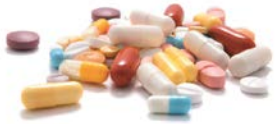


EXPERT
SANTÉ CANADA
MAPAQ

Quality Control Laboratories – QCL from Design to Validation

PBE, Pharma Bio Expert Inc

PBE-Expert Inc – CANADA

Accredited training organisation 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 Bergeur

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)

Presentation Outline

1. Course objectives
2. Objectives of GLP
3. Laboratories and compliance
4. Staff and Direction
5. Rooms and equipments
6. Procedures
7. Calibration and preventive maintenance
8. Raw data
9. Standards
10. Samples
11. Documentation
12. «OOS», CAPA & CC (Complaints Management)
13. Equipments and methods validation
14. 483 Observations / PAI
15. Conclusion
16. Evaluation

REGULATORY FRAMEWORK & REFERENCES

REGULATORY FRAMEWORK & REFERENCES

1. Canadian GMP and american cGMP
2. 25 ISO 17025 Guide General Requirements for the Competence of Testing and Calibration Laboratories.
3. Guide to Inspections of Pharmaceutical Quality Control Laboratories, FDA.
4. Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories, FDA.
5. FDA, Federal Register, Vol. 60, No. 40, March 1, 1995.
6. ICH: Guideline on Validation of Analytical Procedures: Definitions and Terminology.
7. EMEA: ICH Topic Q 2 B, Validation of Analytical Procedures: Methodology, November 6, 1996.
8. Analytical Method Validation, Journal of Validation Technology, Volume 2, No 2, James D. Johnson and Gale E. Van Buskirk

REGULATORY FRAMEWORK & REFERENCES

1. A Life Cycle Approach to the Validation of Analytical Methods during Pharmaceutical Product Development, Part I and II, Pharmaceutical Technology, September 1994, Gerard C. Hokanson.
2. Defining a Master Plan for the Validation of Analytical Methods, Journal of Validation Technology, Vol. 3, No. 4, Paul A. Winslow and Richard F. Meyer.
3. Pre-Approval Inspections PAI/ Investigations
4. CPGM : Compliance Program Guidance Manual.
5. Validation of Analytical Methodology, Journal of Validation Technology, Vol. 3, No. 3, Harry G. Brittain.
6. (FMD135) Field Management Directives Preoperational Reviews of Manufacturing Facilities
7. CPGM 7356.002 & 7346.832

http://www.fda.gov/cder/gmp/PAI-7346832.pdf

http://www.fda.gov/ora/cpgm/7356_002/7356-002FINAL.pdf

1- COURSE OBJECTIVES

1- Course Objectives

1. Explain the different sections of Good Manufacturing Practices applicable to quality control laboratories.

2- GLP OBJECTIVES

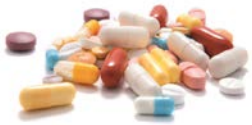
2- GLP Objectives

Ensure reliable, accurate and authentic data to make the right decisions:

1. Raw materials releasing, during production and for finished product.
2. Stability.
3. Recall.
4. Investigation.
5. Development.

2- GLP Objectives

....



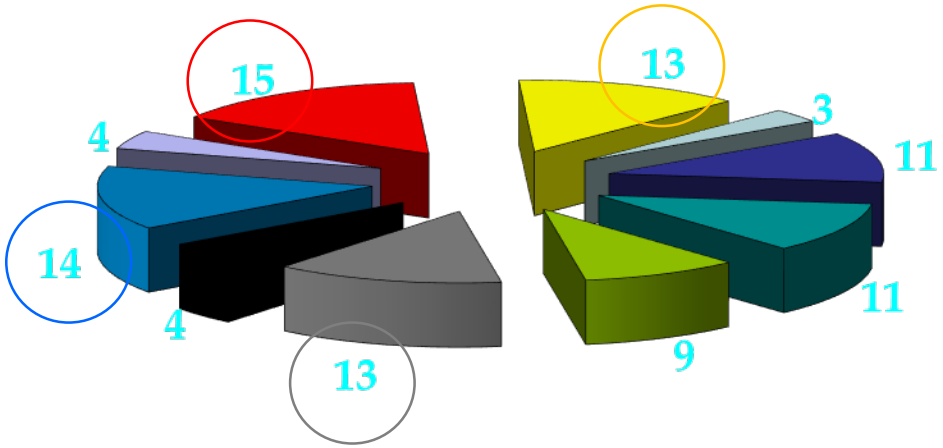
3- QCL LABORATORIES AND COMPLIANCE

3- QCL laboratories and compliance

Non-compliance frequently observed by the FDA:

1. Inadequate validation of analysis methods.
2. Inadequate validation of equipments.
3. Repetition of poorly defined analysis.
4. Inadequate analyst training.
5. Unofficial notes.

3- QCL laboratories and compliance



- Component control
- Records and reports
- Other
- Water System
- Process Validation
- Stability Program
- *Equipment cleaning*
- Plant
- Laboratories controls
- Processes controls

3- QCL laboratories and compliance

CPGM 7346.832

FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM GUIDANCE MANUAL PROGRAM 7346.832

CHAPTER 46 – NEW DRUG EVALUATON

SUBJECT: PRE-APPROVAL INSPECTIONS / INVESTIGATIONS * REVISION: March 2005 revision to the PAI Program updates sample routing instructions (see especially pages 24-26) and change "forensic" to "profile." (Other material from March 2004 issuance has not been updated.) *	IMPLEMENTATION DATE April 5, 2005 COMPLETION DATE October 1, 2007

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
Use appropriate product codes.	(SEE BELOW)

PROGRAM/ASSIGNMENT CODES

46832	NDA Pre-Approval Inspections/Methods Validation
46832B	NDA * Profile * Sample Collection/Analysis
46832C	NDA Biotest Sample Collection/Analysis
*46832M	Therapeutic Biologics Products (main program is 56002M) *
52832	ANDA Pre-Approval Inspections/Methods Validation

3- QCL laboratories and compliance

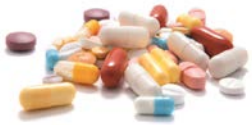
COMPLIANCE AUDIT :

24. Audit Findings.
25. Audit Summaries.
26. Description of Major Changes
27. Obstacles
28. Follow-up of Past Nonconformities
29. Nonconformities
30. Areas not Audited

3- QCL laboratories and compliance

Verify if the laboratory (QCL):

....



4- PERSONNEL AND MANAGEMENT

4- Personnel and Management

The person in charge of the laboratory:

1. is experienced
2. has a degree in science related to the work being carried out
3. has practical experience in the field or reports to a person with those qualifications

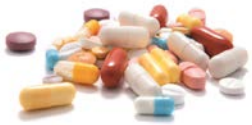
Canadian GMP, C.02.015

4- Personnel and Management

The person in charge of the laboratory:

1. ….

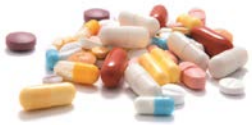
Canadian GMP, C.02.015



5- ROOMS AND EQUIPMENTS

5- Rooms and Equipments

1. Similar principles as fabrication installations (GMP):
   a. Dedicated Rooms :
      i. Reception,
      ii. Chemical reagent room,
      iii. Physico-Chemical Laboratory
      iv. Microbiological Laboratory
      v. Administrative offices …
   b. Clean premises,
   c. Orderly,
   d. Used according to determined functions,
   e. Rooms and work tables sufficiently spaced and functional



5- Premises and Equipments

2. 21 CFR 211 subpart C- Buildings & Facilities 11.42 Design and construction features (cGMP-FDA):

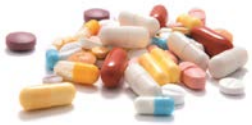
a. .
   i. ..
   ii. ..
   iii. ..
   iv. ..
   v. ..

b. ..

c. ..

d. ..

e. ..



6- PROCEDURES

7- CALIBRATION AND PREVENTIVE MAINTENANCE

8- RAW DATA

9- STANDARDS

10- SAMPLES

11- DOCUMENTATION

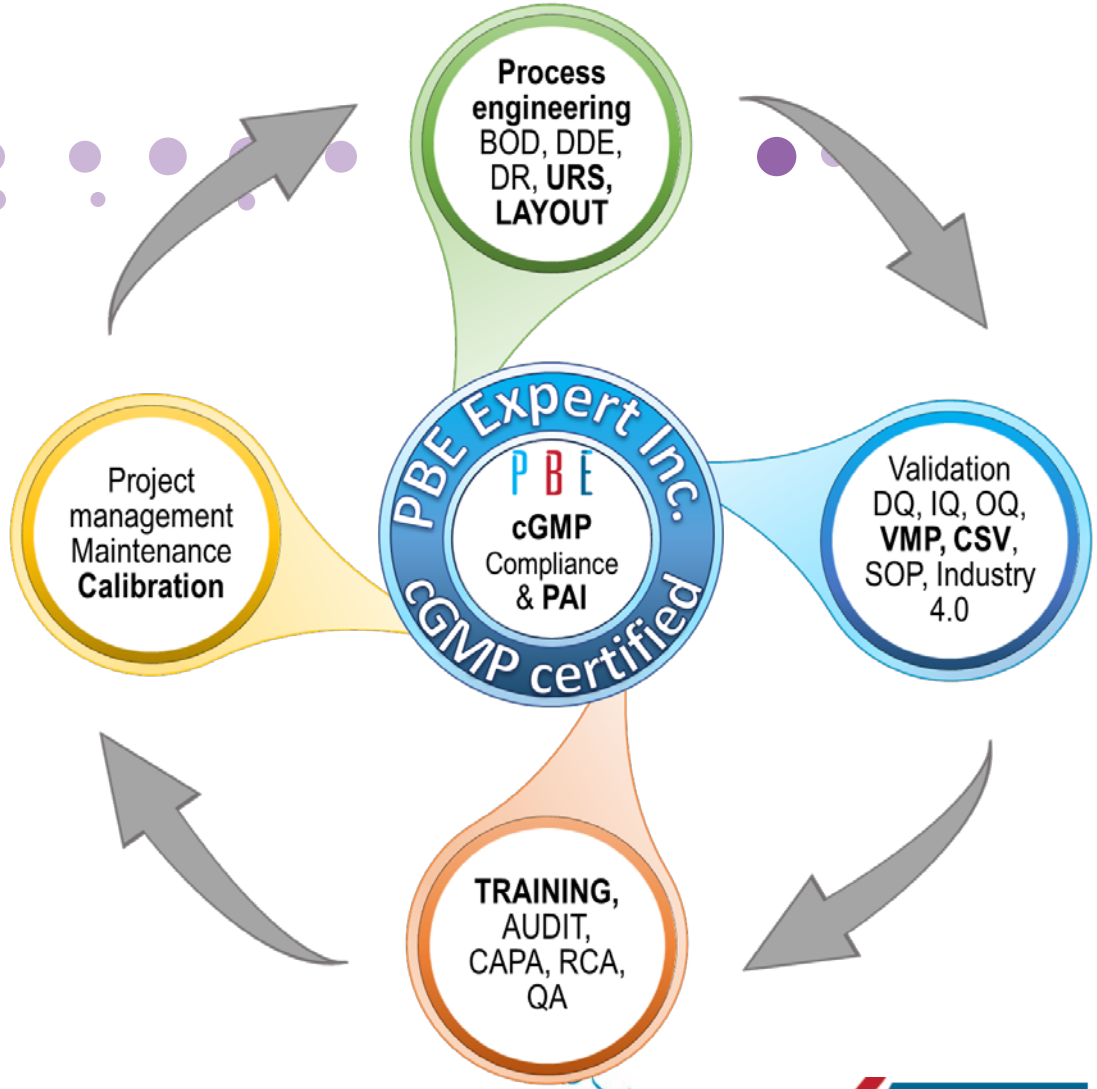
12- «OOS», CAPA & CC

13- EQUIPMENTS VALIDATION

14- METHODS VALIDATION

15- EXAMPLES OF 483 OBSERVATIONS/PAI

16- CONCLUSION



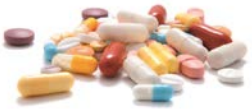
PBE PharmaBio EXPERT cGMP

EXPERT SANTÉ CANADA MAPAQ

PBE EXPERT


VURS
FURS
PURS
Product
Profit
Process
Partner
Performance
People
Plant
Project
8
11
1
13
1
25
20
21
PBE Expert Inc.
PBE
URS
cGMP certified

PBE Expert Inc.
we Process, Build, Engineer



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