TECHNICAL UNIVERSITY OF MOMBASA

Faculty of Applied and Health Sciences

DEPARTMENT OF MEDICAL SCIENCES

DIPLOMA IN MEDICAL LABORATORY SCIENCES
(DMLS 12 M)

AML 2250: GOOD CLINICAL LAB PRACTICE

SPECIAL/SUPPLEMENTARY: EXAMINATIONS

SERIES: MARCH 2014

TIME: 2 HOURS

INSTRUCTIONS:

You should have the following for this examination

- *Answer booklet*

This paper consists of **TWO** sections.
Answer all questions in **Section A** and **B.** ½ marks deducted for any wrong answer in **Section A**.

*This paper consists of **8** **PRINTED** pages*

SECTION A (40MARKS)

1. The following fall under lab personnel except
- **a)** Terms and conditions of service
- **b)** New staff orientation
- **c)** Personal orientation
- **d)** Personal file

2. The following activities are usually covered by standard operation procedures, except.
- a) Principle
- b) Test itmes
- c) Reference items
- d) Reagents
- e) Age of the participant

3. The following are contents of standard operating procedure's except
- a) Clinical management of patients
- b) Objectives
- c) Record keeping
- d) Prescription procedures
- e) Analytical plan

4. Which of the following is not a GCLP principle
- a) Sterilization
- b) Organization and personnel
- c) Equipment and reagents
- d) Standard operating procedures
- e) Facilities

5. The following accesses the quality assurance of a laboratory, except
- a) Accuracy
- b) Reproducibility
- c) Suitability of reagents
- d) Equipment maintenance
- e) Punctuality

6. The analytical plan should consist of the following, except
- a) Name and address of the sponsor
- b) Name of the office assistant
- c) Name and address of the investigator
- d) Name and address of the trial facility
- e) Name of the analytical project manager

7. Analytical plan should not contain the following information except
- a) Clinical trial number
- b) SOP's
- c) Equipment

d) Address of the participants
e) Name of the participants

8. The following is true about retention and storage of records, except
   a) Record of all phone calls made from the trial facility
   b) Records of report of the maintenance and calibration of equipment
   c) Records of quantification, training experience and job description of personnel
   d) Records of all Audits performed by the quality audit function
   e) The analytical plan data, sample/specimens (where appropriate) analytical results if issued the trial report

9. The following falls under laboratory equipment and maintenance except
   a) Work areas
   b) Design
   c) Storage
   d) Archiving
   e) Equipment maintenance policy

10. 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) Biohazard symbols should be used on all containers / equipments containing biohazard materials
   e) Laboratory personnel should be trained in managing fire and non-fire emergencies such as large spillage gas leakage

11. Choose the correct statement: The role of the analytical manager/study director for the laboratory generally includes the following.
   a) Evaluation of laboratory recourses 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 sop's
   e) Generation of a final report

12. The following individuals are responsible for maintaining safety in the workplace
   a) Employer
   b) Individual worker
   c) Safety representative
   d) Department of labor
   e) All of the above

13. Regarding the documents storage requirement for GLP: Choose the correct statement
   a) Designated storage areas are required
   b) Environmental control is essential including temperature, humidity and pest control

c) Loused controlled access
d) Fire proof cabinets
e) All of the above

14. The following is true about quality audit, except
a) Any corrective action indicated should be
b) All audit results should be recorded
c) Analytical project manager and trial facility management should respond to these audit reports in a timely manner
d) The finding of the quality audit should only be reported to the sponsor
e) Should be conducted by competent person(s)

15. The following is true about test results and reports, except
a) Authorization of results
b) Maintenance
c) Policy and personal results
d) The information written should be accurate
e) The test result should be sent back to the study doctor

16. The following is fabe about sample collection and handling except
a) Access control
b) Daily back-up
c) Description of involvement in sample collection
d) Specimen audit trails
e) Should be left on the bench

17. What is the role of a quality manager
a) First aid
b) Ensure compliance with all safety regulations
c) Regular review of SOP's
d) Laboratory drugs' to participants
e) Prescribing drug to participants

18. 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
e) All of the above

19. What is the role of an analytical staff
a) Sign and date analytical plan
b) Perform and trial requirements in accordance with trials protocols, analytical plans and SOPs
c) Approve analytical plans
d) Write and analytical report
e) Fill the severe adverse effectors forms

20. 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
d) The analytical plan should be retained as part of the records for the trial
e) The analytical plane may form part of the contractual agreement with the sponsor

21. What is the contract of a trial protocol
a) EQA processing
b) First Aid
c) Trial objectives, purposes and design
d) Safety
e) Past studies

22. The following is true about waste disposal, except
a) Should be consistent t with local regulations
b) Should be dumped in the sea
c) Appropriate collection, storage and disposal
d) Should have documented procedures
e) All the above

23. The following should not be considered when storing trial materials
a) Centrifuging
b) Labeling of tubes and freezers
c) Temperature
d) Back up facilities
e) All the above

24. Specific method validation in a trial facility involves the following except
a) People
b) Motor vehicle
c) Equipment
d) Actual method works
e) All the above

25. The following true about equipment qualification
a) Never been used before
b) Design
c) Big
d) Installation
e) Date of manufacture

26. Reagents should be correctly labelled with the following, except
a) Material
b) ?
c) ?
d) Pidive of manufacturer
e) Date of expiry

27. 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
e) All the above

28. What should e done incase of biohazard spills
a) Wear personal protective equipment
b) Call the police
c) Leave the lab completely
d) Not flood the area with disinfectant
e) All the above

29. Segregation of waste must be take place
a) At the site of final disposal
b) In the waste storage area
c) In the laboratory
d) In the cleanness cupboard
e) In the open field

30. The following items quality as clinical waste , except
a) Used vacutainers
b) Clean but damaged vacutainers
c) Used needles
d) Decontaminated paper towels used to mop up a spillage of blood
e) A pair of scissors

31. HEPA filters trap
a) Viruses
b) Chemicals
c) Smells
d) Padiomudides
e) Radicals

32. Following a spoilage 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 all the spillage procedures were followed
e) Whether the staff was drunk

33. All human blood must be considered infection rules
a) The patient is over 65 years old and polite
b) Screened as HIV
c) Less than 5ml is collected and processed
d) Screened as Hepatitis B
e) None of the above

34. Class II biosafety cabinet offer
    a) Product (sample) protection
    b) Non operator protection
    c) The same level as class I BSC'S
    d) Lower level of user protection as class I BSC's
    e) Immunity protection

35. Disposable latex shoes can be re-used if
    a) They are decontaminated with 70% ethanol before re-use
    b) They are carefully removed and stored before use
    c) No new gloves are available
    d) Disposable gloves can never be reused
    e) Disposable gloves can be washed and then re-used

36. 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) Records of such maintenance or calibration should be retained.
    d) Dry item of equipment that is out of service for any reason should be clearly identified as such
    e) They should be serviced everyday

37. What is the purpose of risk assessment ?
    a) to generate paper work
    b) to impress the safety officer during inspection
    c) To inform staff (and others) of the risks associated with their work and what they need to do in order to conduct if safety
    d) To consider work
    e) To report to the police

38. A hazard could be….
    a) Substance
    b) Item of equipment
    c) Activity
    d) Card board box
    e) All the above

39. The production afforded by PPE is affected by
    a) The condition of the PPE
    b) The manner in which it is put on
    c) When it is worm
    d) How it is disposed of
    e) All the above

40. Which of the following statements is true?
    a) Lab plastic were is checked in the factory therefore does not need checking on delivery before use
    b) Modern equipment only requires maintenance on breakdown
    c) The mammal only needs to be read when the equipment fails

d) New equipment doesn't require maintenance
e) None of the above is true

SECTION B

1. i) Define the following terms
   a) Analytical project manager **(2marks)**
   b) Analytical report **(2marks)**
   c) Quality audit **(2marks)**
   d) Trial material **(2marks)**
   e) Trial protocol **(2marks)**

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

2. i) What is the role of facility management in ensuring organization and personnel in a trial facility **(10marks)**
   ii) With short notes on a trial facility **(10marks)**

3. i) Outline the application of SOP's **(10marks)**
   ii) Write short notes on specimen collection under GCLP **(10marks)**