Code :BT05502

RA

III B.Tech II Semester(R07) Regular & Supplementary Examinations, April/May 2011
REGULATORY AFFAIRS & CLINICAL TRIALS
(Biotechnology)
(For students of RR, R05 regulation readmitted to III B.Tech II Semester R07)

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

Answer any FIVE questions
All questions carry equal marks

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1. What is a clinical trial? Write about the ethical and safety considerations in a clinical trial.
2. What are the special features of a clinical trial protocol involving human embryo?
3. Write the roles and responsibilities of internal and external auditors.
4. Write about the roles and responsibilities of an investigator according to ICH GCP.
5. What are the essential documents to be audited?
6. Why is it necessary that clinical research have to meet the needs of regulatory affairs?
7. What are the supplements and other changes to an approved application?
8. Explain the impact in UK to the regulations in 2004 and now in 2006.

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