

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (REGULATORY AFFAIRS)
SEMESTER	2
COURSE TITLE	REGULATORY ASPECTS OF DRUGS & COSMETIC
COURSE CODE	13MR0201
COURSE CREDITS	4

Objective:

- 1 This course is designed to impart fundamental knowledge on the drug development process, and 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 about the regulatory requirements, documentation requirements, and registration procedures for marketing drug products and cosmetics in regulated and semi-regulated countries.

Course Outcomes: After completion of this course, student will 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 in the US and EU.
- 3 Cosmetics regulations in regulated and semi-regulated countries.
- 4 A comparative study of India with other global regulated markets.

Pre-requisite of course:--

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
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

Contents : Unit	Topics	Contact Hours
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 the 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 the import, manufacture, distribution, and sale of cosmetics in the 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 Japan. Legislation and regulations for import, manufacture, distribution, and sale of cosmetics in Japan.	12
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 the prequalification program, 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
Total Hours		60

Textbook :

- 1 The Pharmaceutical Regulatory Process, Ira R. Berry, Marcel Dekker Series, Vol.144., 2004

References:

- 1 Generic Drug Product Development, Solid Oral Dosage forms, Generic Drug Product Development, Solid Oral Dosage forms, LeonShargel and Isader Kaufer, Marcel Dekker series, Vol.143., 2005
- 2 The Pharmaceutical Regulatory Process Second Edition , The Pharmaceutical Regulatory Process Second Edition , Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 , Informa Health care Publishers., 2019
- 3 New Drug Approval Process: Accelerating Global Registrations , New Drug Approval Process: Accelerating Global Registrations , by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190., 1987
- 4 Guidebook for drug regulatory submissions, Guidebook for drug regulatory submissions, Sandy Weinberg, By JohnWiley & Sons. Inc., 2009
- 5 Drugs: From Discovery to Approval, Second Edition , Drugs: From Discovery to Approval, Second Edition , by Rick Ng., By JohnWiley & Sons. Inc., 2004
- 6 New Drug Development: A Regulatory Overview, Eighth , New Drug Development: A Regulatory Overview, Eighth , by MarkMathieu, Parexel international , 2008
- 7 Pharmaceutical Risk Management , Pharmaceutical Risk Management , by Jeffrey E. Fetterman, Wayne L.Pines, and Gary H. Slatko., Food and Drug Law institute, 2008
- 8 Preparation and Maintenance of the IND Application in eCTD Format , Preparation and Maintenance of the IND Application in eCTD Format , byWilliam K. Sietsema., FDA, 2008
- 9 Country Specific Guidelines, Country Specific Guidelines, from, official websites, 2000
- 10 WHO good practices for pharmaceutical quality , WHO good practices for pharmaceutical quality , control , laboratories, 1999
- 11 Roadmap to an ASEAN economic community Edited , Roadmap to an ASEAN economic community Edited , by Denis Hew., ISEAS Publications, Singapore, 2005
- 12 ASEAN, Rodolfo C., ASEAN, Rodolfo C., Severino., ISEAS Publications, 2005
- 13 Building a Future with Brics: The Next Decade for Offshoring, Building a Future with Brics: The Next Decade for Offshoring, MarkKobayashi-Hillary, Springer, 2003
- 14 Outsourcing to India: The Offshore Advantage, Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade Performance and Regional Integration of the CISCountries., Lev Freinkman., 2004
- 15 The World Bank, The World Bank, Washington, DC, 2015
- 16 Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World , Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World , by Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes139., 2020
- 17 The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN, The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN, by Linda Low and Lorraine , Carlos Salazar , 2010
- 18 Doing Business in the Asian Countries, Doing Business in the Asian Countries, Balbir Bhasin, Business Expert Press, 2018
- 19 Realizing the ASEAN Economic Community: A Comprehensive Assessment., Realizing the ASEAN Economic Community: A Comprehensive Assessment., Michael G Plummer (Editor), Chia Siow Yue (Editor, Institute of South east Asian studies, 2009

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery

Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
10.00	20.00	25.00	25.00	10.00	10.00