KATHMANDU UNIVERSITY
End Semester Examination
February/March, 2019

Marks Scored:

Level : B. Tech.
Year : IV

Course : BIOT 403
Semester: I

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date FEB 2 1 2019

SECTION "A"
[20 Q. × 0.75 = 15 marks]

Choose and encircle the most appropriate answer among the given choices.

1. Transparency in SPS measures is ensured by
   a) National Codex Committee
   b) Standardization Committee
   c) Notification Authority
   d) Enquiry Point

2. In manufacturing Industry, 15% of defects are due to
   a) Management
   b) Machine defects
   c) Poor quality control
   d) Production operators

3. Defects in ISO 9001 certified production process can be improved by
   a) establishing QC system
   b) change in procurement
   c) validation of process
   d) marketing channel

4. Risk management policy option relates to
   a) risk assessment
   b) hazard characterization
   c) risk balancing policy
   d) risk communication

5. Sulphonamide contamination in milk is a
   a) physical hazard b) chemical hazard c) no hazard d) biological hazard

6. Which one of the following is not used in meat processing plant for assuring safe supply of meat?
   a) GVP b) GMP c) GTP d) MRL

7. Codex is applicable to
   a) food industry b) consumers c) food regulators d) all of them

8. Product description in the label falls under the jurisdiction of
   a) Agriculture agreement
   b) SPS agreement
   c) TBT agreement
   d) Conformity assessment

9. Which of the following is an accepted personal hygiene practice?
   a) Wearing jewelry and false fingernails
   b) Smoking and eating in food production areas
   c) Wearing caps and hats
   d) Wiping hands on a soiled apron

10. The analysis of non-conformities (NC) with a constant sample size is given by
    a) Standard deviation
    b) Range
    c) U chart
    d) C chart

11. Who introduced the concept of 'internal customer' in process steps?
    a) Philip Crosby
    b) Joseph Juran
    c) Kaoru Ishikawa
    d) Kaizen

12. Which one of the following is assigned low score in "The Malcolm Baldridge Quality Award Criteria"?
    a) information and analysis
    b) human resource utilization
    c) quality results
    d) strategic quality planning

13. Which of following statement is false?
    a) A critical limit is the threshold that must be met to ensure that each critical control point effectively controls a microbiological, chemical, or physical hazard
    b) There must be at least two critical control points in the flow of food in order for a HACCP system to be implemented
    c) Many steps in food production are considered control points, but only a few qualify as critical control points
    d) A critical control point, a step, or procedure in food preparation where controls can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels

14. Which of the following statements is false?
    a) Keeping things clean is the responsibility of every person working in the industry
    b) Cleanliness goes beyond the removal of visible soi
    c) A good sanitation program , if properly organized , will function successfully without the support of top management
    d) A good sanitation program starts with a neat, clean, and properly maintained building

15. The ratings in RPN for "S x O x D" are scored on a scale from
    a) 0-10
    b) 10-20
    c) 20-30
    d) 30-40

16. Product Realization Process is irrelevant to:
    a) design and development
    b) purchasing
    c) product validation
    d) customer-related process

17. Approved limit of mycotoxins in food products is determined by:
    a) Codex
    b) IPPC
    c) OIE
    d) NBSM

18. Surveillance Audit is conducted
    a) Before certification
    b) After three months of certification
    c) One in six months
    d) Once in six months till the certification period is over

19. Which one of the following is an appropriate body to conduct risk assessment of pesticide globally?
a) IAEA b) JMPR c) OECD d) JECFA

20. Which of the following is a histamine poisoning?
a) Ciguatoxin b) Scombrotoxin
c) Mycotoxin d) Paralytic Shellfish Poisoning (PSP)

SECTION "B"

[10 Q. × 0.5 = 5 marks]

Fill in the blank space(s) with suitable word(s) or value(s) or symbol(s).

21. Harmonization of national standard with Codex and its application help smoothen_____

22. 'Zero defects' in antibiotics production enterprise is represented by _____.

23. The acceptable limit of contaminants in food product is determined by _____

24. According to ISO 9001 Certification system, establishment of quality policy is the responsibility of _____ _____.

25. The upper control limit in control chart is represented by the equation _____.

26. All pages of Quality Manual should be signed by _____as per ISO 9001 criteria.

27. Limits of contaminants in Codex Standard are fixed on the basis of _____.

28. Kaoru Ishikawa has pioneered _____.

29. The gap analysis in any organization is carried out by_____.

30. _____is the international body for defining HACCP.

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SECTION "C"

(Long answer questions)

[3 Q. × 7 = 21 marks]

Attempt *ANY THREE* questions.

1. Explain the salient features of SPS Agreement from the perspective of exploring agro-food trade in international market.

2. Compare and contrast FMEA and HACCP models for assessing safety assurance of pasteurization process of dairy enterprise.

3. In a newly established vitamin production plant , the yield of the final product Vitamin B 12 in various batch operation is as follows:

SN	Batch Production	Average Yield %
1	1 – 10	35
2	11 – 20	40
3	21 – 30	45
4	31 – 40	55
5	41 – 50	55
6	51 – 60	60
7	61 – 70	65
8	71 – 80	70

Select the appropriate Statistical tools to indicate performance data of the newly established vitamin manufacturing industry

4. Case study

A Biotech R & D Institute was assigned the task of optimizing glucosinolates content in Broccoli at various ecological niches of Nepal ranging from plain Terai near river belt, and at different altitudinal range. The options may vary from different temperature, humidity, etc. including the appropriate cultivars, varietal selection, genetic improvement etc. The consumers at large prefer broccoli as an important component of vegetable intake. The influence of various steps in production chain on the glucosinolates content mainly comprises of cultivation, storage, processing, packaging, storage. The intended improved products in a ready-to –eat meal with a health benefit contain broccoli, potato, and marinated salmon. The health benefit originates from glucosinolates in the raw broccoli. Research indicates that these phytochemicals play an important role in the prevention of various diseases mostly ageing diseases like cancer. Researchers demonstrate that various steps in the production chain of vegetable can influence the final intake of these glucosinolates. To improve the final product, various steps in production

chain have to be known and qualified. However, changing production processes will also influence other quality characteristics. A very high amount of glucosinolates is toxic as well. Therefore, it is essential to optimize the level of glucosinolates in broccoli preserving in post-harvest operations and finally in the cooked vegetables in the meal. The QFD models embodying 'House of Quality' can translate customer's demands into practicable technical language.

Discuss:

a) How do you develop 'House of Quality' for optimizing glucosinolate content in broccoli?
b) How do you establish correlation matrix, planning matrix, and technological matrix?
c) Develop quality improvement modality for glucosinolate content in broccoli

SECTION "D"

(Short answer questions)

[6 Q. × 5 = 30 marks]

Attempt *ANY SIX* questions.

5. How do you categorize Juran's ten steps quality improvement into Deming's Wheel?

6. What is the significance and application of "Triple Role" in quality management concept enshrined in ISO9001?

7. Develop Strategic Planning for strengthening R & D capacity of Department of Biotechnology.

8. What are the prerequisite requirements for obtaining ISO 9001 Certification?

9. How do you justify 'Integrated Model' of TQM as proactive for quality improvement?

10. How do you determine CP and CCP in KU canteen?

11. How do you use Control Chart in process monitoring of Biotech Industry?

SECTION "E"

[2 Q. × 2 = 4 marks]

12. Distinguish between (*ANY TWO*)
    a) Hazard Characterization and Risk Categorization
    b) Quality Control and Inspection
    c) JUSE and JECFA