GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Pharmaceutical Management and Regulatory Affairs (Branch -16)

Year – II (Semester – III) (W.E.F. June 2013)

Subject: - Regulatory Affairs-II (Theory) Subject Code: 1931601

Sr. No.	Course Content
1	A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations.
2	Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.
3	Loan license (contract manufacture).
4	Recent amendments to Drugs and Cosmetic Act and other relevant rules.
5	Certification and licensing procedures.
6	Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
7	Quality, safety and legislation for cosmetic products and herbal products.
8	Approval of New Drug: Investigational new drug (IND) submission, format and content of IND, content of investigator brochure, clinical research protocols, objective and protocol Design. FDA guidelines for clinical trials, reviews and approval of a clinical study, general consideration of the new drug approval (NDA), specific requirements, content and format of NDA, manufacturing and control requirements of NDA. New Chemical Entity (NCE).
9	International business and inland & foreign trade, procedure of exporting and importing goods. General international environment; political, legal, socio-cultural and economic factors, tax aspects, marketing factors, labor factors and economic integration. BOP analysis, foreign exchange control, governmental policies, international finance, economic community, IMF, managing multinationals/ globalization of operations.
10	Emerging Trends in Biotechnology Patenting.
11	Patent Cooperation Treaty
12	Strategies for effective Patent Drafting. IP Issues in contract Manufacturing. Exporting to the US and Prelitigation Consideration

Reference Books :

1. Original Laws of the Respective Country.
2. Original Laws published by Govt. of India.
3. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
4. Export Marketing by Cherian and Parab; Himalaya Publishing House, Delhi
5. Handbook of Procedures, Import and Export Promotion; Government of India, New Delhi
6. International Financial Management–An Indian Perspective by Varshney, R.L. and Bhashyam, S.; Sultan Chand & Co., New Delhi.

7. International Financial Management by Weston, J. Fred and Brat W. Sorge.; New York, McGraw Hill.

Subject: - Regulatory Affairs-II (Practical)

Laboratory examination including oral and practical examination in general course Illustrative of theory section in the syllabus.