Exam Date & Time: 15-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmaceutical Regulatory Science [PQA-BP804ET]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Which of the following phase of clinical trial uses healthy volunteers to evaluate the safety of a new drug? (1)

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

2) The ethical and scientific quality standards for designing, conducting, recording and reporting trials that involves participation of human subjects is known as: (1)

1)	GLP		2)	GDP		3)	GMP		4)	GCP	

3) The provision for submitting a generic drug application under ANDA was created under (1)

1)	Drug price Competition and Patent Term Restoration Act		2)	Drug Price Competition Act		3)	Biologics Price Competition and Innovation Act		4)	Prescription Drug User Fee Act	

4) Under which paragraph certification ANDA is filed if the generic company wishes to enter the market before patent expiry. (1)

1)	Paragraph I		2)	Paragraph II		3)	Paragraph III		4)	Paragraph IV	

5) Which is the application submitted to FDA seeking approval to initiate clinical trial? (1)

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

6) The headquarters of the CDSCO is located at (1)

1)	Delhi		2)	Kolkata		3)	Bengaluru		4)	Ahmedabad	

7) The SUGAM portal under CDSCO is used to submit applications for attaining (1)

1)	Marketing approval		2)	Clinical trial approval		3)	Import license		4)	All the above	

8) Phase-II clinical trials are for (1)

1)	Safety		2)	Efficacy		3)	Safety and efficacy		4)	Marketing approval	

9) Expedited Review is for (1)

1)	The proposals presenting no		2)	For all		3)	Preclinical trials		4)	The proposals presenting	

	more than minimal risk to research participants			trials						more than minimal risk to research participants	

10) Pharmacovigilance in UK under

												(1)
1)	Yellow card scheme		2)	MEDWATCH		3)	CDSCO		4)	NCC		

11) One of the following is an additional element of informed consent form

												(1)
1)	Withdrawal criteria		2)	Purpose		3)	Confidentiality		4)	Contact information		

12) A profession which acts as a interface between the pharmaceutical industry and drug regulatory agencies across the world is known as

												(1)
1)	Quality Assurance		2)	Marketing Management		3)	Regulatory Affairs		4)	National Regulatory Agency		

13) Federal register is published by

												(1)
1)	National Archives and Records Administration		2)	Office of Generic Drugs		3)	Food and Drug Administration		4)	Office of policy, legislation and International Affairs		

14) NAFDAC is national regulatory agency of

										(1)
1)	Brazil		2)	Nigeria		3)	Nicaragua		4)	Morocco		

15) National regulatory agencies of the following countries are named as food and drug administration.

												(1)
1)	USA, Thailand, Saudi Arabia		2)	USA, Singapore, China.		3)	USA, Malaysia, Australia		4)	USA, South Africa, Nepal		

16) Following is not a center under USFDA

												(1)
1)	.Oncology centre of excellence		2)	.Office of external affairs		3)	Office of Operations		4)	Patient support center		

17) A patient takes an antihistaminic drug. After half an hour when he was walking through a busy foot path falls and injures himself. This can be classified as

												(1)
1)	Adverse drug reaction		2)	Adverse event		3)	Accident		4)	None of the above		

18) Certificate of suitability (CEP) is issued by

										(1)
1)	EDQM		2)	FDA		3)	CDSCO		4)	NMPA		

19) A non-specific rule or principle that provides direction to action is called

										(1)
1)	Guidance		2)	Guidelines		3)	Regulatory document		4)	Act		

20) Following is not a part of orange book

1)	Approved over-the-counter (OTC) drug products		2)	Drug products with approval under Section 505		3)	A cumulative list of approved products that have never been marketed		4)	A comprehensive alphabetical listing		(1)

II Long Answers

Answer all the questions.

1) Draw a flow chart and explain the steps involved in generic drug review process (10)

2) Give a pictorial representation on contents of regulatory dossier filing as per ICH. (5Marks)
Bayer Pharmaceuticals is planning to export analgesic products to the United States. As regulatory personnel brief on the procedure for export from India. (5 Marks) (10)

III Short Answers

Answer all the questions.

1) Briefly explain the types of toxicity studies conducted in animal models as a part of new drug development. (5)

2) Write the regulatory overview of Phase 3/Pivotal clinical trial. (5)

3) Explain the procedure adopted in Canada for healthcare system (5)

4) Enlist the contents of regulatory dossier to be submitted to Malaysia & Vietnam. (5)

5) Explain the essential elements of the informed consent processes (5)

6) List the objectives of Institutional Review Board (5)

7) Mr. Karaly wants to export some drugs to United States of America. He doesn't know how to go about it. Which book he should refer and why? (5)

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