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Unit 4 - Week 2

Register for Certification exam

Course outline

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Assignment 2

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-13, 23:59 IST.**

Dear Participants,

We covered three lectures this week.

Lecture 4: Drugs & Cosmetics Act and Rules
In this lecture, the objectives of Drugs & Cosmetics (D & C) Act, how many parts it contains, total number of chapters, Rules etc. were explained in detail. We studied mainly all the Rules related to new drugs and clinical trials. Similarly, all the forms related to clinical trial and new drug were explained. All the Schedules to the Rules 1945 (from Schedule A to Y) was explained in brief. We covered all the central drug testing laboratories as well as the state laboratories.

Lecture 5: Guidelines relevant to clinical trials and new drugs
In this lecture, we discussed all the relevant guidelines related to both clinical trials and new drugs. We were introduced to the GCP guideline of 2001 by CDSCO and covered all important guidelines before 2013 and after 2013. 2013 onwards various guidelines were released.

Lecture 6: Drug development process: overview
In this lecture, we discussed in very brief the major steps involved in the discovery and development of a drug. All the stages of drug development like product characterization, formulation, delivery, packing development, pharmacokinetics, pharmacodynamics, preclinical toxicology, IND application etc. We also studied acute toxicity studies, repeated dose studies, genetic toxicity studies, reproductive toxicity studies, carcinogenicity studies. We also studied bioanalytical testing (for biologicals). This lecture also covered all the phases of clinical trials in very brief.

Best of luck for completing the assignment 2

1) Name the 'FORM' number which deals with the application for grant of permission to import or manufacture a new drug or to undertake clinical trial ***1 point***

- FORM 44

Government of India
Ministry of Human Resource De

Accepted Answers:
FORM 44

2) Which Schedule addresses GMP (Good Manufacturing Practice)? ***1 point***

- Schedule H
- Schedule O
- Schedule K
- Schedule M

No, the answer is incorrect.
Score: 0

Accepted Answers:
Schedule M

3) Central Drug Laboratories (CDL) Kasauli is responsible for testing vaccines, sera, biologicals and OPV testing ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

4) The guideline pertaining to the registration of ethics committee was release in which year? ***1 point***

- 2011
- 2012
- 2013
- 2014

No, the answer is incorrect.
Score: 0

Accepted Answers:
2013

5) The steps in approval process for new medicine involves discovery and development, preclinical research, laboratory and preclinical animal testing for safety followed by clinical trials, regulatory review and approval, manufacturing and sale license etc. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

6) When did Clinical Trials Registry – India (CTRI) became mandatory for regulatory trials in India? ***1 point***

- 1st March 2009
- 1st March 2011
- 15th June 2009
- 15th June 2011

No, the answer is incorrect.

Score: 0

Accepted Answers:
15th June 2009

7) Phase III study is also known as _____study. ***1 point***

- Human toxicology
- Human pharmacology
- Therapeutic exploratory
- Therapeutic confirmatory

No, the answer is incorrect.
Score: 0

Accepted Answers:
Therapeutic confirmatory

8) All types of preclinical toxicology studies to be conducted should be as per Schedule _____, Appendix _____ ***1 point***

- M, I
- Y, I
- Y, II
- Y, III

No, the answer is incorrect.
Score: 0

Accepted Answers:
Y, III

9) Structure Activity Relationship (SAR) is associated with target selection in drug discovery and development. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

10) ADME is _____ ***1 point***

- Adsorption, Distribution, Metabolism, Enhancement
- Absorption, Distribution, Metabolism, Enhancement
- Absorption, Distribution, Metabolism, Excretion
- Assimilation, Distribution, Metabolism, Excretion

No, the answer is incorrect.
Score: 0

Accepted Answers:
Absorption, Distribution, Metabolism, Excretion

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