Nirma University

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Regulatory Affairs)

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/ PW	T	C	Duration		Component Weightage		
							SEE	LPW/ PW	CE	LPW/ PW	SEE
1	MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA202T	Regulatory Aspects of Herbal & Biologicals	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA203T	Regulatory Aspects of Medical Devices	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA205P	Regulatory Affairs Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MRA206S	Seminar/Assignment-II	-	7	-	4	-	-	-	1.00	-
Total			**16**	**19**	**-**	**26**	-	-	-	-	-
			35								

L: Lectures, P/T: Practicals/Tutorial, C: Credits
LPW/PW: Laboratory / Project WorK
SEE: Semester End Examination
CE: Continuous Evaluation

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA201T**
Course Title	**Regulatory Aspects of Drugs and Cosmetics**

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 the course, the student shall be able to know -

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

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the basics of global regulatory requirements.
2. Describe the process of drug discovery, development and generic product development.
3. Explain the guidelines for registration and approval process for API, drug products (including orphan drugs) and cosmetics in US, Canada and EU.
4. Express the organization, legislations, regulations and registration procedures of PMDA.
5. Apply the knowledge of regulatory requirements for emerging market.
6. Compare the regulatory requirement for registration of drugs in Brazil, ASEAN, CIS and GCC countries.

Syllabus: **Teaching hours**: **60 Hours**

UNIT I **12 Hours**

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.

UNIT II **12 Hours**

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**.**

UNIT III **12 Hours**

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.

UNIT IV **12 Hours**

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).

UNIT V **12 Hours**

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.

Suggested Readings^: (Latest edition)

1. Shargel, L., & Kanfer, I. *Generic drug product development: solid oral dosage forms*. CRC Press.
2. Ira, Berry, *The Pharmaceutical Regulatory Process*, Marcel Dekker Series, Vol 144.
3. Ira, Berry. & Robert, Martin. *The Pharmaceutical Regulatory Process, Drugs and the pharmaceutical sciences*, Vol.185. Informa Healthcare Publishers.
4. Richard, G. *New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences*, Vol.190.
5. Weinberg, S. *Guidebook for Drug Regulatory Submissions*. John Wiley & Sons.
6. Ng, R. Drugs: F*rom discovery to approval*. John Wiley & Sons.
7. Mathieu, M. P., Keeney, R., & Milne, C. P. *New drug development: a regulatory overview*. Parexel International Corp.
8. Jeffrey, F., Wayne, Pines & Gary, H. *Pharmaceutical Risk Management.*
9. William, K. *Preparation and Maintenance of the IND Application in eCTD Format.*
10. http://www.pmda.go.jp/english
11. http://www.fda.gov
12. http://portal.anvisa.gov.br/wps/portal/anvisa-ingles
13. http://www.ema.europa.eu
14. Country Specific Guidelines from official websites
15. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
16. Denis, H. *Roadmap to an ASEAN economic community*. ISEAS Publications, Singapore , ISBN981-230-347-2
17. Rodolfo, S. *ASEAN*. ISEAS Publications, Singapore, ISBN 978-981-230-750-7
18. Kobayashi-Hillary, M. *Building a future with BRICS: the next decade for offshoring* (Vol. 4643). Springer Science & Business Media.

19. Kobayashi-Hillary, M. *Outsourcing to India: The offshore advantage*. Springer Science & Business Media.
20. *The world Bank*, Washington, DC, ISBN: 0-8212-5896-0.
21. Abbott, F. M., Dukes, M. N. G., & Dukes, G. *Global pharmaceutical policy: ensuring medicines for tomorrow's world*. Edward Elgar Publishing.
22. Low, L., & Salazar, L. C. *The Gulf Cooperation Council: a rising power and lessons for ASEAN* (No. 12). Institute of Southeast Asian Studies.
23. Bhasin, B. *Doing business in the ASEAN countries*. Business Expert Press.
24. Plummer, M. G., & Yue, C. S. *Realizing the ASEAN economic community: A comprehensive assessment. Institute of Southeast Asian Studies*.

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^ this is not an exhaustive list

(M. Pharm - Regulatory Affairs)

(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA202T**
Course Title	**Regulatory Aspects of Herbal and Biologicals**

Scope:

This course is designed to impart fundamental knowledge on regulatory requirements, licensing and registration, regulation on labelling of biologics in India, USA and Europe. It prepares the students to learn in detail on regulatory requirements for biologics, vaccines and blood products.

Objectives:

Upon the completion of the course the student shall be able to -

1. Know the regulatory requirements for biologics and vaccines.
2. Understand the regulation for newly developed biologics and biosimilars.
3. Know the pre-clinical and clinical development considerations of biologics.
4. Understand the regulatory requirements of blood and/or its components including blood products and label requirements.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the requirement of similar biologics from development to market authorization in India.
2. Discuss the regulatory requirements for the biosimilars in US and EU.

3. Know preclinical and clinical development of biologics.
4. Apply knowledge of regulatory aspects of vaccines, blood products and biological products in India, US and EU.
5. Compare quality, safety, and legislation for herbal products in India, US and EU.

Syllabus: **Teaching hours**: **60 Hours**

UNIT I **12 Hours**

India :

Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT II **12 Hours**

USA:

Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

UNIT III **12 Hours**

European Union:

Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

UNIT IV **12 Hours**

Vaccine regulations in India, US and European Union:

Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network).

UNIT V **12 Hours**

Herbal Products:

Quality, safety and legislation for herbal products in India, USA and European Union.

Suggested Readings^: (Latest edition)

1. Pisano, D. J., & Mantus, D. S. *FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics*. Taylor & Francis US.
2. Wang, W., & Singh, M. *Biological drug products: development and strategies*. John Wiley & Sons.
3. Singh , M. ,Srivastava, I. *Development of Vaccines: From Discovery to Clinical Testing*, Wiley.
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India.*
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)
12. www.ayush.gov.in

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA203T**
Course Title	**Regulatory Aspects of Medical Devices**

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know -

1. Basics of medical devices and IVDs, process of development, ethical and quality considerations.
2. Harmonization initiatives for approval and marketing of medical devices and IVDs.
3. Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
4. Clinical evaluation and investigation of medical devices and IVDs.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the definition, classification and principles of medical devices and IVDs.
2. Describe the principle of ethics in clinical investigations of medical devices.
3. Explain the quality system regulations and ISO certification for medical devices.
4. Report regulatory approval process for medical device in US and EU.
5. Apply the knowledge of regulatory approval process for medical device in ASEAN, China and Japan.

Syllabus: **Teaching hours**: **60 Hours**

UNIT I **12 Hours**

Medical Devices:

Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF:

Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT II **12 Hours**

Ethics:

Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011).

Quality: Quality System Regulations of Medical Devices:

ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.

UNIT III **12 Hours**

USA:

Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT IV **12 Hours**

European Union:

Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

UNIT V **12 Hours**

ASEAN, China & Japan:

Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.

IMDRF study groups and guidance documents.

Suggested Readings^: (Latest edition)

1. Pisano, D. J., & Mantus, D. S. *FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics*. Taylor & Francis US.
2. Kahan, J. S. *Medical Device Development: A Regulatory Overvie.*
3. Tobin, J. J., & Walsh, G. *Medical product regulatory affairs: pharmaceuticals, diagnostics, medical devices*. John Wiley & Sons.
4. Medina, C. *Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics*. CRC Press.
5. Country Specific Guidelines from official websites.
6. http://www.pmda.go.jp/english
7. http://www.fda.gov
8. http://www.ema.europa.eu
9. www.iso.org
10. www.eng.sfda.gov.cn
11. www.asean.org

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA204T**
Course Title	**Regulatory Aspects of Food & Nutraceuticals**

Scope:

This course is designed to impart the fundamental knowledge on regulatory requirements, registration and labeling regulations of nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on regulatory aspects for nutraceuticals and food supplements.

Objectives:

Upon completion of the course, the student shall be able to -

1. Know the regulatory requirements for nutraceuticals.
2. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the terminologies for food and nutraceuticals.
2. Discuss the guidelines and GMPs for nutraceuticals.
3. Explain regulations for food safety and nutraceuticals in India.
4. Report regulations for food safety and nutraceuticals in US.

5. Apply the knowledge of food safety and nutraceuticals in EU.

Syllabus: **Teaching hours**: **60 Hours**

UNIT I **12 Hours**

Nutraceuticals:

Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT II **12 Hours**

Global Aspects:

WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT III **12 Hours**

India:

Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT IV **12 Hours**

USA:

US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S.

UNIT V **12 Hours**

European Union:

European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.

Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

Suggested Readings^: (Latest edition)

1. Hasler, C. M. *Regulation of functional foods and nutraceuticals: a global perspective* (Vol. 5). John Wiley & Sons.
2. Bagchi, D. *Nutraceutical and functional food regulations in the United States and around the world*. Academic press.
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf

5. Pathak, Y. V. *Handbook of Nutraceuticals Volume II: Scale-Up, Processing and Automation* (Vol. 2). CRC Press.
6. Fortin, N. D. *Food regulation: law, science, policy, and practice*. John Wiley & Sons.
7. Country Specific Guidelines from official websites
8. www.cdsco.nic.in
9. www.fda.gov
10. www.ema.europa.eu
11. www.who.int
12. www.nsf.org

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
-	-	12	6

Course Code	**MRA205P**
Course Title	**Regulatory Affairs Practical II**

Syllabus: **Teaching hours**: **180 Hours**

1. Case studies on change management/ change control deviations and Corrective & Preventive Actions (CAPA).
2. Documentation of raw materials analysis as per official monographs.
3. Preparation of audit checklist for various agencies.
4. Preparation of submission to FDA using eCTD software.
5. Preparation of submission to EMA using eCTD software.
6. Preparation of submission to MHRA using eCTD software.
7. Preparation of Biologics License Applications (BLA).
8. Preparation of documents required for Vaccine Product Approval.
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products.
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization.
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization.
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization.
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization.
15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization.
16. Checklists for 510k and PMA for US market.

17. Checklist for CE marking for various classes of devices for EU.
18. STED Application for Class III Devices.
19. Audit Checklist for Medical Device Facility.
20. Clinical Investigation Plan for Medical Devices.

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