TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR:

DEGREE

AML 4104 : GOOD CLINICAL LABORATORY PRACTICE

SUPPLIMENTARY/ SPECIAL EXAMINATION

SERIES: SEPTEMBER 2018

TIME: 2 HOURS

DATE: Pick Date Sep 2018

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of Choose No Section(s). Attempt ALL questions.

Circle the correct answer in section A.

Section A

Section A (30 Marks)

1. Good clinical laboratory practice includes all of the following except

a) Staff training

b) Manufacturing protocols

c) Organization of facility

d) SOP development

e) Management of Equipments

2. Which of the following is not considered if a vaccination campaign results in death

a) Storage conditions
b) Mode of transport
c) Batch number of the vaccines
d) Good manufacturing process
e) Previous immunization

3. Which one of the following equipment is included in the specimen tracking protocol

a) Electronic microscope
b) Biosafety cabinet II
c) Incubator
d) centrifuge
e) Freezer

4. The Helsinki declaration is basis of_____

a) GCP
b) GLP
c) GMP
d) COTU
e) KMLTTB

5. Which one of the following is handled in Biosafety level 4

a) Cholera stool samples
b) Sputum with MDR- Mycobacterium
c) Anthrax bacilli
d) Blood with Dengue virus
e) Blood with Ebola virus

6. Records showing operation and maintenance of an equipment are found in the _____

a) Inventory of Equipments

b) Workshop records

c) Equipment log

d) Temperature chart

e) Company files

7. Global transport of infectious samples is regulated by_____

a) National carriers regulation

b) Biosafety protocol

c) Risks document

d) IATA regulations

e) Transport SOP

8. Which of the following document is used to identify location of equipments in an institution?

a) Laboratory policy

b) Order list

c) Procurement policy

d) Tracking Equipments

e) Inventory

9. Which one of the following documents represents formal reporting and communication between the laboratory staff and management?

a) Minutes of departmental meetings

b) Mobile network protocols

c) Personal files

d) Working manuals

e) Organizational charts

10. The speed of the following laboratory equipment is periodically recorded

    a) Centrifuge

    b) Incubator

    c) Portable Water bath

    d) Refrigerator

    e) pH Meter

11. The following statements are true about Quality Control logs except

    a) Disciplinary action against laboratory staff is recorded

    b) Ranges of results are availed

    c) Positive and negative controls are specified

    d) Laboratory staff indicate initials after control runs

    e) Corrective measures are recommended

12. Handling and storage of hazardous chemicals in the laboratory is found in

    a) Personal Protective equipment

    b) SOPs

    c) First Aid documents

    d) Chemical Inventory

    e) Material Safety Data Sheet

13. The lead person in clinical trials is the

    a) Laboratory director

    b) Sponsor

    c) The principal investigator

    d) Quality assurance officer

    e) Cabinet secretary of health

14. The following is true on the Tuskegee research except

    a) Good clinical practice was not followed

    b) The study subject were not informed of the risks and benefits

    c) The study was ethically biased

    d) Subjects benefited from the discovery of penicillin

    e) Participants were suffering from syphilis

15. Which of the following is the most common source of quantitative errors in the laboratory?

    a) Preparing normal saline

    b) Using the weighing balance

    c) Reading pH values

    d) Adjusting temperature controls

    e) Pipetting

16. Which one of the following is not included in maintenance logs?

    a) Validation

    b) Cost of equipment

    c) Inspections

    d) Standardization

    e) preventive maintenance

17. The laboratory director is consulted before rejection of the following specimen

    a) Blood from diabetic patients

    b) Urine from expectant mothers

    c) Cholera stool samples

    d) Cerebral Spinal fluid

    e) Sputum with MDR Mycobacterium

18. The national body that gives accreditation to Ethical Review Boards is

    a) Commission of Higher Education

    b) KEMRI

    c) NEMA

    d) KMLTTB

    e) NACOSTI

19. The following statements are true about Laboratory information Systems except

    a) Access by the study subjects is not restricted

    b) The system generates final results

    c) Coded information is entered

    d) Access is restricted

    e) The system is audited

20. Which of the following resulted from Helsinki Declaration?

    a) World Health Organization

    b) Good manufacturing process

    c) Good proposal writing

    d) ISO

    e) Good clinical Practice

21. Copies of accurate and complete results of a study are generated by

    a) Laboratory director

    b) Principal Investigator

    c) Laboratory personnel

    d) Laboratory information Systems

    e) Data entry clerks

22. Which one of the following document is immediately referred to. if a spill of pathogenic spores was reported.

a) First Aid plan

b) SOPs

c) Laboratory policy

d) Decontamination plan

e) Evacuation plan

23. Which one of the following is not essential for Biosafety level 1?

a) Labels

b) Use of disinfectants

c) Wearing gloves

d) Biosafety cabinet

e) Laboratory coats

24. Financial requirements of clinical trials are provided by

a) Laboratory director

b) World Bank

c) The principal investigator

d) Quality assurance officer

e) Sponsor

25. Compensation of study subjects in clinical trials is indicated in

a) The constitution

b) Bill of rights

c) Consent forms

d) Minutes of the Ethical review committee

e) Affidavits sworn by the Principal investigators

26. The laboratory director is consulted before rejection of the following specimen

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Section B

Question 31

i) Explain the packaging and transport of infectious specimen (10 Marks)

ii) Differentiate the constitution and functions of an Ethical Review Board and Scientific Steering Committee (10)

Question 32

Discuss in detail the safety policy for the different Biosafety levels (20 Marks)