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**AUDIT & REGULATORY AFFAIRS**

**UNIT I**

1) Quality audit system mainly classify as

1. Internal audit
2. External audit
3. Regulatory audit
4. **All of the above**

2) Goal of primary objective is

1. **To analyze the accuracy of book**
2. Detection and prevention of error
3. Detection and prevention of roads
4. None of the above

3) What is the function of management audit

1. To satisfy the tax collector
2. **To evaluate performance**
3. To assess the companies social performance
4. To look into how many is spent

4) The following is not responsibility of managing audit program

1. Plan develop implement and improvement audit progress
2. To find required resources
3. **To satisfy the tax collector**
4. To analyze the existing activity

5) What are the responsibility of team leader

1. Make a final conclusion on all audit phase
2. Prepare an audit strategy
3. Examine accuracy
4. **All of the above**

6) Which of the following is not step of audit process

a ) Notification **b) Observation** c) Field work d) Planning

7) Basic team member of internal audit are

a) Chief executive b) Audit committee c) External auditor  **d) All of the above**

8) As progress of audit their maybe some cases when the fact suggest a breakdown of quality management system either partially or completely is known as

a) Non confirmative b) Deficiency **c) Both a and b** d) None of the above

9) In accurate labelling is a critical defect ?

**a) True** b) False

10) Fail to finish all batch record entries is

a) Measured defect **b) Minor defect** c) Critical defect d) None of the above

**UNIT II**

1) Quality is a degree of

a) Greatness  **b) Excellence** c) Agreement d) None of the above

2) According to WHO PUC is part of

**a) GMP** b) GCP c) GLP d) None of the above

3) Quality control activity based on identifying in actual product

a) Stand **b) Defect** c) Both a & b d) None of the above

4) To identify and prepare the required Sop's related to control of quality is responsibility of which department

**a) QA** b) QC c) Production d) all of the above

5) Which of the following parameter insure by GMP

a) Quality b) Safety c) Efficacy **d) All of the above**

6) For the sampling and testing in process material should be tested for which of the following parameter

a) Strength b) Identity c) Purity **d) All of the above**

7) Quality monitoring and audit responsibility hold by which department

a) QA **b) QC** c) Production d) All of the above

8) The scope of sanitation and hygiene covers

a) Equipment b) Personnel c) Premises **d) All of the above**

9) Which department is responsible for evaluation of batch record

a) QA **b) QC** c) Both A and B d) None of above

10) High level of personal hygiene should followed and observed by all those concerned with process

a) Warehousing **b) Manufacturing** c) Transporting d) None of the above

**UNIT III**

1) What is the size range of granule particle?

**a) 0.2 to 4.0 mm** b) 0.2 to 4.0 mm

c) 0.2 to 0.4 mm d) 0.2 to 0.4mm

2) Which of the following is coating composition?

a) Polymer b) Solvent c) Plasticizers **d) All Of The Above**

3) GMP insure which of the following parameters

a) Quality b) Safety c) Efficacy **d) All Of These**

4) Which of the following areas user for the destroy or store in appropriate material

a) Sampling area b) Storage area **c) Rejected material** d) Dispensing area

5) Which of the following responsibility of warehouse keepers

1. **Warehouse storage management**
2. Goods in storage
3. Supplier and receive
4. carrying transporting items

6) Which of the following is not factors affecting on tablet coating

**a) Dissolution** b) Tablet properties c) Coating process d) Coating composition

7) Which of the following is granulation method

a) Wet granulation b) Dry granulation c) Compression **d) all**

8) Which is the resolution of ultra micro balance?

**a) 0.1µg** b) 1.0µg c) 0.1mg d) 0.01mg

9) What does GDP stand for

1. Good dispatch practices
2. Good dispatch processes
3. **Good distribution practices**
4. General distribution process

10) What does mean by "FEFO"

1. **First expire first out**
2. First expect first out
3. First edit first outcome
4. First ensure first out

**UNIT IV**

1) What does mean by GCLP

1. **Good control laboratory practice**
2. Good control laboratory performance
3. Good contain laboratory practice
4. Good quality laboratory practice

2) Which are following temperature measurement device

a) Thermocouples b) PRTs c) Incubators **d) All**

3) What is the full form of PRTs

1. **Platinum thermometer resistance**
2. Platinum thermocouple resistance
3. Plate thermometer resistance
4. Platinum thermostat resistance

4) Which of the following generic is steps involved in audit

**a) Initiation** b) Limit c) Attendance d) Quality Control

5) Which of the following is auditor interpersonal skill?

a) Act b) Fairness c) Technical Expertise  **d) All Of The Above**

6) What does mean by lims

1. **Laboratory information management system**
2. Laboratory instrument management system
3. Laboratory information manageable system
4. None of the above

7) Process audit examine the following production process

a) Calibration gauge b) Pressure reading c) None of these **d) Both**

8) Which of the following steps for planning and conducting audit

1. Choose procedure
2. Choose auditing team
3. Set up an audit time table
4. **All of the above**

9) Which of the following are reviewed microbial procedures

**a) Preparation of media** b) Humidity c) Quality d) Control contamination

10) Self inspection is also known as

a) Audit b) External Audit **c) Internal Audit** d) None

**UNIT V**

1) An internal quality audit should be designed primarily to answer which of the following questions

1. Is the process effective?
2. What is the degree of management compliance?
3. How can the process be made more efficient?
4. **What is the level of overall compliance?**

2) Which of the following method is used to determine whether a process functions properly for its intended use

1. Capacity
2. **Inspection**
3. Validation
4. Design review

3) Who should evaluate the performance of a quality improvement team leader

1. **Team members**
2. External auditor
3. Companies general manager
4. Other team leaders

4) The audit report includes all of the following action except

1. Details of what has been examined
2. Reporting the non compliance
3. **Carrying out all corrections needed**
4. Indicating the auditor responsible for the follow up

5) Six Sigma methodology defines three Core steps

1. Analyze improve control
2. Analyze design verify
3. **Define measure analyze**
4. Define measure control

6) Which of the following would not normally be considered as a cost of quality?

1. **Marketing cost**
2. Prevention cost
3. Internal failure cost
4. Inspection cost

7) To insurance success in implementing quality initiative the most important factor is

1. An empowered workforce
2. Training program that explains and promote the quality initiative
3. **Upper management support**
4. Are reward and recognition program

8) Confidence interval is used as a test for the following except

1. Comparing the mean with true value
2. Comparing the means of two different data sets
3. **Comparing the accuracy of two different data sets**
4. Comparing the precision of two different data sets

9) Which one of the following is not a quality assurance measure ?

1. Identify the person having the overall responsibility for quality
2. Having laboratory equipment calibrated to recognized standards
3. Using reference materials
4. **Providing a comprehensive marketing plan**

10) ETP stands for

1. **Effluent treatment plant**
2. Effluent transport plant
3. Effective transport plan
4. None of the above