

Code No: R05322306

Set No. 1

III B.Tech II Semester Regular Examinations, Apr/May 2008
REGULATORY AFFAIRS AND CLINICAL TRIALS
(Bio-Technology)

Time: 3 hours

Max Marks: 80

Answer any FIVE Questions
All Questions carry equal marks

1. Explain the Importance of EU clinical Directive. [16]
2. How to assess the mental competence of a person to recruit for the studies. [16]
3. Write the roles and responsibilities of internal and external auditors. [16]
4. Write briefly about GCP guidelines followed in India and discuss how the directives will affect clinical research. [16]
5. How “in company” audits are done. [16]
6. Explain Case Report Form used in clinical research. [16]
7. Steps used in subject treatment and submissions for use of investigational new drug. [16]
8. Write about UK ethics approval system. [16]

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Set No. 2

III B.Tech II Semester Regular Examinations, Apr/May 2008
REGULATORY AFFAIRS AND CLINICAL TRIALS
(Bio-Technology)

Time: 3 hours

Max Marks: 80

Answer any FIVE Questions
All Questions carry equal marks

1. What is case report form and what are the essential principles of CRF. [16]
2. Write about the role of ethics committee in the conduct of clinical trials. [16]
3. Write about retrospective of clinical Audit. [16]
4. What is GCP by ICH. Write about the guidelines mentioned in the ICH GCP? [16]
5. Auditing of quality management system. Explain. [16]
6. Explain. Medicine Health care Research Agency-QSE. [16]
7. Write short notes on the following:
 - (a) Waivers
 - (b) Adverse drug experiences
 - (c) Post marketing 15-day "Alert Reports". [6+6+4]
8. Brief the recent developments in Ethical guidelines. [16]

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Set No. 3

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(Bio-Technology)

Time: 3 hours

Max Marks: 80

Answer any FIVE Questions
All Questions carry equal marks

1. Write the significance of clinical trials in biomedical research. [16]
2. Write about the obligations of investigators to obtain informed consent. [16]
3. Write about different types or Audit findings and explain follow-up GCP audit reports. [16]
4. What are the legal sanctions the sponsor will face in case of non-compliance of EU directives on GCP for clinical trials? [16]
5. Explain Auditing of Investigation Drug. [16]
6. Principles based on International Conference on Harmonization GCP guidelines. [16]
7. Procedures for submission of supplement to an approved application. [16]
8. Write short notes on
 - (a) WHO
 - (b) FDA. [8+8]

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Set No. 4

III B.Tech II Semester Regular Examinations, Apr/May 2008
REGULATORY AFFAIRS AND CLINICAL TRIALS
(Bio-Technology)

Time: 3 hours

Max Marks: 80

Answer any FIVE Questions
All Questions carry equal marks

1. Write about the features of information security followed by the organizations. [16]
2. What are the basic criteria followed to recruit the patients for clinical trials. [16]
3. Write how the standard operating procedures monitors a particular clinical study. [16]
4. Write about the responsibilities of the investigator as stipulated by FDA directives. [16]
5. Explain briefly about sponsor's audit. [16]
6. Requirements for Labeling of Investigational Medicinal Product. [16]
7. Explain the steps involved in Investigational New Drug application. [16]
8. What type of preparation you should do for inspection. [16]
