Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

FINAL EXAMINATION
(TAKE HOME)
SEMESTER I
SESSION 2020/2021

COURSE NAME	:	QUALITY ASSURANCE & QUALITY CONTROL IN BIOTECHNOLOGY
COURSE CODE	:	BNN 20303
PROGRAMME CODE	:	BNN
EXAMINATION DATE	:	JANUARY/FEBRUARY 2021
DURATION	:	3 HOURS
INSTRUCTION	:	ANSWERS **ALL** QUESTIONS **OPEN BOOK EXAMINATION**

THIS QUESTION PAPER CONSISTS OF **SIX (6)** PAGES

Q1 (a) Quality management is an approach to improve the effectiveness and flexibility of business as a whole. Debate the **FIVE (5)** basic tenets, which made up the quality management.

(10 marks)

(b) During manufacturing of *Kytron* (a specialty pharmaceutical product), pre compression had to be performed to determine the operating parameters for tablet compression, leading to different settings for every batch. Complaints had also been received on the air bubbles and low fill volumes of *Kytron* that were produced.

(i) By using a Fishbone diagram, demonstrate potential problem sources related to packaging materials and documentation.

(10 marks)

(ii) Propose **FIVE (5)** ways to improve the production system of this pharmaceutical product.

(5 marks)

Q2 (a) Process design means the complete delineation and description of specific steps in the production process and linkage among the steps that will enable the production system to produce products of the desired quality, in the required quantity. However, some products (especially cell therapy products) is considerably more challenging due to incomplete understanding of their mechanisms of action, difficulties in product characterization and variability of starting materials.

(i) Identify **ONE (1)** technique/design that can be implemented to overcome these challenges (for upstream cell manufacturing processes). Propose its process flow.

(5 marks)

(ii) Based on your answer in **Q2(a)(i)**, summarize the process flow that must be taken into consideration during production of this product.

(5 marks)

(b) As a project manager for a development of a new product in the company, develop the design process approach that you will employ, to ensure that this new product can be feasibly developed with adherence to schedules and cost.

(15 marks)

Q3 (a) In pharmaceutical stability studies, the monitored attributes change over time, which may lead to generation of non-acceptable quality of product. During stability study, we can determine whether the collected data follow the in control or out-of-control trends, hence estimated the shelf life of the product.

(i) Analyse the reliability of product in (1), (2), (3), (4) and (5) in **Figure Q3(a)(i)**.

(5 marks)

(ii) Assess **TWO (2)** limitations of control chart.

(? marks)

(b) On an industrial scale, the procedure for yoghurt production follows: preparation and standardization of milk, pasteurization, homogenization, cooling to incubation temperature, inoculation with starter culture, fermentation, post fermentation treatment, refrigeration and packaging. Post fermentation, fruits ade added into some of the yogurt to product yogurt dessert. Based on the information provided, propose a processing map for yogurt drink and dessert.

(8 marks)

(c) Company X is producing Titanium casting for biomedical applications. However, the company experienced frequent product rejections which need to be rectified. **Table Q3(c)** is a summary of defects in the product. From the Table, produce a Pareto diagram. Based on the generated diagram, deduce the improvements that are crucial for acceptance of the titanium casting in the market.

Table Q3(c)

No.	Type of defects	Total number of defects	Defects percent
1	Shrink	71	71
2	Porosity	18	18
3	Shell inclusion	6	6
4	Hard alpha inclusion	3	3
5	Tungsten inclusion	2	2

(10 marks)

Q4 (a) The development of a new drug is time-consuming and costly. In order to make sure that research and development process is going accordingly and does not incur additional cost, one must prepare the timeline for the whole process of drug development. Based on **Table Q4(a)**, construct the timeline starting from potential drug discovery until its commercialization.

Table Q4(a) : List of activities and duration.

Activity Letter	Activity Description	Predecessor	Duration	Overlap
A	API Manufacturer Search	None	1 year	None
B	Preclinical studies	A	3 years	None
C	Clinical studies	B	5 years	None
D	FDA Approval	C	2 years	None
E	Inquiry	None	1 month	1 month with A
F	Analytical Development	E	11 months	11 months with A
G	Process Optimisation	F	9 months	9 months with B
H	Performance Qualification	G	3 months	3 months with B
I	Validation	H	6 months	6 months with D
J	Commercialisation	I	2 months	2 months with D

(10 marks)

(b) Part of quality control involves the validation and verification of commercial manufacturing process. As the quality control officer in a factory manufacturing a biopharmaceutical, decide on **TEN (10)** critical points where problems could arise and extensively evaluate on the operational parameters involved. Refer to **Figure Q4(b)** for assistance.

(15 marks)

- END OF QUESTION -

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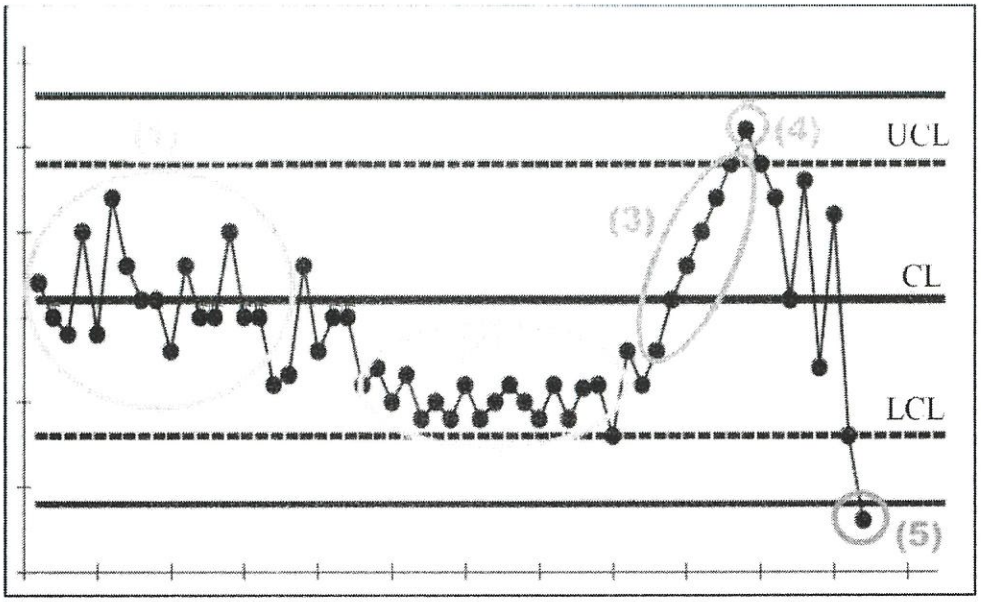

Figure Q3(a)(i)

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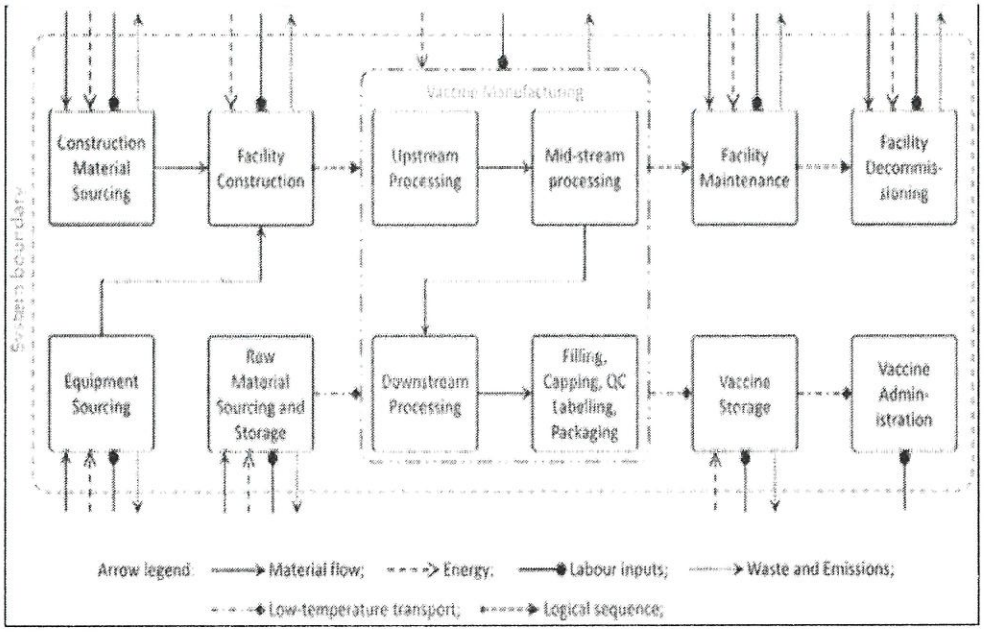

Figure Q4(b)