BP606T. PHARMACEUTICAL QUALITY ASSURANCE

UNIT 1: QUALITY ASSURANCE AND QUALITY MANAGEMENT CONCEPTS, TQM, ICH GUIDELINES, QUALITY BY DESIGN (QBD), ISO 9000 & ISO14000, NABL ACCREDITATION

1. _____ is not considered as a key element of TQM.

a) Focus on the customer

b) Employee involvement

c) Continuous improvement

d) All of above

2. ISO _____ was originally published in 1987 by the International Organization for Standardization (ISO).

a) 14000

b) 9000

c) 2008

d) 2015

3. Amongst the sequence of seven quality management principles ___is stands for Leadership.

a) QMP 1

b) QMP 2

c) QMP 3

d) QMP 4

4. Basic principles and methodology sequence of ISO 14000 series are

A) Plan, Do, Act, Check

B) Plan, Do, Check, Act

C) Do, Act, Check, Plan

D) None

5. ISO 14004 Environmental management systems define guidelines for ____

a) Implementation

b) Requirements for use

c) Incorporating eco-design

d) None of these.

6. The objective of ISO-9000 family of Quality management is

a) Customer satisfaction

b) Employee satisfaction

c) Skill enhancement

d) Environmental issues

7. Quality management principles P-D-C-A stands for

a) Plan-Do-Check-Act

b) Plan-Do-Correct-Act

c) Proceed-Do-Check-Act

d) Proceed-Do-Correct-Act

8. The main objective of quality assurance is:

a) Proof of fitness of product

b) Inspection of quality of product

c) Quality conformance

d) Customer satisfaction

9. Which of the following statement(s) is/are true about quality assurance: A. QA is a set of activities for ensuring quality in the processes by which products are developed. B. QA is a corrective tool and product oriented.

a) B is correct

b) A is correct

c) Both A and B

d) None of these

10. ISO 14004 Environmental management systems define guidelines for ____

a) Implementation

b) Requirements for use

c) Incorporating eco-design

d) None of these

UNIT 2: ORGANIZATION AND PERSONNEL, PREMISES, EQUIPMENTS AND RAW MATERIALS

1. Key Personnel include

a) Head of production

b) Head of quality assurance

c) Head of quality control

d) All the above

2. Responsibilities of the Head of the Production Department are

a) To approve/reject the sample/procedure

b) To check the maintenance of his department

c) Initial and continuing training of his department

d) All the above

3. Rest and Refreshment Rooms should be ……. from other areas

a) Separate

b) Same

c) Communicate directly

d) No correlation

4. The layout and design of the equipment must aim to

a) Minimize risk of errors

b) Permit effective cleaning

c) Labeled as defective if instrument not working

d) All the above

UNIT 3: QUALITY CONTROL, GOOD LABORATORY PRACTICES

1. Other documents like BMR and BPR are prepared using ___by the manufacturing units.

a) Master formulation file

b) Ingredient formula record

c) Master formula record improvement

d) All of above

2. A master formula record is prepared and endorsed by the competent technical staff like manufacturing chemist and ____chemist.

a) Analytical

b) Production

c) Formulation

d) None

3. Methylene blue is use in ____.

a) Leakage test

b) Thermal shock test

c) Clarity test

d) None of these.

4. Folding endurance test is QC test for _

a) Glass container

b) Paper and board

c) Closures

d) All the above

5. Packaging type that has direct contact with product called.

a) Primary

b) Secondary

c) Tertiary

d) None

6. Which guideline stands for evaluation of stability data?

a) Q1B

b) Q1D

c) Q1E

d) Q1C

UNIT 4: COMPLAINTS, DOCUMENT MAINTENANCE IN PHARMACEUTICAL INDUSTRY

1. Quality audit may include questionnaires on GMP requirements covering

a) Personnel

b) Documentation

c) Recall procedures

d) All the above

2. ____ is a set of step-by-step instructions compiled to help workers carry out routine operations.

a) SIP

b) SOP

c) BMR

d) MFR

3. Complaint handling is an essential requirement as per ___.

a) cGLP

b) GLP

c) GMP

d) MFR

4. ___ provides guidance so that responsible firms may conduct an effective recall.

a) 21 CFR 7

b) 22 CFR 3

c) 23 CFR 5

d) None

5. Which of the following is not a QC test of for parenteral containers?

a) Sterility Test
b) Clarity Test
c) Pyrogen Test
d) Leakage Test

6. Which of the following is NOT covered under 'Finished Product Quality Assurance'?

a) Finished product monitoring
b) Special finished product survey
c) Factory visits
d) None of these

UNIT 5: CALIBRATION AND VALIDATION, WAREHOUSING

1. The term calibration is used for

a) Equipment

b) Processes

c) None of these

d) Both a and b

2. Prospective validation is the validation …….production.

a) During

b) Before

c) After

d) all the above

3. Physical dimension of equipment and accessories- comes under which qualification?

a) Design qualification (DQ)

b) Installation qualification (IQ)

c) Operational qualification

d) Performance qualification (PQ)

4. Which guideline stands for evaluation of stability data?

a) Q1B

b) Q1D

c) Q1E

d) Q1C

5. Installation Qualification (I.Q) purpose is to check_

a) Installation site/environment

b) Proper ventilation site

c) Maintenance

d) Equipment stability

6. The term validation in calibration is used for

a) Equipment

b) Processes

c) None of these

d) Both a) and b).