Code No: R05322306 **R05** **Set No. 2**

III B.Tech II Semester Examinations,December 2010
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 advantages and disadvantages of systems audit. [16]
2. What are the ways by which recruited patient acts in the cases of misconduct of the trials. [16]
3. (a) Write about general principles of ICHGCP.
   (b) Explain recent developments in ICHGCP. [8+8]
4. Brief the duties of inspection co coordinator. [16]
5. Discuss Auditing of IRB/IEC. [16]
6. Content and format of an abbreviated New Drug application. [16]
7. List out the different Forms used in regulatory affairs of clinical trials. [16]
8. Write about the roles and responsibilities of a monitor according to ICH GCP. [16]

⋆ ⋆ ⋆ ⋆ ⋆

Code No: R05322306 **R05** **Set No. 4**

III B.Tech II Semester Examinations,December 2010
REGULATORY AFFAIRS AND CLINICAL TRIALS
Bio-Technology

Time: 3 hours **Max Marks: 80**

Answer any FIVE Questions
All Questions carry equal marks

⋆ ⋆ ⋆ ⋆ ⋆

1. List out the different Forms used in regulatory affairs of clinical trials. [16]
2. Write about the roles and responsibilities of a monitor according to ICH GCP. [16]
3. Content and format of an abbreviated New Drug application. [16]
4. Write about the advantages and disadvantages of systems audit. [16]
5. Discuss Auditing of IRB/IEC. [16]
6. Brief the duties of inspection co coordinator. [16]
7. What are the ways by which recruited patient acts in the cases of misconduct of the trials. [16]
8. (a) Write about general principles of ICHGCP.
   (b) Explain recent developments in ICHGCP. [8+8]

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Code No: R05322306 **R05** **Set No. 1**

III B.Tech II Semester Examinations,December 2010
REGULATORY AFFAIRS AND CLINICAL TRIALS
Bio-Technology

Time: 3 hours **Max Marks: 80**

Answer any FIVE Questions
All Questions carry equal marks

⋆ ⋆ ⋆ ⋆ ⋆

1. Brief the duties of inspection co coordinator. [16]
2. Write about the roles and responsibilities of a monitor according to ICH GCP. [16]
3. Discuss Auditing of IRB/IEC. [16]
4. (a) Write about general principles of ICHGCP.
   (b) Explain recent developments in ICHGCP. [8+8]
5. Content and format of an abbreviated New Drug application. [16]
6. What are the ways by which recruited patient acts in the cases of misconduct of the trials. [16]
7. List out the different Forms used in regulatory affairs of clinical trials. [16]
8. Write about the advantages and disadvantages of systems audit. [16]

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Code No: R05322306 **R05** **Set No. 3**

III B.Tech II Semester Examinations,December 2010
REGULATORY AFFAIRS AND CLINICAL TRIALS
Bio-Technology

Time: 3 hours **Max Marks: 80**

Answer any FIVE Questions
All Questions carry equal marks

⋆ ⋆ ⋆ ⋆ ⋆

1. List out the different Forms used in regulatory affairs of clinical trials. [16]
2. Discuss Auditing of IRB/IEC. [16]
3. Write about the advantages and disadvantages of systems audit. [16]
4. (a) Write about general principles of ICHGCP.
   (b) Explain recent developments in ICHGCP. [8+8]
5. What are the ways by which recruited patient acts in the cases of misconduct of the trials. [16]
6. Content and format of an abbreviated New Drug application. [16]
7. Brief the duties of inspection co coordinator. [16]
8. Write about the roles and responsibilities of a monitor according to ICH GCP. [16]

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