GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL REGULATORY AFFAIRS

SEMESTER: II

Subject Name: REGULATORY ASPECTS OF DRUGS & COSMETICS
Subject Code: MRA201T

Scope: This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives: Upon completion of this course the student should be able to

1. process of drug discovery and development and generic product development
2. Regulatory approval process and registration procedures for API and drug products inUS, EU
3. Cosmetics regulations in regulated and semi-regulated countries
4. A comparative study of India with other global regulated markets

Sr No	Course Contents	Total Hrs
1	USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA/ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada	12
2	European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia	12
3	Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in	12

	Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	
4	Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	12
5	Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries	12

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer,MarcelDekkerseries,Vol.143
2. The Pharmaceutical Regulatory Process, Edited byIra R. Berry Marcel DekkerSeries,Vol.144
3. The Pharmaceutical RegulatoryProcess, Second Edition Editedby Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185InformaHealthcarePublishers
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc.
6. Drugs: From Discovery to Approval, Second Edition By RickNg
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. PinesandGary H. Slatko
9. Preparation and Maintenance of the IND Application in Ectd Format By William K.Sietsema
10. Country Specific Guidelines from official websites
11. .http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications,Singapore2005,ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, LevFreinkman
16. The world Bank,Washington,DC,ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M.Abbott, Graham Dukes, Maurice Nelson Graham Dukes
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN byLindaLow andLorraine CarlosS alazar(Nov 22,2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert PressISBN:13:978-1-60649-108-9

20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South eastasianstudies,Singapore