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
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

1. Canadian GMP and american cGMP
3. Guide to Inspections of Pharmaceutical Quality Control Laboratories, FDA.
4. Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories, FDA.


3. Pre-Approval Inspections PAI/Investigations


6. (FMD135) Field Management Directives Preoperational Reviews of Manufacturing Facilities

7. CPGM 7356.002 & 7346.832
   http://www.fda.gov/ora/cpgm/7356_002/7356-002FINAL.pdf

23/05/2018
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

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<th>PRODUCT CODES</th>
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<td>Use appropriate product codes.</td>
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**PROGRAM/ASSIGNMENT CODES**

- 46832  
  NDA Pre-Approval Inspections/Methods Validation

- 46832B  
  NDA * Profile * Sample Collection/Analysis

- 46832C  
  NDA Biostest Sample Collection/Analysis

- 46832M  
  Therapeutic Biologics Products (main program is 56002M)*

- 52832  
  ANDA Pre-Approval Inspections/Methods Validation

**CHAPTER 46 - NEW DRUG EVALUATION**

**SUBJECT:**
PRE-APPROVAL INSPECTIONS / INVESTIGATIONS

**IMPLEMENTATION DATE:**
April 5, 2005

**COMPLETION DATE:**
October 1, 2007

**DATA REPORTING**

* REVISION: March 2005 revision to the PAI Program updates sample routing instructions (see especially pages 24-25) and change “forensic” to “profile.” (Other material from March 2004 issuance has not been updated.) *
3- QCL laboratories and compliance

COMPLIANCE AUDIT:

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. .....
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
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
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