TECHNICAL UNIVERSITY OF MOMBASA

Faculty of Applied & Health Sciences

DEPARTMENT OF MEDICAL SCIENCES

AML 2102: GOOD CLINICAL LABORATORY PRACTICE

END OF SEMESTER EXAMINATION
SERIES: APRIL 2014
TIME ALLOWED: 2 HOURS

Instructions to Candidates:
You should have the following for this examination

- *Answer Booklet*

Answer **ALL** questions
This paper consists of **SEVEN** printed pages

Question One (Compulsory)

1. The following is true about retention and storage of records except:
- **a)** Records of all phone calls made from the trial facility
- **b)** Records of all audits performed by the Quality audit function
- **c)** Records of qualification, trainings, experience and job description of personnel
- **d)** Records of reports of bile maintenance and calibration of the equipments

2. The following does not fall under laboratory equipment and maintenance except:
- **a)** Work areas
- **b)** Storage
- **c)** Archiving
- **d)** List of all equipments

3. Analytical plan should not contain the following information except:
- **a)** SOP's
- **b)** Clinical trial number
- **c)** Equipment
- **d)** None of the participants

4. The analytical plan should consist of the following except:
- **a)** Name and address of the sponsors
- **b)** Name of the office assistant
- **c)** Name and address of the investigator
- **d)** Name and address of the trial facility

5. What are the GCLP principles:
- a) Sterilization
- b) Organization and personnel
- c) Equipment and reagents
- d) Standard operating procedures

6. The following are general safety measures in a laboratory except
- a) Documentation of laboratory policies and procedures
- b) All laboratory personnel should be aware about the lab safety policies and procedures
- c) Lab personnel should not clean the floor in case of spillage
- d) Laboratory personnel should be trained in managing fire and non fire emergencies such as large spillage gas leakage etc.

7. The following assess the quality audit of a laboratory except:
- **a)** Accuracy
- **b)** Reproducibility
- **c)** Pluetuality
- **d)** Suitability of reagents

8. The following area not contents of a standard operating procedure except:
- a) Clinical management of patients
- b) Objectives

c) Record keeping
d) Prescription procedures

9. The following activities are usually covered by standard operating procedures except:
a) Agree of the participants
b) Test items
c) Reference items
d) Reagents

10. The following fall under laboratory personnel except:
a) Terms and conditions of service
b) New staff orientation
c) Personal file
d) Board regulation

11. The following is true about test results and reports except:
a) Maintenance
b) Policy and provisional results
c) The test results should be sent back to the study doctor
d) Authorization of rest results

12. The following is false about sample collection and handling except:
a) Access control
b) Should be left on the bench
c) Daily back-up
d) Specimen audit trials

13. The following is true about quality audit except:
a) Should be conducted by competent persons
b) The findings of the quality audit should only be reported to the sponsor
c) All audit results should be recorded
d) Any corrective actions should be indicated

14. Laboratory infrastructure should have the following except:
a) Quality water supply for analytical purpose
b) Uninterrupted power supply
c) Admission ward
d) Specimen collection nom/area

15. Choose which statement is false GCP refers to:
a) The organization of a study rather than the scientific contents
b) The rules for conducting a clinical study
c) A pharmaceutical company marketing drugs
d) Regulations to assure the scientific quality and integrity of data from non clinical laboratory studies

16. Staff personnel records need to include the following information except:
a) Confidentiality is not needed
b) Copy of registration with the health profession council or equivalent profession board
c) Job description and curriculum vitae
d) Training records and evidence of ongoing profession development

17. With respect to standard operating procedural (SOPS) choose the incorrect statement.
    a) Obsolete documentation must be archived
    b) SOP's need to be document controlled
    c) SOPs need to have objectives
    d) Annual review of SOPs is mandatory

18. Regarding the document storage requirement for GLP choose the correct statements:
    a) Designated storage areas are required
    b) Environmental control is essential including temperature, humidity and pest control
    c) Locked controlled access
    d) Fire proof cabinets

19. The following individuals are responsible for maintaining safety in the workplace:
    a) Employer
    b) Individual worker
    c) Department of labour
    d) Safety representatives

20. Choose the correct statement concerning the role of the analytical manager/study director for the laboratory generally include the following:
    a) Evaluation of laboratory resources to conduct the study
    b) Development of the study protocol
    c) Design and distribution of the study plan
    d) To ensure compliance with study plan and SOPS

21. What should be done in case of biohazard spills:
    a) Wear personal protective equipment
    b) Call the police
    c) Leave the lab completely
    d) Not flood the area with disinfectants

22. The following are the responsibilities of the testing personnel except:
    a) First Aid
    b) Participate in the EQA Program
    c) Take any corrective action
    d) Maintain EQA records

23. Reagents should be correctly labeled with the following except:
    a) Material
    b) Concentration
    c) Date prepared
    d) Picture of the manufacturer

24. The following is true about equipment qualification:
    a) Never been used before
    b) Design
    c) Big

d) Installation

25. Specific method validation in a trial facility involves the following except:
    a) People
    b) Motor vehicle
    c) Equipment
    d) Actual method works

26. The following should not be considered when storing trial materials:
    a) Centrifudging
    b) Labelling of tubes and freezers
    c) Temperature
    d) Back-up facilities

27. What is the role of a quality manager
    a) First aid
    b) Ensure compliances with all safety regulations
    c) Prescribing drugs to participants
    d) None of the above

28. The following is true about a safety officer except:
    a) EQA processing
    b) First aid
    c) Prevention of laboratory acquired infection
    d) Ensure compliance with all safety regulations

29. What is the role of an analytical staff
    a) Sign and date analytical plan
    b) Perform trial requirements in accordance with trail protocols, analytical plans and SOPS
    c) Approve analytical plans
    d) Write a analytical report

30. The following is true about analytical plans except:
    a) Treatment of subjects, assessment and statistical analysis
    b) Identification of the work
    c) Names and address of the sponsor, investigator, trial facility analytical project manager
    d) The analytical plan may form part of the contractual agreement with the sponsor

31. What is the content of a trial protocol
    a) EQA processing
    b) First aid
    c) Trial objectives, purpose and design
    d) Safety

32. The following is true about water disposal except:
    a) Should be consistent with local regulations
    b) Should be dumped in the sea
    c) Appropriate collection, storage and disposal
    d) Should have documented procedures

33. The following is true about equipment used in clinical trials except:
    a) Should be suitably located and of appropriate design
    b) Should be periodically inspected
    c) They should be serviced everyday
    d) Records of such maintenance or calibration should be retained

34. Disposable latex gloves can be reused if:
    a) They are decontaminated with tools ethanol before reuse
    b) They are carefully removed and stored before use
    c) Disposable gloves can never be reused
    d) No new gloves are available

35. Class II biosafety cabinet offers:
    a) Product (sample) protection
    b) Non operator protection
    c) Lower level of users production as class I BSC's

36. All human blood must be considered infections unless:
    a) The patients is over 65 years old and polite
    b) Less than 5m/s is collected and processed
    c) Screened for Hepatitis B and HIV
    d) None of the above

37. Following a spillage an accident investigation should establish:
    a) Who was to blame
    b) Whether adequate precautions were in place
    c) Whether hazardous substance could be substituted with a less hazardous one
    d) Whether the staff was drunk

38. HEPA filters trap
    a) Viruses
    b) Chemicals
    c) Smells
    d) Radionultides

39. The following items qualify as clinical waste except:
    a) Used vacitainers
    b) Clean but damaged valutainers
    c) Used needles
    d) Decontaminated paper towels used to map up a spillage of blood

40. Segregation of waste must take place:
    a) At the site of final disposal
    b) In the waste storage area
    c) In the laboratory
    d) In the cleaners cupboard

SECTION B

Question One

a) Define the following terms:
   (i) Analytical project manager **(2 marks)**
   (ii) Analytical report **(2 marks)**
   (iii) Quality audit **(2 marks)**
   (iv) Trial materials **(2 marks)**
   (v) Trial protocol **(2 marks)**

b) Describe the responsibilities of the analytical project manager **(10 marks)**

Question Two

a) What is the role of facility management in ensuring organization and personnel in a trial facility? **(10 marks)**

b) Write short notes on a trial facility. **(10 marks)**

Question Three

a) Outline the application of Standard Operating Procedures (SOPS) **(10 marks)**

b) Write short notes on specimen collection under GCLP. **(10 marks)**