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 13M -MID

AMP 4151 : GOOD CLINICAL LABORATORY PRACTICE

SPECIAL/SUPPLEMENTARY EXAMINATION

OCTOBER 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. Good laboratory practice (GCLP) applies only to:
   a) Clinical trials
   b) Human studies
   c) Drug studies
   d) Animal studies
   e) Vaccine studies

2. Which of the following is not a benefit of a Good clinical laboratory practice (GCLP) compliant study
   a) Study subjects are not consented
   b) Results are reliable
   c) Resources are not wasted
   d) Results can be reproduced
   e) Results can be compared to those of similar studies

3. Which of the following documents must be available before study initiation
   a) Study monitor report
   b) Equipment manual
   c) Standard operating procedure (SOP)
   d) Analytical method
   e) Study protocol

4. Standard operating procedure (SOP) control entails the following except:
   a) Version number
   b) Dated signature
   c) Historical copies made available
   d) Amendments documented
   e) Only current copies made available

5. An equipment register may include the following information except:
   a) Equipment identification
   b) Name of operator
   c) Date received
   d) Location of the equipment
   e) Date approved for use.

6. Internal quality audits should be done by:
   a) A qualified audit
   b) A certified auditor
   c) Someone with knowledge on work audited
   d) A quality assurance professional
   e) Facility manager

7. On satisfactory of an audit report, who is responsible ensuring a response is documented and corrective action taken.
   a) Analytical staff
   b) Quality audit personnel
   c) Archives
   d) Study sponsor
   e) Analytical project manager

8. Which one of the following is not a content of a curriculum vitae (CV)
   a) Education level
   b) Publications
   c) Tribe
   d) Professional
   e) Membership to professional bodies

9. All the following are responsibilities of the trial investigator except
    a) Appointing lab staff
    b) Maintain trial master file
    c) Reporting adverse events
    d) Comply with study protocol
    e) Lead the trial site

10. Which of the following is not a requirement for job descriptions
    a) It outlines duties and responsibilities
    b) It is updated regularly
    c) It is signed dated by employee and management
    d) It details salary of the staff
    e) It is kept in the staff personnel file

11. Analytical result should contain the following information except
    a) Clinical trial number
    b) Name or initials of the analyst
    c) Name of the patient
    d) Signature of authorized signatory
    e) Date and time of testing

12. Who should provide the final report after a trial
    a) Principal investigator
    b) Trial sponsor
    c) Study monitor
    d) Analytical project manager
    e) Lab manager

13. Laboratory equipments should not be released for use until approved by :
    a) Trial sponsor
    b) Analytical staff
    c) Principal investigator
    d) Equipment supplier
    e) Laboratory manager

14. Which of the following factors are not part of facility requirements in a clinical trial
    a) Size
    b) Colour
    c) Location
    d) Space
    e) Construction design

15. Good clinical laboratory practice (GCLP) were first prepared in
    a) 1989
    b) 1999
    c) 2001
    d) 2005
    e) 2003

16. Appointment of a study monitor is the responsibility of
    a) Study sponsor
    b) Principal investigator
    c) Facility manager
    d) Analytical project management
    e) Archivist

17. Which of the following is not a content of the analytical plan
    a) Name and addresses of the analytical project manager
    b) Name and addresses of the facility manager
    c) Levels of staff remuneration
    d) Identification of work to done in the trial
    e) Trial proposed starting and completion date

18. Which one of the following persons does not form laboratory personnel under good clinical laboratory practice (GCLP)
    a) Facility management
    b) Study monitor
    c) Quality auditor
    d) Archivist
    e) Analytical staff

19. The principles defined in good clinical practice (GCLP) are intended to:
    a) Prevent fraud
    b) Assure accuracy of data produced
    c) Protect subjects involved in the trial
    d) Minimize trial costs
    e) Benefit the trial sponsor

20. Lab waste segregation must take place
    a) In the open field
    b) At the cleaners cupboard
    c) In the laboratory
    d) At the waste storage area
    e) At site of final disposal

21. Laboratory trial facility should have the following except
    a) Quality water supply
    b) Uninterrupted electricity
    c) Analytical area
    d) Specimen receipt area
    e) Admission ward

22. Which statement is not true on use of lab equipments
    a) Should be suitably located
    b) Should be serviced daily
    c) Should periodically be inspected
    d) If not operational should be marked as "out of service"
    e) Records of maintenance should be filed

23. Which of the following is not a principle of good clinical laboratory practice (GCLP)
    a) Organization and personnel
    b) Equipment and reagents
    c) Facilities
    d) Sterilization
    e) Standard operating procedures

24. The following areas are covered by SOPS, except
    a) Age of participants
    b) Principle of the test
    c) Test items
    d) Reagents to be used
    e) References

25. Documents storage area should fulfill the following requirements except
    a) Accessed controlled
    b) Free from pests
    c) Coloured in black
    d) Protected from fie
    e) Should be designed area.

26. Which of the following individuals is not responsible for maintaining safety in the work place
    a) Analytical staff
    b) Facility manager
    c) Cleaner
    d) Archivist
    e) Study sponsor

27. Who is responsible for subcontracting of any work outside trail facility
    a) Study sponsor
    b) Facility management
    c) Study monitor
    d) Principal investigator
    e) Analytical project manager

28. Good clinical laboratory practice (GCLP) is the merging of which standards
    a) GMP and GCP
    b) GLP and GMP
    c) GCP and GTP
    d) GCP and GLP
    e) GP and GL

29. Who is responsible for documenting an SOP deviation
    a) Quality Assurance staff
    b) Study sponsor
    c) Archivist
    d) Lab manager
    e) Staff who deviated the SOP

30. In which year was to " Declaration of Helsinki" made
    a) 1974
    b) 1964
    c) 1979
    d) 1962
    e) 1975

SECTION B

31. (a) Briefly discuss the contents of a study protocol **(10marks)**

(b) Discuss the roles and responsibilities of the study sponsor **(10marks)**

32. (a) Explain the importance of quality control (QC) in laboratory analytical testing **(10marks)**

(b) Describe steps to be followed before a test method is validated for use in a clinical trial **(10marks)**