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

AML 4151: GOOD CLINICAL LABORATORY PRACTICE

SPECIAL/SUPPLEMENTARY EXAMINATION

FEBRUARY 2013 SERIES 2 HOURS

Instructions to candidates:

This paper consist of **TWO** sections **A** and **B**

Section A –Contains MCQS, any wrong response will be penalised. Answer **ALL** questions in **Section B**.

SECTION A – MCQs – (30marks)

1. Who has the overall responsibility for the Good Clinical Practice (GCP) compliance of a trial?
   a) Principal Investigator
   b) Sponsor
   c) Quality Assurance
   d) Laboratory Management

2. Which one of the
   a) That everyone knows how to do their job
   b) That everyone understands what is to be audited
   c) That everyone is trained consistently
   d) That the quality and integrity of the work performed and data generated

3. Quality audit reports should not include
   a) Observations
   b) Nonconformities
   c) Corrective actions
   d) Recommendations

4. An equipment register may include the following records EXCEPT?
   a) Equipment identification
   b) Date received
   c) Name of the operator
   d) Location of the equipment

5. Who is responsible for ensuring methods are validated and fit for use
   a) Quality Assurance
   b) The Analytical Project Manager
   c) The Sponsor
   d) Equipment supplier

6. A formal authorized document that describes all aspects of the work to be performed by the laboratory faculty is called
   a) Raw data
   b) Study Protocol
   c) Analytical Plan
   d) Standard operating procedure

7. Who is responsible for documenting an standard operating procedure (SOP) deviation
   a) Analytical Project Manager
   b) Quality Assurance
   c) Person who deviated
   d) Principal Investigator

8. Which one of the following should be trained in the use of equipment?
   a) Sponsor
   b) Laboratory Management
   c) Laboratory Staff
   d) Quality Assurance

9. The person who does the internal Quality audits should be
   a) A qualified analyst
   b) A certified Auditor
   c) A QA professional
   d) Knowledgeable in the work audited

10. Which of the following is NOT the responsibility of the Analytical Project manager?
    a) Agreeing to the Analytical Plan by dated signature
    b) Writing Standard operation procedures for laboratory staff
    c) Ensuring the results are only issued under the dated signature of authorized signatory
    d) Signing and dating the analytical plan

11. Which of the following is the objective of the Quality Audit?
    a) To catch staff doing thing and prevent errors
    b) To catch up all the gossip
    c) To ensure staff are following their Standard operating Procedures
    d) To provide locked and separate archives for storages and retrieval of data, reports and samples

12. The historically first international guideline pertaining to research involving human participants was the:
    a) Declaration of Helsinki
    b) Declaration of Japan
    c) Nuremberg code
    d) WHO ethical Guideline

13. Laboratory prepared reagents must be labeled with the following except.
    a) Date of preparation
    b) Use by date
    c) Concentration
    d) Name of the supplier

14. The CRF is defined as the following
    a) Case report form
    b) Clinical Record form
    c) Clinical Register form
    d) Combined records form

15. Equipments should not be released for use until it is approved for use by
    a) The trial sponsor
    b) The principal investigator
    c) The laboratory Manager
    d) Quality Assurance

16. Why should Standard operating procedures be periodically reviewed?
    a) To fulfill requirements of the study protocol
    b) It is a requirement from the study sponsor
    c) To ensure that they remain current and up to date
    d) Maintain clean copies in circulation

17. The analytical staff are responsible for the following EXCEPT?
    a) Maintain awareness of Good Clinical Practice and Good Clinical Laboratory Practice
    b) Maintain prompt, accurate and complete records
    c) Signature dating of Analytical plan
    d) Maintaining quality of their data

18. A study monitor will report any deviations to the
    a) Principle investigator
    b) Facility management
    c) Trial Sponsor
    d) Analytical Project Manager

19. Helsinki Declaration was made in:
    a) 1962
    b) 1974
    c) 1979
    d) 1964

20. Standard Operating Procedures must be approved by the following person
    a) The Principal Investigator
    b) Analytical Project Manager
    c) The SOP Author
    d) The Archivist

21. Good laboratory practice (GLP) applies only to:
    a) Clinical Trials
    b) Laboratory studies
    c) Human studies
    d) None of the above

22. Which one of the following factors is NOT considered in laboratory facilities
    a) Size
    b) Construction
    c) Location
    d) Colour

23. Standard operating procedures should be written by
    a) Trial sponsor
    b) The principal Investigator
    c) Someone who understands the procedures
    d) Quality Assurance Manager

24. Poor housekeeping may reflect the following underlying problem
    a) Not following up the study protocol
    b) Lack of responsibilities
    c) Lack of Standard operating Procedures
    d) None of the above

25. On satisfactory completion of an audit report who is responsible for ensuring a response is documented and corrective action taken
    a) Quality Auditor
    b) Study monitor
    c) Sponsor
    d) Analytical Project Manager

26. When a laboratory Standard Operating Procedure contradicts the Analytical Plan
    a) The SOP will be used and differences not documented
    b) The Trail sponsor will stop the SOP use
    c) Amendments to the SOP will be made to conform to Analytical Plan
    d) The trial will be stopped by sponsor

27. The facility Management can make the following appointments EXCEPT
    a) Analytical Project Manager
    b) Quality Audit personnel
    c) Study monitor
    d) Archivist

28. The principles defined in Good Clinical Practice are intended to :
    a) Prevent fraud
    b) Assure the accuracy of the data produced
    c) Minimize trial costs
    d) Protect the subjects / Patients involved

29. Which of the following is not a function of Standard operating procedure?
    a) To leave a permanent record of the methodology employed
    b) To establish uniform procedures to ensure quality and data integrity
    c) To communicate procedures to those undertaking them
    d) To motivate the analytical staff.

30. Which one of the following is not a benefit from a Good Clinical Laboratory Practice compliant Study?
    a) Study subjects are not consented
    b) Results are reliable
    c) Wasting of resources is minimized
    d) Results can be compared to those of other good clinical lab practice compliant studies

SECTION B – (40marks) Answer ALL questions

1. Define the following terminologies
    a) Good Clinical Practice (GCP) **(2marks)**
    b) Good Laboratory Practice (GLP) **(2marks)**
    c) Good Clinical Laboratory Practice (GCLP) **(2marks)**
    d) Quality Assurance **(2marks)**
    e) Standard Operating Procedure (SOP) **(2marks)**
2. Discuss the responsibilities of Analytical Project Manager **(10marks)**
3. Discuss laboratory facilities requirements under GCLP **(10marks)**
4. Explain the benefits of GCLP compliant studies **(10marks)**