X

Unit 5 - Week 3

Register for Certification exam

Course outline

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Assignment 3

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-20, 23:59 IST.**

Dear Participants,

I hope you enjoyed the lectures. We covered three lectures this week.

Lecture 7: Good Clinical Practice
In this lecture, we studied that GCP is the standard for clinical studies or trials that encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies. GCP compliance ensures that the rights, safety and well-being of study subjects (human participants) in a clinical trial are protected and the data generated are credible and accurate. We also studied about the definitions, the pre-requisites for the study, and responsibilities of all stakeholders. Record keeping and data handling; quality assurance; statistics, special concerns (vaccines, contraceptives, phyto-pharmaceuticals etc.) were succinctly covered in this lecture.

Lecture 8: Schedule Y: Overview
In this lecture, we understood what is Schedule Y? We also had a brief overview of its history and all the amendments. This lecture covered all the salient features of Schedule Y. It also addressed all the rules related to Schedule Y which were briefly discussed along with all the forms and fees related to clinical trials.

Lecture 9: Schedule Y: Appendices
In this lecture, we discussed all the appendices of Schedule Y. We learnt that these appendices are the requirements for approval/marketing of new drug, subsequent new drug, (includes FDC, biologicals, vaccines, phyto-pharmaceutical drug). We understood that appendices are developed to help the applicant in generating the data necessary for regulatory submissions.

Best of luck for completing the assignment 3.

1) Who is responsible for selection of investigator and institution in a clinical trial? ***1 point***

- Ethics committee

Government of India
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Accepted Answers:
Sponsor

2) For global clinical trial which GCP should be followed? ***1 point***

- Indian GCP (2001)
- ICH GCP E6 (R2) (2016)
- Both the above
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Both the above

3) Which of the following is not one of the function of ethics committee? ***1 point***

- Review trial protocol
- Approve trial
- Pay compensation to study subjects (human participants)
- Review periodic study progress reports

No, the answer is incorrect.
Score: 0

Accepted Answers:
Pay compensation to study subjects (human participants)

4) Investigator responsibilities includes patient care, safety and documentation throughout the journey _____. ***1 point***

- Before clinical trial
- During clinical trial
- After clinical trial
- All of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
All of the above

5) Form 46 is the application for grant of permission to import or manufacture a new drug or to undertake clinical trial ***1 point***

- Ture
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

6) _____ is about the permission/approval for manufacture of a new drug formulation. ***1 point***

- Form 44
- Form 45
- Form 46
- Form 47

No, the answer is incorrect.
Score: 0

Accepted Answers:
Form 46

7) _____ deals with ethics committee and _____ deals with the undertaking by the investigator ***2 points***

- Appendix VII, Appendix VIII
- Appendix VIII, Appendix VII
- Appendix VIII, Appendix IX
- Appendix IX, Appendix VIII

No, the answer is incorrect.
Score: 0

Accepted Answers:
Appendix VIII, Appendix VII

8) Registration of ethics committee [G.S.R. 72(E) dated February 08, 2013] is covered under _____ and permission to conduct clinical trial [G.S.R. 63(E) dated February 01, 2013] is covered under _____ ***2 points***

- Rule 122DD, Rule 122DAC
- Rule 122DA, Rule 122DAB
- Rule 122DAB, Rule 122DAC
- Rule 122DAC, Rule 122DD

No, the answer is incorrect.
Score: 0

Accepted Answers:
Rule 122DD, Rule 122DAC

9) Rule 122DAB and Rule 122DD were published in 2013. ***1 point***

- Ture
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
Ture

10) Appendices _____ were introduced to Schedule Y in 2005. ***1 point***

- I to X
- I to XI
- VII to XI
- VII to X

No, the answer is incorrect.
Score: 0

Accepted Answers:
VII to XI

11) ***5 points***

Match the following

(A) Appendix IV	(1) Fixed Dose Combinations
(B) Appendix V	(2) Animal toxicology
(C) Appendix III	(3) Stability testing of new drugs
(D) Appendix VI	(4) Animal pharmacology
(E) Appendix IX	(5) Informed consent

- A-1; B-2; C-3; D-4; E-5
- A-2; B-3; C-4; D-1; E-5
- A-3; B-4; C-5; D-2; E-1
- A-4; B-5; C-2; D-1; E-3

No, the answer is incorrect.
Score: 0

Accepted Answers:
A-4; B-5; C-2; D-1; E-3

12) The contents of the proposed protocol for conducting clinical trials as per Appendix X mentions the name(s) of clinical laboratories and other departments and/or facilities participating in the study. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

13) In the Appendix VII, the 'Undertaking by the investigator' encompasses the signature of investigator with date. ***1 point***

- Ture
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
Ture

14) Fixed Dose Combinations can be divided into _____ groups. ***1 point***

- One
- Two
- Three
- Four

No, the answer is incorrect.
Score: 0

Accepted Answers:
Four

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