(University of Choice)

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

MAIN CAMPUS

UNIVERSITY EXAMINATIONS
2022/2023 ACADEMIC YEAR

SECOND YEAR SECOND SEMESTER MAIN EXAMINATIONS

FOR THE DIPLOMA
IN
MEDICAL BIOTECHNOLOGY

COURSE CODE: BBD 222

COURSE TITLE: QUALITY ASSURANCE & GOOD LABORATORY PRACTICE

DATE: 21ST APRIL 2023 **TIME: 8.00 – 10.00AM**

INSTRUCTIONS TO CANDIDATES

This paper is divided into three sections, **A B** and **C,** carrying respectively: Multiple Choice Questions (**MCQs**), Short Answer Questions (**SAQs**) and Long Answer Questions (**LAQs**).Answer all questions. **DO NOT WRITE ON THE QUESTION PAPER.**

TIME: 2 Hours

MMUST observes ZERO tolerance to examination cheating

This Paper Consists of 4 Printed Pages. Please Turn Over.

SECTION A: Multiple Choice Questions (20 Marks)

1.ISO stands for:

a) International Standardization for organization
b) International Organization for Standardization
c) International Standard Operation
d) International of Standard

2. The International Standard that best provides guidance for quality and competence formedical laboratories

a) ISO 9001:2008
b) ISO 17025:1999
c) ISO 15189:2012
d)ISO 17043:2010

3.Which statement would be most correct in addressing quality issues in a laboratory?

a) Responsibility for quality participation falls to the Quality Manager
b) Responsibility for quality participation falls to the "top management" including the Laboratory Head
c) Maintenance of quality is everyone's responsibility
d) While everyone should be involved, main responsibility rests with the Quality Manager

4. The rationale for implementing an overall quality management system in the laboratory is to:

a) Prevent any possibility of testing error
b) Differentiate between qualitative and quantitative methods
c) Prevent potential errors in the laboratory's path of workflow
d) Help to ensure that testing performed by the laboratory is accurate and reliable

5. All of the following are essential elements of the quality management system **EXCEPT**:

a) Equipment management
b) Personnel management
c) Customer discrimination
d) Process control

6. A shortened form of an SOP

a) Job description
b) Job Aid
c) Job qualification
d) Instrument manual

7. The laboratories national accreditation body in Kenya

a) WHO
b) CSLI
c) ISO
d) KENAS

8. Training staff to acquire skills outside their discipline

a) Cross-training
b) Retraining
c) Continuing education
d) Continuous professional development

9. The following are good practices when using gloves **EXCEPT**
a) Remove gloves when leaving the working area
b) Never reuse gloves
c) Wash contaminated gloves to save on cost of buying new ones
d) Dispose well after use
10. Which is **TRUE** about needles and sharps disposal
a) Recap needles before disposal
b) Put sharps in a puncture-resistant, leak proof container
c) Fill the sharps container to the brim
d) You can use ordinary boxes
11. A document providing detailed hazard and precautionary information of a chemical
a) MSDS
b) SOP
c) Instrument printout
d) Job Aid
12. Determining the source of problems in a laboratory equipment is referred to as;
a) Validation
b) Verification
c) Troubleshooting
d) Calibration
13. Which one is **FALSE** about Internal Audits
a) Conducted by staff working on another area of the same laboratory
b) Determines if the lab is meeting its own standards
c) Helps prepare for external audits
d) Conducted by agencies from outside the laboratory
14. The following statements are true for Quality Control (QC) **EXCEPT**
a) Use of control materials to monitor the accuracy and precision of analytical phase processes
b) Doesn't evaluate the operator's performance
c) Validates the reliability of the system
d) Evaluates environmental conditions that may impact test results
15. Freeze-dried controls are:
a) Reconstituted before use
b) Thawed before use
c) Diluted before use
d) Used as they are
16. Which one **DOESN'T** ensure customer satisfaction?
a) Timely results
b) Having incompetent staff
c) Good sample collection facilities
d) Confidentiality of the patient information
17. The following are sources of pre-analytical errors **EXCEPT**
a) Collecting the wrong sample
b) Mislabeling or failing to label the sample
c) Sending the report to wrong location
d) Storing the sample incorrectly prior to testing
18. Which action in occurrence management addresses the cause of the error

a) Remedial action
b) Preventive action
c) Remediation
d) Corrective action

19. Standard Operating Procedures:
a) Ensures consistency in laboratory results
b) Are not updated on a regular basis
c) Should not be detailed
d) Their approval by laboratory management not necessary

20. Orientation of new employees achieves the following **EXCEPT**
a) Acquaint them with personnel policies and ethics
b) To easily manipulate them thereafter
c) To know their work schedules
d) To know the organization's employee benefits

SECTION B: Short Answer Questions (40 Marks)

1. Discuss the good laboratory practices involved in conducting clinical trials **(8 Marks)**
2. Enumerate any 8 benefits of adhering to laboratory quality standards**(8 Marks)**
3. Define SOP and highlight the characteristics of a good SOP **(8 Marks)**
4. Define the followings terms as used in laboratory test methods: **(8 Marks)**
   a) Sensitivity
   b) Specificity
   c) Accuracy
   d) Precision
5. State 8 criteria for sample rejection in the laboratory **(8 Marks)**

SECTION C: Long Answer Questions (60 Marks)

1. Discuss the functions of Kenya Bureau of Standards (KEBS), Pharmacist and Poisons board(PPB), KMLTTB in regulation and quality assurance in Biomedical laboratory testing **(20 Marks)**
2. Discuss personnel, equipment and organization as quality management systems elements **(20mks)**
3. a. Discuss the pre-analytical, analytical and post analytical sources of errors in the laboratory **(10 Marks)**
   b. Describe the role of a quality manager in processing and packaging of food products in food industries **(10mks)**