Exam Date & Time: 25-May-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmaceutical Regulatory Science [PQA-BP804ET-S2]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) What is the review period of FDA on an IND application? (1)

1)	30 days		2)	90 days		3)	180 days		4)	1 year	

2) Which is the application submitted to FDA seeking approva to market a generic drug? (1)

1)	IND		2)	NDA		3)	ANDA		4)	SNDA	

3) What is the period of marketing exclusivity provided for an innovator company for a new chemical entity? (1)

1)	180 days		2)	3 years		3)	5 years		4)	7 years	

4) Which phase of clinical trial is called as "Pivotal trials"? (1)

1)	Phase 1		2)	Phase 2		3)	Phase 3		4)	Phase 4	

5) Duration of acute toxicity study is (1)

1)	1 day		2)	14-20 day		3)	180 days to 1 year		4)	2-3 years	

6) Module 5 under CTD format deals with

1)	Physicochemical study report		2)	Analytical report		3)	Clinical study report		4)	Stability study report	

(1)

7) Details of packaging material is presented in _____ type of DMF (1)

1)	Type I		2)	Type II		3)	Type III		4)	Type IV		5)	Type V		

8) Monitors are appointed by (1)

1)	Regulatory authorities		2)	Sponsor		3)	Investigator		4)	IRB	

9) Type -I Immunological ADR is

1)	Ig E Mediated		2)	Cytotoxic		3)	Immune complex		4)	Cell mediated	

(1)

10) Time line for reporting an ADR by sponsor to licencing in India is (1)

1)	One week		2)	24 hours		3)	14 calendar days		4)	One month	

11) Pharmacovigilance programme of India was officially started in India in (1)

1)	23rd January 2004		2)	23rd October 2004		3)	23rd November 2004		4)	23rd May2004	

12) A drug which is being studied to see if the disease or medical condition improves while taking it is known as (1)

1)	Investigational drug		2)	Approved drug		3)	Recalled drug		4)	Orphan drug	

13) Primary Federal agency for conducting and supporting medical research is known as (1)

1)	National Institutes of Health (NIH).		2)	National Cancer Institute - (NCI)		3)	National Library of Medicine - (NLM)		4)	National Archives and Records Administration (NARA)	

14) Set of specifications for application dossier for the registration of medicines and designed to be submitted to selected regulatory agencies is called (1)

1)	Investigational drug application		2)	Abbreviated drug application		3)	Drug master file		4)	Common technical document	

15) Patients hospitalized with Covid-19, the illness caused by infection with SARS-CoV-2 were administered Remdesivir. Under what category this was done? (1)

1)	Clinical trial		2)	Compassionate use		3)	Standard treatment protocol		4)	Pharmacovigilance	

16) A batch of ibuprofen tablets were ordered to be removed from the market by USFDA based on the inspection of some records by inspectors. What is action called? (1)

1)	Drug Withdrawal		2)	Drug Recall		3)	Drug Investigation		4)	Post Market Surveillance	

17) A file submitted to FDA that may be used to provide confidential detailed information about facilities, process or articles used in manufacturing, processing packing and storing of one or more of human drugs is called (1)

1)	Common technical document		2)	New drug application		3)	Abbreviated new drug application		4)	Drug master file	

18) The statutes formed by the legislature for a particular subject is called (1)

1)	An Act		2)	A Law		3)	A guideline		4)	Guidance Document	

19) The addendum to orange book doesn't contain information on (1)

1)	Over The Counter products		2)	Discontinued Drug Product Lists		3)	Drug Products with Approval under		4)	Drug products with tentative approval	

							Section 505					

20) Drug products in identical dosage forms and route(s) of administration that contain identical amounts of the identical active drug ingredient are called (1)

1)	Pharmaceutical Alternatives		2)	Pharmaceutical Equivalents		3)	Therapeutic Alternatives		4)	Therapeutic Equivalents		

II Long Answers

Answer all the questions.

1) Draw an organizational chart for PMDA (6 Marks)
Write the major functions of PMDA (4 Marks) (10)

2) Enlist the committees under the European Medicines Agency (EMA) governing the pharmaceuticals. (5 Marks)
Enlist the contents of non - clinical & clinical study reports of dossier submission as per ICH. (5 Marks) (10)

III Short Answers

Answer all the questions.

1) Discuss the stages of new drug development mandated by Pharmaceutical regulatory Science. (5)

2) What are the two titles of the Hatch-Waxman act? How the act balanced the interests of the customers, innovator company and the generic drug industry? (5)

3) What is post market monitoring and why it is important? explain with one marketed product as per Australian regulatory agency? (5)

4) Why is Module 1 not a part of CTD. Justify? (5)

5) List the responsibilities of Monitor (5)

6) Compare Clinical Trials against Clinical practice (5)

7) Explain "21 CFR Part 211 Subpart A §§ 211.1 - 211.3.
On which month and date these provisions are updated every year? (5)

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