Code :R5322306

R5

III B.Tech II Semester(R05) Supplementary Examinations, April/May 2011
REGULATORY AFFAIRS & CLINICAL TRAILS
(Biotechnology)

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

Answer any FIVE questions
All questions carry equal marks

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1. Write about the role of ethics committee in clinical trials.
2. Write about the ethical principles followed by the monitors in clinical research trials.
3. Write the salient features of an audit plan.
4. Write about the legal and regulatory sanctions against the sponsor in case of noncompliance of Indian directives on GCP for clinical trials in India.
5. Explain briefly about sponsor's audit.
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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