F.Y. M.Ph
09/04/25
Sem - I

Time: 3 Hrs **Marks:75**

Q. 1 Attempt all multiple-choice questions (MCQ) 20M

1	Time involved in ISO certification for large organization is ----months	a	6-8
		b	12-15
		c	20-22
		d	8-12
2	The process of alteration of information in an electronic record without hampering original record is ---	a	LMS
		b	eSign
		c	Audit trail
		d	Access control system
3	The lowest level in six sigma is known as ----belt	a	Black
		b	Yellow
		c	White
		d	Green
4	Reducing waste, preventing mistakes, lowering costs etc. are the major benefits of -----	a	Quality management systems
		b	cGMP
		c	ISO 14000
		d	ICH Q10
5	The development in ISO 9001:2015 is ---- based approach unlike ISO 9001:2008	a	process
		b	Customer satisfaction
		c	Variability
		d	Materials
6	The data driven approach using statistical methodology for eliminating defects is known as	a	McKinsey 7s
		b	Six sigma
		c	OOT
		d	Operation excellence
7	Investigations and analysis of Deviation Results help in identifying the	a	Completion status of a batch
		b	Dispatch status of a batch
		c	New material from existing sources
		d	Root Cause of Failure
8	Six sigma follows usually ------ methodology	a	DMAIC
		b	CDMAI
		c	AMICD
		d	MICDA

9	Line Clearance procedures comprise of the following three stages	a	Clearing, Cleaning, Checking
		b	Checking, Cleaning, Clearing
		c	Clearing, Checking, Cleaning
		d	Cleaning, Checking, Clearing
10	A quality metric given by the ratio of orders completed by scheduled date to total number of orders is ----	a	Schedule realization
		b	Yield
		c	Capacity utilization
		d	Throughput
11	When the packaging material of a 'Complaint Sample' is different from that of the 'Retention Sample' the investigation may be concluded as	a	A Confirmed Complaint
		b	A Suspicion of tampering
		c	A non-confirmed complaint
		d	Out of specification case
12	The alternative name for Pareto chart is ---	a	scatter diagram
		b	80:20 rule
		c	Run rule
		d	Control rule
13	Mission is defined as	a	Organization's deadlines and targets
		b	Statement of organization's purpose and scope of its operation
		c	The desired future position of organization
		d	Organization's operational plan
14	Name the management in which supervisor is not the boss but is a facilitator	a	Management by objectives
		b	Competitive management
		c	Maslow's management
		d	Total quality management
15	Cost of quality (COQ) = Cost of prevention activities (C_p) + Cost of appraisal activities (C_a) + Cost of failure because of rejections of products (C_f) + Cost of lost opportunities (C_o) is ____	a	PAF model
		b	Process model
		c	Opportunity model
		d	Cost benefit model

16	Which is the formal recognition by an authoritative body of competence to work to specified standards?	a	Certification
		b	Validation
		c	Accreditation
		d	Compliance
17	The behavior of people in organization and their habits, beliefs and values concerning quality and providing that quality to their customers is called	a	Quality mamnagement
		b	Quality culture
		c	Quality objective
		d	Quality policy
18	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
19	Which of the following is disadvantage of benchmarking?	a	Identification of gaps in process when compared with others
		b	Cannot change all required improvement at once.
		c	Sharing the best practices
		d	Learning from others experience and practices
20	Which from the following is important for implementation of TQM in organization?	a	Globalization
		b	Growing social status
		c	Employee Involvement
		d	Research Funding

Q 2. Attempt <u>any Two</u> question **20 M**

i) Explain the stability testing of drug products as per ICH guidelines on following points: Stress testing, Selection of batches, Testing frequency and Storage conditions

ii) Elaborate 'Six System Inspection Model' by enlisting all of them. Discuss their significance and explain any three systems of your choice.

iii) Explain the terms:

a) Knowledge management b) Quality manual

c) Quality metrics d) Operational excellence

Q 3. Attempt <u>any Seven</u> questions **35M**

i) Enlist all elements of McKinsey"s 7s Management Model. Briefly explain any four elements of the model

ii) Add a note on Total Quality Management. State advantages of TQM

iii) Explain the concept of CAPA and its application throughout the product lifecycle

iv) Explain the term: Quality by Design. Give simplified flow chart of QbD process

v) Explain the term "Process capability" Discuss how it is measured?

vi) Discuss any five factors affecting customer perception

vii) Define benchmarking and list out the types for the same. Discuss any two types of benchmarking

viii) Explain how batch review and annual product review help in building up of a quality environment.

ix) Discuss the advantages of the Benchmarking and Statistical process control

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