

Time: 3 Hours

Total Marks: 75

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

20M

Sr No	Questions	Options
1	CFR-21 Part 11 is related to:	a Medical Device Regulations b Food Safety Standards c Electronic Records and Signatures d Environmental Impact Assessment
2	Process capability is a measure of:	a Employee productivity b The ability of a process to produce conforming products c Marketing effectiveness d Raw material availability
3	One of the advantages of benchmarking is:	a Decreased Awareness of Industry Trends b Limited Access to External Knowledge c Enhanced Adaptability to Changes d Isolation from External Practices
4	What distinguishes customer delight from customer satisfaction?	a Satisfaction is a one-time occurrence b Satisfaction is achieved through cost reduction c Delight is achieved by exceeding customer expectations d Delight is solely based on product price
5	Which of the following is an example of an appraisal cost in the cost of quality?	a Employee training programs b Scrap and rework costs c Product testing and inspection d Warranty repairs
6	Which of the following is a leading quality metric in manufacturing?	a Customer Satisfaction Score b Return on Investment c On-time Delivery d Employee Attendance Rate
7	What is the primary objective of regulatory compliance in Quality Management?	a Maximizing Profit b Ensuring Legal Conformity c Reducing Employee Turnover d Accelerating Production Speed

8	In ISO 9001:2015, which clause focuses on the "Leadership" of an organization?	a	Clause 4
		b	Clause 5
		c	Clause 6
		d	Clause 7
9	In the context of quality, what does the dimension of "Durability" refer to?	a	The consistency in meeting specified standards
		b	The presence of additional features beyond basic functionality
		c	The ability of a product to withstand wear, stress, and environmental conditions
		d	The appearance and feel of the product
10	What role does the Quality Management Review play in achieving Operational Excellence?	a	Avoiding Customer Feedback
		b	Identifying Opportunities for Improvement
		c	Ensuring Cost Reduction
		d	Implementing Short-Term Fixes
11	According to Genichi Taguchi's Loss Function, what happens when a product or process deviates from the target or ideal value?	a	Gradual increase in quality costs
		b	Linear decrease in quality costs
		c	Immediate elimination of quality costs
		d	No impact on quality costs
12	Which statistical tool is commonly used to measure the dispersion of data points in a process?	a	Mode
		b	Mean
		c	Median
		d	Range
13	In the context of ICH stability zones, which zone represents a hot and humid climate?	a	Zone I
		b	Zone II
		c	Zone III
		d	Zone IV

14	In the context of Quality Risk Management, what is the initial step in the risk management process?	a	Risk Control
		b	Risk assessment
		c	Risk review
		d	Risk ranking
15	In developing a tablet formulation using QbD, what could be considered a Critical Quality Attribute (CQA)?	a	Employee Training
		b	Dissolution rate
		c	Package size
		d	Tablet color
16	Why is Quality Risk Management important in the pharmaceutical industry?	a	To ignore variations in manufacturing processes
		b	To enhance decision-making and ensure product quality
		c	To avoid regulatory compliance
		d	To minimize any form of risk
17	All of the following are 7S elements in the McKinsey model except _____.	a	Strategy
		b	Structure
		c	Sales
		d	Shared Values
18	Company X is interested in comparing its production efficiency with that of its direct competitors. Which type of benchmarking is Company X employing?	a	Financial Benchmarking
		b	Process Benchmarking
		c	Performance Benchmarking
		d	Strategic Benchmarking
19	In response to a batch failure due to a deviation in the manufacturing process, what could be a suitable Corrective Action as part of CAPA?	a	Implementing a new product variant without further investigation
		b	Minimizing documentation to expedite the process
		c	Updating the employee training program to address the specific deviation
		d	Ignoring the deviation and proceeding with the batch release
20	NABL is associated with the accreditation of:	a	Manufacturing Plants
		b	IT Companies
		c	Laboratories
		d	Hospitals

Q 2. Attempt any Two question

20 M

- i) Elaborate on how QbD principles contribute to a systematic and science-based approach to process development.
- ii) Discuss the key components of the Six System Inspection model and quality systems in pharmaceutical quality management.
- iii) Explain the core principles and implementation of Total Quality Management and how they contribute to organizational excellence.

Q 3. Attempt any Seven questions

35M

- i) Discuss how the alignment of strategy, structure, systems, and shared values contributes to effective quality management.
- ii) Enumerate the principles underlying the six sigma process? Discuss any one example of six sigma process.
- iii) Discuss the importance of vendor qualification in pharmaceutical manufacturing.
- iv) Explain the critical aspects of drug stability testing as outlined in the ICH guidelines for drug substances.
- v) Define SPC and discuss how SPC helps in early detection of deviations and continuous improvement.
- vi) Explain the concept of cost of quality and its various categories.
- vii) Explain Benchmarking Process and discuss the limitations of it in Quality management system.
- viii) Give the differences between deviations, Out of Specifications (OOS), and Out of Trend (OOT) occurrences in pharmaceutical manufacturing.
- ix) Enlist types of benchmarking and explain the reasons for benchmarking.