TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR:

DMLS

AML 2105: GOOD CLINICAL LABORATORY PRACTICE.

SPECIAL/ SUPPLIMENTARY EXAMINATIONS

SERIES: SEPTEMBER 2018

TIME: 2 HOURS

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of Choose Nochoose Sect/Quest. AttemptChoose instruction.

Circle the correct answer in section A.

Section A (Answer All questions)

1. The following are responsible for GCP, except?
   A. Mentors
   B. Research subjects
   C. Ethics committee
   D. Regulatory bodies
   E. Sponsors

2. Which of the following report was written is 1979?
   A. Nuremberg code
   B. Declaration of Helsinki
   C. Belmont report
   D. Code of federal regulations
   E. International standards organization

3. The following are included in the Belmont report except
   A. Respect for persons
   B. Informed consent
   C. Beneficence
   D. Projection of persons rights and well being
   E. Justice

4. The following is true about GLP except?
   A. Test systems
   B. Promotes international acceptance of tests
   C. Quality assurance programs
   D. Standard operating procedures
   E. Performance of the study

5. Which of the following is not true about laboratory certification.
   A. Adequate space
   B. Storage
   C. Done by internal agent
   D. Hygiene
   E. Ventilation

6. Which of the following is true about facility management in GCLP?
   A. Person trails
   B. Approves analytical plans and ensuring it is followed
   C. Ensures results are accurately recorded
   D. Retails all records that support the work conducted
   E. Responsible for quality data

7. Which of the following is true about planning in GCLP?
   A. Should reflect the requirements of the clinical protocol
   B. Should not be detailed
   C. Should be detailed
   D. Should be controlled
   E. None of the above

8. Which of the following is not among the organization and personnel in GCLP?
   A. Facility management
   B. Analytical staff
   C. Analytical project manager
   D. Activist
   E. None of the above

9. Class II biosafety cabinet offer
   A. Product (sample) Protection
   B. Non-operator protection
   C. The same level of used protection as class I BSc's
   D. Lower level of user protections as class I BSc's

E. Immunity to the staff

10. Which of the following statements is time?
    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 manual only needs to be read when the equipment fair
    D. Modern equipment should not be serviced
    E. None of the above is true

11. Disposable gloves can be reused if
    A. They are decontaminated with 70% ethanol before reused
    B. They are carefully removed and stored before reuse
    C. No new gloves can be reused
    D. Disposable gloves can be washed and reused
    E. If the are decontaminated with 0.5% sodium hypochlorite

12. Regarding the document storage requirements for GLP choose the correct statements
    A. Designed storage areas are required
    B. Environmental control is essential including temperature humidity and pest control
    C. Locked control access
    D. Fire proof cabinet
    E. All of the above

13. The following individual are responsible for maintaining safety in the work places
    A. Employer
    B. Individual worker
    C. Safety representative
    D. Department of labour
    E. All of the above

14. Shoes covering the entire (including toe) should be worn in the lab so as to
    A. Keep the workers feet warm
    B. Protect from spills of hazardous biological material
    C. Maintain a smart look in the laboratory
    D. Avoid being sent away by the lab manager
    E. Allow easy breakage of the glassware

15. Choose the correct statements 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 standard operating procedures
    E. Generation of final report

16. Analytical plan should not contain the following information except
    A. Clinical final number
    B. Name of the participant
    C. Address of the participants
    D. SOPs
    E. Equipment's

17. The following is true about detection and storage of records except.
    A. The analytical plan, data samples/specimens (where appropriate), analytical results and if issued the final analytical report
    B. Records of all audits performed by the audit function
    C. Records of qualification, training, experience description of personnel
    D. Record of reports of all maintenance and calibration of the equipment
    E. Record of all phone call made from the trial facilities

18. The following do not fall under laboratory equipment and maintenance except.
    A. List of all equipment
    B. Work areas
    C. Storage
    D. Archiving
    E. Equipment maintenance policy

19. The following fall under lab personnel except
    A. Terms and condition of services
    B. New staff orientation
    C. Personnel file
    D. Board registration
    E. Marriage details

20. The following activities are usually covered by sops except.
    A. Test items
    B. Referent items
    C. Apparatus
    D. Reagents
    E. Principles

21. The following are not contents of an SOP except
    A. Clinical management of patient
    B. Objective
    C. Record keeping
    D. Prescription procedures
    E. Reagents expiry date

22. The following should not be considered when starting trial materials
    A. Centrifuging
    B. Labeling of tubes and freezers
    C. Temperature
    D. Back –up facilities
    E. Storage racks

23. Specific method validation in a trial facilities involves the following except:
    A. Never been used before
    B. Design
    C. Big
    D. Installation
    E. Model

24. The following is time about equipment qualification except
    A. Never been used before
    B. Design
    C. Big
    D. Installation
    E. Modal

25. Reagents should be correctly labeled with the following except.
    A. Material
    B. Concentration
    C. Date prepared
    D. Date of expiry
    E. Picture of the manufacturer

26. The following are the responsibilities of the testing personnel, except.
    A. First Aid
    B. Participate in EQA program
    C. Take corrective actions
    D. Maintain EQA records
    E. Participate in SOPs training

27. What should be done incase of biohazard skills?
    A. Wear personal protective equipment
    B. Cell the police
    C. Leave the lab immediately
    D. Flood the area with water
    E. Scram for help

28. The following is false about sample collection and handling except
    A. Access control
    B. Daily backup
    C. Description of involvement is sample collection
    D. Specimen audit trails
    E. Material safety data sheets

29. The following is true about test results and reports except
    A. Authorization of results
    B. Policy on provisional results
    C. Maintenance
    D. Accuracy
    E. Repeating of tests

30. What are the roles of a quality manager?
    A. First Aid
    B. Ensure compliance with all safety regulations
    C. Regular review of SOPS
    D. Processing of samples
    E. Employing staff

31. Biosafety cabinets must be cleaned and decontaminated
    A. After spillages
    B. Every time after use
    C. Before use
    D. Before an engineer visits
    E. It is one important to clean BSC's because the air flows contaminated clean the contamination

32. The following is true about a safety officer, except
    A. EQA processing
    B. First aid
    C. Prevention of laboratory acquired infections
    D. Ensure compliance with all safety regulation
    E. All the above

33. The following are true about equipment used in clinical trials, except
    A. Should be suitable located and of appropriate design
    B. Should be periodically inspected
    C. Record of such maintenance any unscheduled maintenance or calibration should be retained
    D. Any item of equipment that is out service for any reason should be clearly identified as such
    E. They should be serviced every day

34. What is the role of an analytical staff
    A. Sign and date analytical plan
    B. Perdome trials requirements in accordance with trial protocols, analytical plans and SOPS
    C. Approve analytical plant
    D. Write an analytical report
    E. Fill the server adverse effects forms

35. The following is true waste deposable 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
    E. All of the above

36. The following should be considered when storing trial materials
    A. Centrifuging
    B. Labeling tubes and freezers
    C. Temperature
    D. Back-up facilities
    E. All of the above

37. A hazard could be _____
    A. Substance
    B. Item of equipment
    C. Activity
    D. Cardboard box
    E. All of the above

38. The following is true about quality audit, except
    A. Any corrective action indicated should be done
    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 findings of the quality audit should only be reported to the sponsor
    E. Should be conducted by competent person

39. Laboratory infrastructure should have the following except:
    A. Quality water supply for analytical purpose
    B. Uninterrupted power supply
    C. Admission ward
    D. Analytical work area
    E. Specimen collection alarm rounds

40. If oxygen depletion alarm sounds
    A. Mute it and finish your task quickly before leaving
    B. Evaluate the area is you can see vapour approving your breathing zone
    C. Ask for somebody to observe you incase you collapse
    D. Evacuate the area immediately
    E. Call the fireman

Section B (Answer All questions)

41. (i) Discuss the Helsinki declaration **(10marks)**

(ii) State the principles of GCLP **(10 marks)**

42. (i) Define the following :

a) Analytical plan **(2marks)**

b) Analytical report **(2marks)**

c) Investigator **(2marks)**

d) Raw data **(2marks)**

e) Sponsor **(2marks)**

(ii) Outline trial facility management responsibilities **(10marks)**

43. (i) Discuss the application of standard operating procedures (SOPS) **(10marks)**

(ii) State the contents of the analytical report **(10marks)**