



**UNIVERSITI TUN HUSSEIN ONN MALAYSIA**

**FINAL EXAMINATION  
SEMESTER I  
SESSION 2018/2019**

COURSE NAME : QUALITY ASSURANCE & QUALITY CONTROL IN BIOTECHNOLOGY

COURSE CODE : BNN 20303

PROGRAMME CODE : BNN

EXAMINATION DATE : DECEMBER 2018 / JANUARY 2019

DURATION : 3 HOURS

INSTRUCTION : ANSWERS ALL QUESTIONS

**TERBUKA**

THIS QUESTION PAPER CONSISTS OF SEVEN (7) PAGES

**Q1** Organizations today face a continuous barrage of requests to improve quality. They may throw front-line staff into quality training workshops in the hope that this will improve the management of quality. Management may decide to attend quality management workshops to become acquainted with the latest strategy; exposing themselves to Six Sigma, Lean Manufacturing, Process Management, and Quality Awards. The development of a strategic quality plan is the key to determining the right quality initiatives for your organization.

- (a) Define the term;
  - (i) Control (1 mark)
  - (ii) Quality Control (1 mark)
  
- (b) A quality system uses the business model with a focus on the customer and includes the dynamics of continual improvement, change, planning, and renewal. Identify **SIX (6)** basic functional areas that business model must considered in applying quality system model. (3 marks)
  
- (c) Kaoru Ishikawa developed seven basic visual tools of quality to analyze and interpret data. These tools have been used worldwide by companies, managers of all levels and employees.
  - i) Determine **TWO (2)** functions of check sheets to organization/company according to Ishikawa theory. (2 marks)
  - ii) **Table Q1 (c)(ii)** show record failures on production of computer during quality inspection. As future quality technologist, interpret the data from your company into histogram. (4 marks)

**Table Q1 (c)(ii): Checks list and record failures on production department.**

Checks list	Total
Power up	4
Boot up	15
Sink test	5
Case damage	4
Keyboard damage	0
Monitor damage	3
Bundled s/w included	7



- (iii) Control charting is the most technically sophisticated tool of the 7 quality tools. It was developed in the 1920s by Dr. Walter A. Shewhart of the Bell Telephone Labs. The purpose was to improve the process effectiveness and therefore reduce costs. Explain the rationale on adapting this tool into organization quality control system. (4 marks)

- (d) The operation manager of Xendrax Ltd is 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 of production time 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 of production time is computed for each are as follows in **Table Q1 (d)**.

**Table Q1 (d): Sample number of machine No. 3**

Sample Number	Sample Range (s)	Sample Mean (s)
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 production time of 46s for the process with an average range 0.9s. Validate the production process of machine No. 3 by drawing the appropriate control charts. Interpret your findings on process average and process variability. You may use **Table Q1 (d)i)** to determine the trend of machine No.3 control chart.

(10 marks)

- Q2** (a) Project management is the process planning, organizing and also managing the effort to accomplish a successful project. A project is a one-time activity that produces a specific output or outcome, for example, a building or a major new computer system.

- (i) Identify **FIVE (5)** activities that project management must encompass before the planning and execution of a project.

(5 marks)

- (ii) Define the term ‘scheduling’ and ‘tracking’ used in project management system.

**TERBUKA** (2 marks)

- (iii) In project management, communicating effectively in a large project is one of the main challenges especially for a new project leader or members. Based on your opinion, explain how this challenge could be encountered, so that the company is able to sustain their professional image in for the public.

(3 marks)

- (b) A Gantt chart is a type of bar chart that illustrates a project schedule. This chart lists the tasks to be performed on the vertical axis, and time intervals on the horizontal axis. Gantt charts illustrate the start and finish dates of the terminal elements and



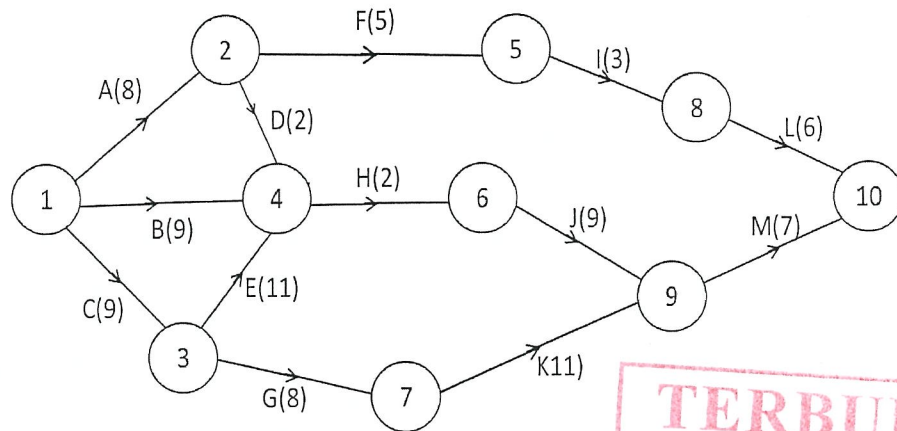
summary elements of a project. **Table Q2 (b)** shows the activities prepared by project leader to start up a new TrayX project. Interpret the information and demonstrate the schedule in a Gantt chart.

(5 marks)

**Table Q2 (b): Project Schedule for TrayX Project**

Activity Letter	Activity Description	Predecessor	Duration (months)	Overlap (months)
A	Train project team	None	1	None
B	Project paperwork and systems design	A	2.5	None
C	Modify purchased package	B	2	1
D	Manual systems flow	B	1.5	1
E	Modify in-house procedures	B	4	1
F	Test and implement modifications to purchased package	C	1.5	0.5
G	Test and implement manual	D	1.5	0.5
H	Test and implement modifications to in-house procedures	E	1.5	0.5

- (c) An engineering project is modeled by the activity network shown in **Figure Q2 (c)**. The activities are represented by the arcs. The number in brackets on each arc gives the time, in days to complete the activity. Each activity requires one worker. The project is to be completed in the shortest time.



**Figure Q2 (c): Activities network model.**



- (i) Estimate the early time and late time for each event. (5 marks)
- (ii) Select the critical activities for this project. (2 marks)
- (iii) Evaluate activities D, E and F in order to find total float.

(3 marks)

**Q3** A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction (ISO9001:2015). It is expressed as the organizational goals and aspirations, policies, processes, documented information and resources needed to implement and maintain it.

(a) Discuss the improvement of organizational learning and knowledge in quality system.

(3 marks)

(b) Describe the purpose of integrative systems in quality management.

(2 marks)

(c) The goal of self-assessment is to observe current practices, to assess those practices and to identify gaps in deployment. As internal auditor, explain four-step process in performing self-assessment for your company.

(6 marks)

(d) The audit process is based on a framework of standards, concepts, procedures, and reporting practices. List **FOUR (4)** types of performance audits that assist management in maintaining output standard.

(4 marks)

(e) Propose the steps involve in basic quality audit and explain each based on your understanding.

(10 marks)

**Q4** (a) “Quality by Design”(QbD) is one of methodology initiated by the US Food and Drug Administration’s (FDA).QbD requires a thorough understanding of a product and its process of manufacture, necessitating an investment in time and resources upfront in the discovery and development of a product. For QbD, the product and process knowledge base must include an understanding of variability in raw materials, the relationship between a process and product's critical quality attributes (CQAs), and the association between CQAs and a product's clinical properties.

(i) Define the term “Critical Quality Attributes (CQA)”.

(2 marks)

(ii) Identify **THREE (3)** benefits of implementing quality by design in biotechnology industry.

**TERBUKA** (3 marks)

(b) Quality function deployment (QFD) describes a method for translating customer requirements into functional design.Sometimes this process of translation is referred to as the voice of the customer. Set up **EIGHT (8)** steps that involve in quality function deployment (QFD).

(8 marks)

- (c) Nowadays, a square, a pencil, and a drafting table, are no longer the tools of the designer. Today, a designer is much more likely to use a computer-aided design (CAD) system. These systems are used in designing anything from an ultralight airplane, to a hamburger, to a home, or to a new intersection that can handle higher volume of traffic. Computer aided tools greatly improved the ability of the designers to generate new a varied designs. Demonstrate how design review and automation play its role in CAD system application. (5 marks)
- (d) Prototyping is an iterative approach to design in which series of product mock-ups is developed until the customer and the designer agree on the final design. In some cases, the customer might not be an external user but upper management that approves the final designs of products.
- (i) Identify **(FIVE) 5** stages in prototypes design cycle. (5 marks)
- (ii) The product life-cycle concepts demonstrate the need for developing new products by showing products design, redesign, and complementary product development on a continuum. Show **TWO (2)** imperatives actions that have come to the forefront in the study of product life cycles. (2 marks)

**-END OF QUESTIONS -**

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**Table Q1 (d)i): Constants (A & D) for control chart.**

n	A <sub>2</sub>	n	A <sub>2</sub>	n	A <sub>2</sub>
2	1.880	7	0.419	12	0.266
3	1.023	8	0.373	13	0.249
4	0.729	9	0.337	14	0.235
5	0.577	10	0.308	15	0.223
6	0.483	11	0.285		

*Constants (A), based on the subgroup size (n), are used in determining control limits for variables charts.*

n	D <sub>4</sub>	n	D <sub>4</sub>	n	D <sub>4</sub>
2	3.267	7	1.924	12	1.717
3	2.574	8	1.864	13	1.693
4	2.282	9	1.816	14	1.672
5	2.114	10	1.777	15	1.653
6	2.004	11	1.744		

*Constants (D), based on the subgroup size (n), are used in determining control limits for range char*

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