GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL REGULATORY AFFAIRS

SEMESTER: II

Subject Name: REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS
Subject Code: MRA202T

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 completion of this course the student should 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

Sr No	Course Contents	Total Hrs
1	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	12
2	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	12
3	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	12
4	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)	12
5	Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union	12

REFERENCES:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, DouglasJ.Pisano, DavidS. Mantus;Informa,2008
2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh ;wiley,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh,IndreshK.Srivastava;Wiley,2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInfo rmation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization inIndia
9. www.cdsco.nic.in
10. .www.ema.europa.eu ›scientificguidelines ›Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)