Question paper for Regulatory Aspects and monitoring in healthcare.

MCQ- 20 Marks- 20 Minutes- 20 Questions- Each carry equal marks

Subjective Type Questions- 15 Marks- 40 Minutes. Each question carries 3 marks

Total time 60 Minutes. Total Marks- 35

MCQ- Select the correct Answer. Each question carries 1 marks. Total 20 Marks

Q1 Acceptance of part of fees received by senior doctor, for referring the case is known AS

A Privileged communication

B Malpraxis

C Dichotomy

D Criminal negligence

ANSWER

Q2 Contributary negligence means:

A Negligence of the Doctor

B Negligence of the Nurse

C Negligence of the Patient

D Negligence of both Doctor and Patient

ANSWER

Q3 Res ipsa loquitor means

A Negligence of surgeon

B Punishment in Negligence

C Liability in Negligence

D Things speaks for itself

ANSWER

Q4 Minimum age required to give valid consent for risky surgery:

A 12 Years

B 16 Years

C 18 Years

D 21 Years

ANSWER

Q5 ReMeDi is

A A Telemedicine Solution

B Holds an Indian Patent

C Multipara monitor kit

D All the above

ANSWER

Q6 Which is not a function of CDSCO

A To regulate Drugs

B To regulate MD

C To regulate Clinical Trains both MD and Drugs

D To draft standards of Medical Devices

ANSWER

Q7 Inspection by CDSCO/NB is not required for Manufacturing License of

A Class A Devices

B Class C Device

C Class D Device

D Class B Device

ANSWER

Q8 How can manufacturer in Germany sell its products in India

A Appoint an Indian Distributor which donot have a Wholesale Drug License to get import License

B Appoint an Indian Distributor which have a Valid Wholesale Drug License to get import License

C Can apply directly from Germany for getting an import license

D All of the above

ANSWER

Q9 Which is the wrong abbreviation-

A ADR-Adverse Drug Reaction

B MDAE- Medical Drug Adverse Event

C SAE- Serious Adverse Event

D PvPI- Pharmocovigilance Program of India

ANSWER

Q10. Which of the following is not correct-

A PSUR is Periodic Safety Update report

B It is to be submitted after the drug has been launched in the market

C PSUR helps to monitor the safety and efficacy of the Drugs in the long run.

D PSUR needs to be filled by the patients.

ANSWER

Q11 Dizziness starts after 30 minutes of taking a BP Drug and it stops

It stops after stopping the drug next day but again starts after taking the drug.

A ADR is certain because of the Drug

B ADR is probable because of drug.

C ADR is unlikely caused by the Drug.

D ADR is possibly caused by the Drug.

ANSWER

Q12 Which is not true:

A Drugs and Cosmetic Act regulate sale of Drugs and Medical Devices.

B Medical Device is also defined as Drugs

C The Drugs Control Act was introduced in 1940 and the Rules in 1945

D Cosmetics is a drug to treat skin infection.

ANSWER

Q13 What HTA does not do

A It helps to introduce a health technology and also upscale the same.

B It helps to discontinue a health technology.

C It helps to allocate the health care budget.

D It helps to analyse Adverse Drug Reaction.

ANSWER

Q14 Following is not the elements of HTA

A Clinical Efficacy

B Safety

C Cost effectiveness

D Colour and weight of the technology.

ANSWER

Q15 Which is not true for SENSIVITY

A It determines correctly the patients with the disease conditions

B 90% Sensitivity means 90% of the patients don't have the disease

C Equals TRUE POSITIVE/(TRUE POSITIVE+FALSE NEGATIVES)

D 90% Sensitivity means 90% of the patients have the disease

ANSWER

Q16 Which is not true:

A Visual Analog Scale is used to rate the state of discomfort of a patient

B Time trade off reflects the choice a person willing to let go a bad state of disease.

C Standard gamble a patient would be willing to embrace death in lieu of paralyzed state.

D Govt budget normally determined to exceed the threshold level.

ANSWER

Q17 Which of the following is not true of HTA

A It should be independent.

B It should include all stakeholders views.

C It should not worry about the costs of technology introduction.

D Should have strong scientific basis.

ANSWER

Q18 GCP or Good Clinical Practices is seen in all except

A Phase-IV of CT

B Periclinal CT

C Phase-III of CT

D Phase-II of CT

ANSWER

Q19 Clinical Trials are conducted

A To determine efficacy of a new drug

B To determine safety of a new drug

C To determine dosage of a new drug

D All the above

ANSWER

Q20 The aim of post marketing studies is :

A Determine efficacy of a drug

B To determine dosage of a drug

C To deal with alteration of drug including absorption, distribution etc.

D To determine safety and comparison with drugs for long term use

ANSWER

Subjective Type Questions- Answer and Five Question- Each Question carry 3 Marks. Total 15 Marks

Q1- Explain the four major principals of Medical Ethics.

Q2- Explain Civil and Criminal Negligence with two examples each.

Q3. Explain the difference between Four phases of clinical trials. Explain why Phase IV trial is different from other three phases.

Q-4- Explain with example the following terms-

Pharmacodynamics , Pharmacokinetics, Placebo, Random Controlled Trials and Blind Trials.

Q-5- Explain the following with examples-

Prosthetic Medical Devices, Invitro Medical Devices , Mobile Health, Telemedicine.

Q6-Exlplian in brief Medical Device Rules, its utility, scope and its implementation plan in Three Phases.

Q7- What is Pharmacovigilance and Materiovigilance and what are its short term and long term goals?

Q8-What is CDSCO and what is its role in Medical Device Regulations and Clinical Trials.

Q9-What are the three steps in Health Technology Assessments? Explain Systematic Review process with and example?

Q10-What is Sensitivity and Specificity of a test. Answer the following:

a) We tested 10 Samples for True Diabetics patients. 9 Samples confirmed Diabetes while one sample showed negative results. Calculate the Sensitivity and explain what it signifies

b) In a given patient population we have 58 persons who are not having Hypertension. However in the testing it identifies 12 persons as having the disease. Calculate the Specificity and explain what does it signify.