INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (REGULATORY AFFAIRS)**
SEMESTER	**2**
COURSE TITLE	**REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS**
COURSE CODE	**13MR0202**
COURSE CREDITS	**4**

Objective:

1 This course is designed to impart fundamental knowledge on RegulatoryRequirements, Licensing and Registration, and Regulation on the Labelling of Biologicsin India, USA, and Europe. It prepares the students to learn in detail about Regulatory Requirements forbiologics, Vaccines, and Blood Products.

Course Outcomes: After completion of this course, student will be able to:

1 Know the regulatory Requirements for Biologics and Vaccines.

2 Understand the regulation of newly developed biologics andbiosimilars.

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.

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	**India** Introduction, Applicable Regulations and Guidelines,Principles for Development of Similar Biologics, DataRequirements for Preclinical Studies, Data Requirements forClinical Trial Application, Data Requirements for MarketAuthorization Application, Post-Market Data for Similar Biologics,Pharmacovigilance, GMP and GDP.	12

DR. MAUSAMI CHANDRAKANTBHAI VAGHELA
Digitally signed by (Name of HOD)

DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)

Contents : Unit	Topics	Contact Hours
2	**USA** Introduction to Biologics; biologics, biological andbiosimilars, different biological products, difference betweengeneric drug and biosimilars, laws, regulations and guidance onbiologics/ biosimilars, development and approval of biologics andbiosimilars (IND, PMA, BLA, NDA, 510(k)), pre-clinical and clinical development considerations, advertising, labeling and packing of biologics.	12
3	**European Union** Introduction to Biologics; directives, scientificguidelines, and guidance related to biologics in EU, comparability/ bio-similarity assessment, Plasma master file, TSE/ BSEevaluation, development and regulatory approval of biologics(Investigational medicinal products and biosimilars), pre-clinicaland clinical development considerations; stability, safety,advertising, labeling and packing of biologics in EU.	12
4	**Vaccine regulations in India, US, and European Union** Clinicalevaluation, Marketing authorization, Registration or licensing,Quality assessment, Pharmacovigilance, and Additional requirementsBlood and Blood Products Regulations in India, US, and EuropeanUnion: Regulatory Requirements of Blood and/or Its ComponentsIncluding Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (InternationalHaemovigilence Network).	12
5	**Herbal Products** Quality, safety, and legislation for herbalproducts in India, USA, and European Union.	12
Total Hours		**60**

Textbook :

1 Biological Drug Products: Development and Strategies, Wei Wang, Manmohan Singh, Wiley, 2013

References:

1 FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus, Informa, 2008

2 Development of Vaccines: From Discovery to Clinical Testing, Development of Vaccines: From Discovery to Clinical Testing, Manmohan Singh, Indresh K. Srivastava, Wiley, 2011

3 Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India., Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India., Government of India, CDSCO, 2016

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

Supplementary Resources:

1 www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/.
2 www.ihn-org.com.
3 www.isbtweb.org.
4 www.cdsco.nic.in.
5 www.ema.europa.eu › scientific guidelines › Biologicals.
6 www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics).

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