Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

FINAL EXAMINATION
SEMESTER I
SESSION 2019/2020

COURSE NAME	:	QUALITY ASSURANCE & QUALITY CONTROL IN BIOTECHNOLOGY
COURSE CODE	:	BNN 20303
PROGRAMME CODE	:	BNN
EXAMINATION DATE	:	DECEMBER 2019 / JANUARY 2020
DURATION	:	3 HOURS
INSTRUCTION	:	ANSWERS **ALL** QUESTIONS ONLY

THIS QUESTION PAPER CONSISTS OF **FIVE (5)** PAGES

Q1 (a) Customer complaints clearly need to be dealt with effectively. An unhappy customer is a negative advocate in respect of your organization; they will be sharing their experiences and dissatisfaction. However, too many companies rely solely on feedback from customers to drive their improvement processes.

(i) Explain **TWO (2)** basic assumptions in this approach, both of which are flawed to improve complaints satisfaction.

(6 marks)

(ii) List out the factors that influenced the concept of costumer value requirements gathering and analysis.

(3 marks)

(b) In quality management leadership can be defines as "*the creation of a vision and environment which inspire people to contribute to organizational goals and nurtures both their capability to do so and their well-being within their endeavors*". One of the most important functions of leaders (at all levels) is to make decisions. In particular, the decisions at the top of the organization set the tone for those taken further down. List **FIVE (5)** key aspects that influenced the decision making process in Quality Management.

(5 marks)

(c) Teamwork is a crucial aspect of Quality Management, while individuals are very important, most of the work undertaken in an organization will be undertaken in teams, whether they are manufacturing teams, management teams or improvement teams. Explain why teamwork is important in quality management in term of task complexity and understanding communication.

(4 marks)

(d) Quality Improvement Teams (QITs) can be formed where there is a specific problem whose solution is unlikely to reside in a single department and which is large enough to justify the establishment of a team to resolve the problem. For example, if test equipment is always breaking down it may require the combined actions of Production, Testing, Technical Departments as well as the Supplier, and a team could be formed which would include all these departments. Determine the benefits of QITs as a powerful problem solving activity in quality management.

(7 marks)

Q2 (a) Ethics deal with such questions at all levels. This subject consists of the fundamental issues of practical decision making, and its major concerns include the nature of ultimate value and the standards by which human actions can be judged right or wrong. There are a range of ethical models which may be applied by an organization, they are dependent upon the ethical stance of the organization concerned and arguments can be made for each one.

(i) Define the following terms: ***egoism, relativism and utilitarianism***.

(3 marks)

(ii) Demonstrate ethical decision model adapted from Vallance, 1995 which suggested when significant business decisions need to be made.

(4 marks)

(iii) Summaries the benefits of ethical behaviour in organization in all type of industries.

(4 marks)

(b) Organizational learning is an influential theory, which has come into popular usage since its inception in the 1990's. Much debate has been entered into over what organizational learning actually means. West and Burnes (2000) build upon this to note that learning organizations have capacity for (amongst other things) systematic problem solving, experimentation, communicating effectively within and beyond the organization and systems thinking.

(i) Highlight **FOUR (4)** major components that suggested by Huber's Model that must have in organizational learning process.

(5 marks)

(ii) Discuss and elaborate characteristics of a learning organization which allow effective integration of the process and the human element of change.

(9 marks)

Q3 (a) Six Sigma is a business management strategy, it originally developed by Motorola in 1986. Six Sigma became well known after Jack Welch made it a central focus of his business strategy at General Electric in 1995, and today it is widely used in many sectors of industry.

(i) Define the outcome of Six Sigma project carried out within an organization.

(2 marks)

(ii) Outline **FIVE (5)** phases of DMADV project methodology according to Design for Six Sigma that used for projects aimed at creating new product or process designs.

(3 marks)

(b) Hospital Kuala Lumpur decided to address the problem that critical patients were not being seen fast enough in the outpatient department (OPD). They set an aim to decrease waiting time, on average, for high acuity patients seen in the OPD from 179 minutes to 30 minutes. Draw a fishbone diagram to investigate the underlying causes of this problem.

(6 marks)

(c) The operations manager of Desbro Ltd has been concerned about machine No. 3 in the assembly line in the factory. In order to make sure that the machine is operating correctly, samples are taken, and the average and range for each sample is computed. Each sample consists of 10 items produced from that machine. Recently, 12 samples were taken and the sample range and average computed are shown in the **Table Q3(c)**.

Table Q3(c): Range and mean number of samples.

Sample Number	Sample Range	Sample Mean
1	1.00	45
2	1.21	44
3	0.81	45
4	1.00	46
5	1.11	47
6	0.72	46
7	0.76	49
8	1.01	48
9	1.02	50
10	0.89	51
11	0.76	49
12	1.10	51

During installation, the supplier sets an average of 46 for the process with an average range 0.9. Validate the production process of machine No. 3 by drawing the appropriate control charts. Interpret your findings on process average and process variability.

(10 marks)

(d) Stratification is the process of dividing members of the population into homogeneous subgroups before sampling. Identify **TWO (2)** stratified sampling strategies used to estimate population statistics from a known population.

(4 marks)

Q4 (a) In many organizations that manufacture / distributor or manage complex systems, the more sophisticated approach is required to arrive at the root causes of systems failures. Although the approach offers more sophisticated techniques for developing potential failure causes and required corrective actions, the technologies involved still follow the four-step problem-solving process.

(i) Outline **FOUR (4)** steps of problem solving process that involved in system failure analysis.

(4 marks)

(ii) Define the term ***system failure analysis***.

(2 marks)

(b) Pharmaceutical industry is constantly looking for ways to ensure and enhance product safety, quality and efficacy. Cross contamination between two products is rarely happened but the effect may render the pharmaceutical products unfit for consumption or reduce its efficacy. Sketch fault tree diagram that can be used to analyze issues on cross contamination between products.

(5 marks)

(c) Quality circles were originally organized along the lines of the factory work center. Ishikawa's concept was that the people in a work center (along with their supervisor) would constitute the quality circle. In that sense, the quality circle team would be exactly the same as the work center team. Discuss the advantages and disadvantages of the principal quality circles.

(6 marks)

(d) Paint defect analysis from an automotive assembly plat showed that, the problems are coming from dirt in pain (65 cases), orange peel (12 cases), sealer paint (5 cases), off-colour (2 cases), scratch (2 cases), sag (21 cases) thin paint (5 cases) and other (1 case). Develop a Pareto chart based on the studies that can help, determine the highest priority to work on first.

(8 marks)

-END OF QUESTIONS-