

MQA-102T

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ODD SEMESTER EXAMINATION, 2022-23

COURSE NAME: -M.PHARM

SEMESTER- I

SUBJECT: -QUALITY MANAGEMENT SYSTEM

TIME: 3 HOURS

MAX

MARKS:75

NOTE: Attempt all parts.

PART A

ATTEMPT ALL QUESTIONS

10X2=20

1. _____ is a series of standards dealing with quality management systems.
 - a. ISO 9000
 - b. ISO 9001
 - c. ISO 9002
 - d. ISO 9003
2. Following is (are) the benefits(s) of ISO 9000 Certificate.
 - a. Greater quality awareness
 - b. Increased market share
 - c. Reduced
 - d. All the above
3. A is the system which provides guidelines for the organization and its employees to identify the needs of customer and to _____ and to meet these needs.
 - a. Design and development
 - b. Deliver the product or services
 - c. Produce
 - d. All the above
4. Cleaner production is the continual effort to _____ without reducing production capacity
 - a. Prevent pollution
 - b. Reduce the use of water and material resources and minimize waste
 - c. Reduce the use of water
 - d. All the above
5. A is the system which provides guidelines for the organization and its employees to identify the needs of customer and to _____ and to meet these needs
 - a. Design and develop
 - b. Deliver the product or services
 - c. Produce
 - d. All the above

6. ISO 9001 has _____ clauses.
 - a. Five
 - b. Six
 - c. Seven
 - d. Eight
7. A situation in which one country, region, or producer can produce a particular commodity more cheaply than another country, region or producer
 - a. Competitive advantage
 - b. Geographical advantages
 - c. Regional advantages
 - d. All the above
8. When operation a quality cost system, in which of the following condition, management action is required
 - a. When the sum of appraisal and prevention costs exceed failure cost
 - b. When 80% of appraisal cost is more than 20% of failure costs (80:20 rule)
 - c. When appraisal costs exceed failure costs
 - d. There is no fixed rule
9. Benefits of integrated management system
 - a. Cost reduction
 - b. Common operational documentation
 - c. Elimination redundancies
 - d. All the above
10. Which of these are 2 principles of the quality management
 - a. Customer management
 - b. Improvement
 - c. Engagement of leadership
 - d. Process approach
 - e. Eat quality streets

PART B

ATTEMPT ANY TWO (2) QUESTIONS

2X10=20

11. Discuss about ICH guidelines for stability testing of drugs substances.
12. Summaries the quality as a strategic decision.
13. Describe regulatory compliance through quality management.

PART C

ATTEMPT ANY SEVEN (7) QUESTIONS

7X5=35

14. Describe the risk management tool.
15. Discuss the change control.
16. Discuss about tools for quality improvement.
17. Explain the statistical control charts.
18. Define the iso management system.

19. Distinguish between out of specification (OOT) and out of trend.
20. Conclude customer focus in term of quality.
21. Describe the concept of IPQC.
22. Explain statistical control charts.