Time: 3 Hrs **Marks: 80**

Q. 1 Attempt all multiple-choice questions (MCQ) **20M**

Sr No	Questions		Options
1	Reported Information on a causal relationship between an Adverse Event and a Drug is known as:	a	Signal
		b	Benefit-Risk Analysis Database
		c	Individual Case Safety Report
		d	Post Marketing Surveillance
2	The informed consent in a clinical trial is……	a	Signed document of the recruited patient for the clinical trial procedures
		b	The subjects do not know which study treatment they receive
		c	Patients injected with placebo and active doses
		d	Fake treatment
3	Uppsala Monitoring Centre is located in…….	a	India
		b	United Kingdom
		c	Sweden
		d	China
4	……is the Active Surveillance type of Pharmacovigilance method.	a	Sentinel sites
		b	Spontaneous reports
		c	Stimulated reports
		d	case series
5	A compilation of the clinical and nonclinical data on the investigational products related to the clinical study is called as:	a	Informed Consent Form
		b	Drug Dossier
		c	Protocol Amendment
		d	Investigator's Brochure

6	The structure and content of Clinical Study Reports are described in……...of Schedule Y 2014.	a	Appendix VII
		b	Appendix IV
		c	Appendix II
		d	Annexure III
7	Aims of Spontaneous Reporting of Adverse Drug Reactions are:	a	Benefit Risk Analysis
		b	Reduce Cost of Drug Therapy
		c	Study of Drug Development
		d	Audit of Clinical Trials
8	Uppsala Monitoring Center holds and maintains one of the following ICSR Database	a	Argus Safety Database
		b	Materiovigilance Database
		c	Vigibase TM
		d	Toxnet
9	Pharmaco-economics is related to:	a	Quantitative Evaluation of Drug Effects
		b	Description and Analysis of cost of Drug Therapy
		c	Benefit-Risk Analysis
		d	Drug Utilization Study in specific Population
10	ICH Guideline entitled Pharmacovigilance Planning:	a	E 2 B
		b	E 19
		c	E 2 C
		d	E 2 E
11	Which of the following is a type of Comparative Studies?	a	Cohort studies
		b	Randomized trials
		c	Qualitative studies
		d	Test controlled studies
12	Which of the following can be called as Phase Zero Clinical Trial?	a	Pre-clinical Drug Development
		b	Trials using Human tissue collected from patients but not conducted in the patient
		c	Post Marketing Surveillance

		d	First-in-man Study to determine Pharmacokinetics of New Drug by giving a low sub therapeutic dose
13	Center for Pharmacovigilance Program of India is located at:	a	IPC, Ghaziabad
		b	CDSCO, New Delhi
		c	AIIMS, New Delhi
		d	CDL, Kolkata
14	ICSR Management System created and maintained by the Uppsala Monitoring Center is:	a	MedDRA
		b	WHO -ART
		c	VigiFlow
		d	Drug Dossier
15	WHO-ART has	a	4 levels hierarchical structure
		b	10 levels hierarchical structure
		c	5 levels hierarchical structure
		d	6 levels hierarchical structure
16	ICH Guideline E-6 is associated with:	a	Good Clinical Practice
		b	Pre-clinical Drug Development
		c	Safety Pharmacology Studies
		d	Good Laboratory Practice
17	A Blind Subject means:	a	The subjects do not know which study treatment they receive
		b	Patients injected with placebo and active doses
		c	Fake treatment
		d	Signed document of the recruited patient for the clinical trial procedures
18	Pharmaco-epidemiology is defined as:	a	The Science of Detection, Reporting and Assessment of Adverse Drug Events
		b	Post Marketing Surveillance

		c	Study of Uses and Effects of Drugs in well-defined Population
		d	A compilation of the Clinical Data of the Investigational Product
19	Pharmacovigilance is done for monitoring of……	a	Drug Safety
		b	Drug Price Control
		c	Animal Experiments
		d	Toxicokinetic Studies
20	Naranjo scale method of causality assessment is……..	a	Probabilistic method
		b	Algorithmic method
		c	Global introspection.
		d	Dose dependent

Q 2. Attempt <u>ANY ONE</u> Question. **12 M**

1. Define and classify ADR, Explain Management of ADR.
2. Write a detailed note on concepts and applications of

Pharmaco-economics & Pharmacoepidemiology

Q 3. Attempt <u>ANY FOUR</u> Questions. **48 M**

1. Describe the Structure and Content of Investigator's Brochure.
2. Give detailed account on Various Active and Passive Surveillance Methods used in Pharmacovigilance.
3. Elaborate on: WHO International Drug Monitoring Programme.
4. Give a detailed account on Good Clinical Practice (ICH-GCP) guidelines.
5. Define the terms: Sponsor and Investigator. Give a detailed account on the Responsibilities of the Sponsor.
