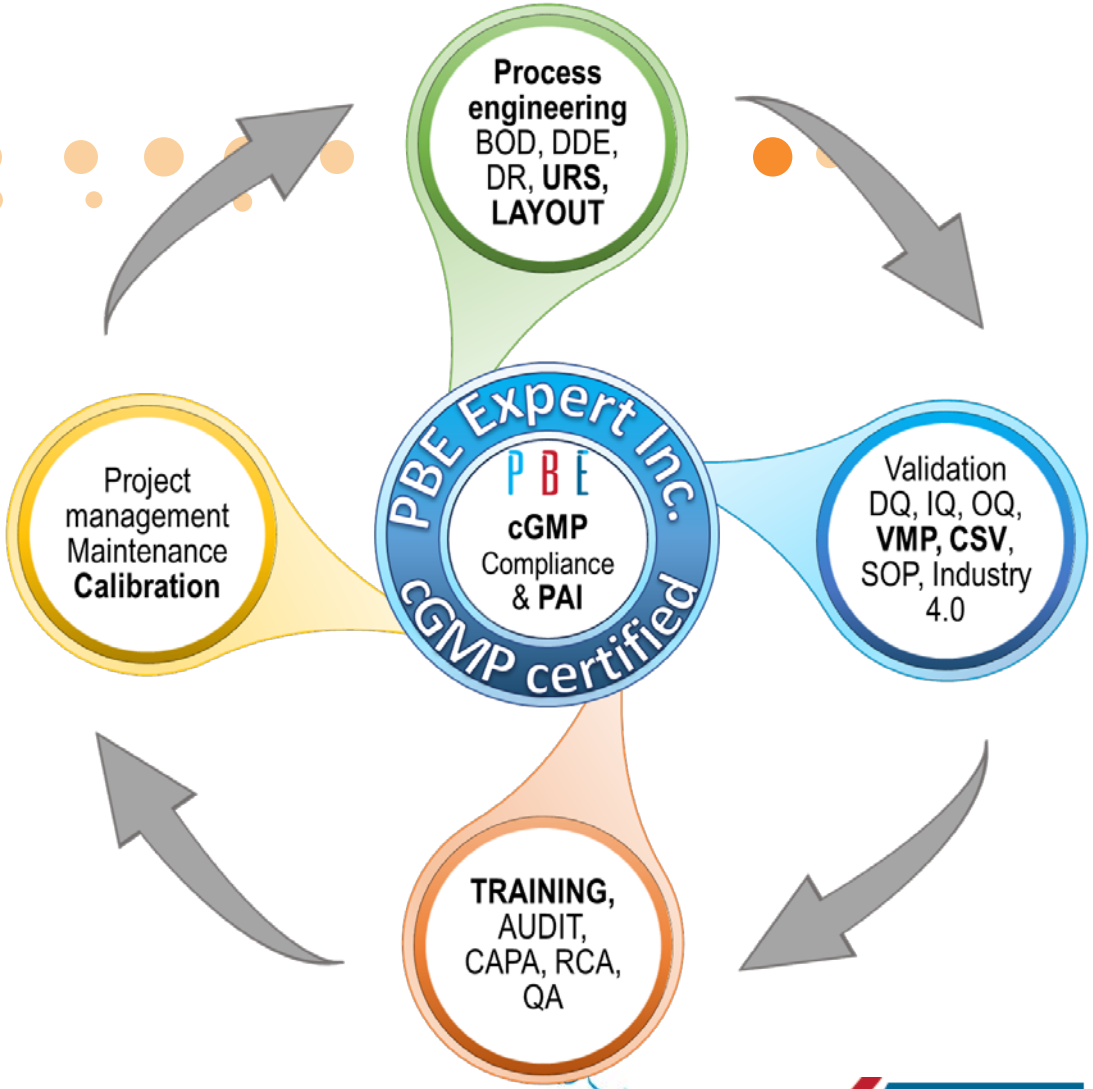
Participation … :

- o Management or « … » .
- o Or live with….
- o Answer…

Assignment #6

Objectives of assignment #6

1. Audit ….
2. Plan ….
3. Auto ….
4. Track ….
5. Development ….
6. Closure ….
7. Control ….



PBE PharmaBio EXPERT cGMP

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PBE PharmaBio EXPERT cGMP

EXPERT SANTÉ CANADA MAPAQ

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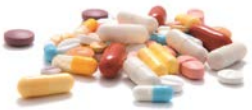

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