GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Pharmaceutical Management and Regulatory Affairs (Branch -15)

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

Subject of Specialization Paper – V -Theory

Subject Name: Drug Regulation and Regulatory Authority

Subject Code: 1931501

Sr. No.	Course Content
1	A detailed study of the following laws, including latest amendments in India: a. The Drugs and Cosmetics Act, 1940 and Rules there under. b. The Pharmacy Act 1948. c. The Drug Prices Controls Order, 1955 and National Pharmaceutical Pricing Authority.
2	Indian Pharmacopoeia Commission: o Indian Pharmacopoeia ▪ IP review process ▪ Guide lines for formation of Monograph ▪ IP reference substances (IPRS) and spectra o National formulary of India o Pharmacovigilance programme of India o Haemovigilance programme
3	New Drug Application & Approval in India from CDSCO as per schedule Y & related provisions.
4	Preparation of documents for New Drug Application (NDA) as per requirements of FDA and EUDRA guidelines.
5	Drug Master Files, Site Master Files, Out of specification.
6	The WHO Guidelines-The WHO Guidelines and their relevance in international registration. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce.
7	Harmonization of regulatory requirements: Study of ICH common technical documents. Harmonization of Pharmacopoeial Standards. ICH, E7, E8 /Toxicological studies / Electronic Records – Signature CID.
8	Regulatory considerations of Pre-clinical and clinical evaluations with special reference to legislation and guidelines of good clinical practice in US, European community and Japan.
9	Introduction to Drug and Medical Device Regulation. Food, drug and medical device laws.

Subject of Specialization Paper – V -Practical

Subject Name: Drug Regulation and Regulatory Authority

Sr. No.	Course Content
1	Preparation of regulatory compliance checklist tabulating cGMP requirements as per 21 CFR 210 and 211.
2	Preparation of global list of documents for registration of IND, NDA,
3	ANDA as per ICH CTD format.
4	Preparation of Annual report for regulatory on approved ANDA
5	Case studies on response with scientific rationale to USFDA Warning
6	Letter
7	Preparation of an IMPD for EU submission.
8	Preparation of a Clinical Trial Protocol for submission to Regulatory.
9	Preparation of regulatory compliance requirements for BA/BE study.
10	Preparation and documentation for Indian Patent.
11	Patent challenge / non infringement (Para IV) case studies.
12	Preparation of Annual Product Quality Review (APQR).
13	Preparation of Periodic Safety Update Report (PSUR).
14	Comparison of key GMP requirements of India, US, EU and Japan of a dosage form
15	Comparison of Clinical Trial Application Requirements of India, US, EU and Japan of a dosage form.
16	Fast track approval in different countries considering different class of drugs (e.g. Anti HIV and anticancer), therapeutic area (rare diseases) etc.
17	Annotated side by side comparison of labels, Prescribing Information and Patient Information Leaflet.
18	Preparation of generic product registration application as per Association of South East Asian Nations [ASEAN] CTD (ACTD)
19	Preparation of a marketing authorization application for OTC, homeopathic and Herbal Medicinal Product.

Reference Books:

• The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
• Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh
• FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
• Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.