



TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR:

DMLS

AML 2105: GOOD CLINICAL LABORATORY PRACTICE.

END OF SEMESTER EXAMINATION

SERIES: DECEMBER 2016

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

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. Retains 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 true?
- A. Lab plastic ware 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 fails
 - 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 reuse
 - 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 they 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 individuals are responsible for maintaining safety in the workplace
- 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

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)**