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 specifie standards
		b	The presence of additional feature beyond basic functionality
		c	The ability of a product to withstan wear, stress, and environmenta 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.
