Technical University of Mombasa

Faculty of Applied and Health Sciences

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR THE DEGREE OF BACHELOR OF MEDICAL LABORATORY SCIENCES

BMLS 13S MID

AML 4104 : GOOD CLINICAL LABORATORY PRACTICES

SEMESTER EXAMINATION

APRIL 2014 SERIES 2 HOURS

Instructions to candidates:

This paper consists of **TWO** sections **A** and **B**
Section A –Contains MCQS, Answer **ALL** questions in **Section B**.

SECTION A – MCQs – (30marks)

1. Which of the following is a purpose of good clinical practice?
   a) Regulators industry representatives
   b) Removers redundancy in development and review process
   c) Harmonization of the regulations and guideline for drug development
   d) Provides industry representatives from Europe, Japan and US
   e) All of the above

2. GCP guidelines are applicable for the following EXCEPT?
   a) Cosmetics
   b) Drugs
   c) Medical devices
   d) Biologist
   e) None of the above

3. The following are responsible for GCP EXCEPT?
   a) Sponsors

b) Ethics committees
c) Study director
d) Regulatory authorizes
e) Prescreen subjects

4. The following are GCP conduct standards EXCEPT?
   a) Scientific soundness
   b) Compliance with protocols
   c) Informed consent
   d) Confidentiality of data
   e) Qualification and training

5. Which of the following is true about continuing review / ongoing benefit risk assessment benefit
   a) Should be conducted in compliance with the approved protocol
   b) Should be conducted only if benefit risk profile remains favourable
   c) Should undergo ethical committee scrutiny
   d) Should be scientifically justified and clear description in detailed protocol
   e) The rights of the participant should be well protected

6. The following are objectives of GLP except
   a) Ensures confidentiality of data
   b) Enhance a true reflection of the results obtained during the study
   c) Enhances data traceability
   d) None of the above
   e) Promotes international acceptance of tests

7. The following is true about standard opening procedures EXCEPT
   a) Explain how procedure are suppsed to work
   b) Written is a chorological listing of action step
   c) They explain how the laboratory is supposal to work
   d) Important for calibration of laboratory equipment
   e) All of the above

8. Equipment records should include the following EXCEPT?
   a) Serial number
   b) Manufactures original SOP
   c) Model identification
   d) Date the equipment was reached is the laboratory
   e) Name of the equipment

9. Laboratory certification involves?
   a) Includes sufficient people
   b) Regulatory agents describe acceptable standards
   c) Original source of specimen must be recorded
   d) Vary among laboratories
   e) Normally done by external agency

10. Reagents and solutions should

a) Be stored under ambient temperatures
b) Be placed in room temperatures
c) Not be opened at room temperature
d) Stored at -70˚C
e) Not have expiration date

11. The following are principles of GCLP except?
a) Facilities
b) Quality control and quality audits
c) Planning, conducting and reports
d) Organization and personnelle
e) None of the above

12. In GCLP , which of the following occur under organization and personnel
a) Archivist
b) Trial data
c) Appropriate facilities
d) Quality control to ensure accuracy
e) Samples

13. The following are responsibilities of quality audit staff except?
a) Performing quality audits
b) Independent monitoring of facility
c) Reports findings to analytical project manager and facility management
d) All of the above
e) None of the above

14. Which of the following statements is true about reagents in GCLP
a) Should be rested prior to use
b) Should be suitably laabelled and stored
c) Should be validated in computer systems
d) May need to keep records of suage
e) All of the above

15. The following statements are true about planning in GCLP except?
a) Should be approved by the management
b) May form part of the contractual agreement with the sponsor
c) Should reflect the requirements of the Clinical protocol
d) Amendments and deviation should be documented
e) Approved plan of the work should be documented

16. In conduct, samples should
a) Be traceable at all times
b) Be labelled most of the times
c) Procedures of handling should be designed to enhance mix-ups
d) Involve external proficiency schemes
e) Involve in-process checks

17. The following is involved in supporting data or information in GCLP except?
    a) Organization charts
    b) System validation records
    c) Clinical trial number and identity of the facility
    d) Histmal file of SOPs
    e) All of the above

18. Standard operating procedures covers the following except?
    a) Record keeping
    b) External proficiency schemes
    c) Methods or control of method
    d) Qc procedures
    e) Audit procedures

19. In GCLP which of the following statement is true about facility management?
    a) Ensures all SOPs are in place
    b) Ensures analytical plan is in exist
    c) Ensures provision of trained staff
    d) All of the above
    e) None of the above

20. Which of the following statement is true about data?
    a) Should be passed through quality control
    b) Should be approved for use
    c) Should be stored in proper facilities
    d) Should be analyzed raw
    e) None of the above

21. The following procedures require ethical approval except?
    a) Involving humans
    b) Involving anonymousness samples
    c) Involving genetically modifies organisms
    d) Involving Bio-harzardsm agents
    e) All of the above

22. The following explain the principle of integrity in good research practice except?
    a) Data recycling
    b) Academic freedom
    c) Confidentiality
    d) Conflict of interest
    e) Data storage

23. Which of the following statements is true about research
    a) Conducted unplanned
    b) Discovering are unexploited
    c) The sponsor's responsibility
    d) Result are recorded and exploited
    e) None of the above

24. The following are avoided in research integrity except?
    a) Fraud
    b) Piracy and paganism
    c) Frankness
    d) Sabotaging work
    e) Breath of confidence

25. Which of the following statements is true about data storage and retention?
    a) Should have public access
    b) Should be stored without back –up
    c) Original data should be authenticated to prevent falsification of data
    d) Should be held for 2 years after publication
    e) None of the above

26. The following statement is true about confidentiality except?
    a) Discussing other researches work without permission should be permitted
    b) Openness is important in cases of commercial exploitation
    c) A and B
    d) None of the above
    e) All of the above

27. The following is involved in publication of data except?
    a) Data should be published in timely fashion
    b) Do not report results
    c) Same data should not be published more than once
    d) Do not exaggerate the importance of results
    e) All of the above

28. The following are examples of conflicts of interest except?
    a) Political
    b) Academic
    c) Personal
    d) Mentorship
    e) Financial

29. The following are examples of misconduct in research except?
    a) Paganism
    b) Fabrication
    c) Sabotage
    d) Honesty
    e) Failure to follow established protocols

30. In good manufacturing practice the following is true about illness except?
    a) No medication allowed in the factory
    b) Doctors certificate on hiring
    c) Wash hands after handling contaminated materials

d) Ensure bandage cover any open would
e) None of the above.

SECTION B ESSAY
(ANSWER ALL QUESTION IN THIS SECTION)

1. (a) Describe the following in food handling practices
   (i) Personnel
   (ii) Equipment
   (iii) Sanitation
   (iv) Receiving & Storage

(10 marks)

(b) In basic biomedical research, describe drug development. **(10 marks)**

2. Describe the following.

(a) Standard operating procedures

(b) Instrumentalism validation

(c) Risk identification

(d) Protocol compliance

(20 marks)