

SP Code: 10022421

Time: 3 Hours

Marks: 75

Q. 1 Attempt all multiple-choice questions (MCQ)

20M

- | Sr No | Questions | Options |
|-------|--|---|
| 1 | Which from the following is important for implementation of TQM in organization? | a Globalization
b Growing social status
c Employee Involvement
d Research Funding |
| 2 | Process capability = | a $\pm 6\sigma$
b $\pm 3\sigma$
c $\pm 3\sigma/2$
d $\pm 6\sigma/3$ |
| 3 | _____ benchmarking focuses on assessing competitive positions through comparing the products and services of other competitors | a Process
b Strategic
c Performance
d Retrospective |
| 4 | Cost incurred to detect defects to assure conformance to quality standards is _____ | a appraisal Cost
b prevention cost
c internal failure cost
d external failure cost |
| 5 | _____ type of customers are less in numbers but promote more sales and profit as compared to other customers and are completely satisfied. | a Need based
b Loyal
c Impulsive
d Discount |

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- 6 Reducing waste, preventing mistakes, lowering costs etc. are the major benefits of -----
- a Quality management systems
 - b cGMP
 - c ISO 14000
 - d ICH Q10
- 7 Functional benchmarking involves:
- a benchmarking your competitors.
 - b benchmarking global competitors in your industry.
 - c benchmarking organizations with regards to specific business activities or processes
 - d benchmarking other multinational firms with similar corporate strategies or similar customers
- 8 The data driven approach using statistical methodology for eliminating defects is known as
- a six sigma
 - b McKinsey 7s
 - c operational excellence
 - d OOT
- 9 The _____ should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system.
- a Quality System
 - b Quality program
 - c Quality planning
 - d Quality policy
- 10 Time involved in ISO certification for large organization is ----months
- a 6-8
 - b 12-15
 - c 20-22
 - d 8-12

- 11 A performance metric that helps to evaluate the progress or achievement of a specific objective
- a Key performance indicator
 - b Critical performance key
 - c Performance index
 - d Key result area
- 12 The alternative name for Pareto chart is ---
- a Scatter diagram
 - b 80:20 rule
 - c Run rule
 - d Control rule
- 13 As per ICH guidelines, stress testing has to be carried out on a single batch of the drug substance, at stated temperatures and relative humidity equal to or more than _____
- a 75%
 - b 70%
 - c 80%
 - d 65%
- 14 The level of effort, formality, and documentation of the QRM process should commensurate with the _____
- a Level of risk
 - b Number of employees in QA
 - c Importance of product to management
 - d Number of steps in product manufacturing
- 15 ICH guideline for stability testing of new drug substances and products is _____
- a Q3 (R2)
 - b Q8 (R2)
 - c Q1A (R2)
 - d Q9 (R2)

- 16 Which of the following is not a benefit of QbD approach? Q?
- Minimize deviation and costly investigations
 - Avoid regulatory compliance problem
 - Reduce inventory
 - Eliminate batch failures
- 17 Which of the following is hard element of McKinsey 7s model?
- Staff
 - Style
 - Skill
 - System
- 18 Which of the following is correct flow for benchmarking process?
- Planning, Data gathering and analysis, Integration, Action and monitoring.
 - Data gathering and analysis, Planning, Integration, Action and monitoring
 - Integration, Planning, Data gathering and analysis, Action and monitoring.
 - Action and monitoring, Data gathering and analysis, Planning and Integration
- 19 Which of the following is True for Six -sigma system?
- The lower the sigma no defects at all
 - The higher the sigma, the higher the defect
 - The lower the sigma, the fewer the defect
 - The higher the sigma , the fewer the defect
- 20 Quality metrics are measurements of _____ of products, services and processes.
- price and quality
 - value and performance
 - quality and shelf life
 - durability and aesthetics

Q 2. Attempt any Two question

20 M

- i) Enlist risk management tool and show schematic representation of an overview of quality risk management process and explain the same in detail.
- ii) Define OOT and OOS. Explain how tracking of OOT can avoid OOS. Enlist the different phases in OOS investigation as per US FDA guidelines.
- iii) What is Total Quality Management and its concept? Explain in Brief tools used in Root cause analysis.

Q 3. Attempt any Seven questions

35M

- i) Write a brief note on customer behavior
- ii) Explain the terms:
 - a) Quality manual
 - b) Operational excellence
- iii) Explain the causes for recall of a product. Classify Recalls based on the category of risks with their timelines.
- iv) Elaborate on the stability testing of drug products as per ICH guidelines with special mention of the products intended for storage in refrigerator.
- v) What is meant by Statistical control charts? State the advantages for the same
- vi) Write a Detail note on McKinsey 7s model
- vii) Define benchmarking. Enlist nine types of benchmarking and elaborate any three types.
- viii) Write a note on Change Management.
- ix) Explain in detail compliance thought development of quality culture