

KATHMANDU UNIVERSITY
End Semester Examination [C]
April 2023

Marks Scored:

Level : B.Tech.

Year : IV

Exam Roll No. :

Time: 30 mins.

Course : BIOT 403

Semester : I

F. M. : 20

Registration No.:

Date

09 APR 2023

SECTION "A"

[20Q. × 0.75 = 15 marks]

Encircle the most appropriate alternative from each set of choices

1. The efficient disinfectant for handling biological hazards is _____.
a. Iodophor b. Hypochlorite c. Saline water d. Alcohol
2. Risk balancing policies (e.g. Cost – benefit) include _____.
a. Zero risk b. ALARA c. ADI d. MRL
3. SPS Agreement includes _____.
a. Horizontal Standard b. Vertical Standard
c. Equivalence d. Method Validation
4. Which of the following ISO standard is used for certification of food safety?
a. ISO 9001 b. ISO 22000 c. ISO 14001 d. ISO 9004
5. Which organization is responsible for deciding Deming Award?
a. ISO b. UNIDO c. UNCTAD d. JUSE
6. Which one of the international body is involved in the definition of HACCP?
a. International Association of Sanitarians
b. Codex Alimentarius
c. International Association of Food Safety
d. Food and Drug Administration
7. Total quality is defined as "conformance to specification" by _____.
a. Edward Deming b. Joseph Juran c. Philip Crosby d. Kaoru Ishikawa
8. The portion of defectives (fraction rejected) is given by _____.
a. p chart b. np chart c. c chart d. u chart
9. The letters SOPs stand for _____.
a. Standard Operating Practices b. Standard Operating Procedures
c. Standard Operational Practices d. Sanitation Operational Principles
10. Who developed "Cause and Effect Diagram"?
a. Deming b. Juran c. Ishikawa d. Crosby

11. Surveillance audit is conducted _____.
 a. Before certification b. After three months of certification
 c. One in six months d. One in six months till the certification period is over

12. SPS Enquiry Point in Nepal is _____.
 a. NBSM b. MOALD c. DFTQC d. DOI

13. Which of the following is **NOT** associated with the hazard analysis portion of the HACCP program?
 a. A review of the menu to identify potential hazards
 b. A risk assessment of both the likelihood that hazards will occur and their severity if they do occur
 c. A series of questions use to facilitate the identification of potential problems in each step in the flow of food
 d. The identification of critical control points whereby hazards can be prevented, eliminated, or reduced to acceptable level

14. Prerequisite programs in HACCP implementation require _____.
 a. Standard b. Accreditation c. Good Practices d. Quality Control

15. Transparency in SPS Agreement is ensured by establishing _____.
 a. Regulatory Body b. Standard Setting Body
 c. Harmonization d. Enquiry Points

16. The requirement of audit for ISO 9001 certified enterprises is called _____.
 a. First Party Audit b. Second Party Audit
 c. Third Party Audit d. System Audit

17. Which one of the following is not related to horizontal part of QFD matrix?
 a. Customer requirement b. Technical description
 c. Technical part d. Competitive technical assessment

18. FMEA team is irrelevant to _____.
 a. Process engineering b. Maintenance
 c. Manufacturing d. Quality monitoring

19. Accuracy of analytical data indicates _____.
 a. Closeness of two repeated data b. Closeness of data with standard value
 c. Divergent of two repeated data d. Precision data

20. Scatter diagram shows _____.
 a. Defects in decreasing order b. Defects in increasing order
 c. Correlation between two variables d. Distribution of observed values

SECTION "B"
[10Q. × 0.5 = 5 marks]

Fill in the blanks

21. The share of responsibility of top management in quality improvement of the enterprises is _____
22. The dispute of quality and safety issues of medicinal plants is resolved on the basis of _____
23. The process of adopting established methods such as AOAC and ISO methods in our laboratory is called _____
24. The agreement between two laboratories in two countries is called _____
25. The presence of *Clostridium botulinum* in meat is called _____
26. The essential feature of ISO 9001:2008 is based on _____
27. Kaoru Ishikawa has pioneered the concept and modality of _____
28. "Zero Defect" in antibiotic production plant is ensured by _____
29. The best performing industries receive _____ in Nepal.
30. The labeling requirements in the packaged medicinal plants products fall under _____

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SECTION "C"

(Long answer questions)

[3Q. × 7 = 21 marks]

Attempt *ANY THREE* questions.

1. Discuss the scientific rationale of risk analysis of pesticide contaminants in vegetable farms in Nepal.
2. Elucidate the principle and application of SPS measures for promoting honey export from Nepal to EU countries.
3. Discuss the essential features of ISO 17025 standard as per obtaining laboratory accreditation from international accrediting body.
4. Narrate the compatibility between HACCP and FMEA for resolving safety issues of biotech enterprises.

SECTION "D"

(Short answer questions)

[6Q. × 5 = 30 marks]

Attempt *ANY SIX* questions.

5. How do you justify "TQM Transition Model" as a startup quality performance tool in emerging biotech enterprises?
6. What are the major preparatory steps for obtaining ISO 9001 certification in educational institutions?
7. Which one is the appropriate statistical tool for determining antibiotic yield in pharmaceutical company?
8. What are the essential criteria for obtaining "Malcolm Baldrige National Quality Award in the USA"?
9. How do you differentiate ISO 9001 and ISO 9004 quality standards?
10. What are the essential components of Business Engineering and its implication in business process redesign?
11. How does QCC help solve problems and improve the output of the pharmaceutical company?

SECTION "E"

12. Distinguish between (*ANY TWO*)
 - a. Histogram and Pareto diagram
 - b. GLP and Accreditation
 - c. System component and Human Component

[2Q × 2 = 4 marks]