DCOP

Subjectwise Course Outcome - [Pharmaceutical Regulatory Affairs - 2023-24]

Second Semester	
Regulatory aspects of food and neutraceuticals [Theory | Regular]	
CO ID.	**Course Outcome**
CO 1	To study the context of food and nutraceutical regulations
CO 2	To comprehend WHO guidelines on nutrition & dietary supplement
CO 3	To recognizethe regulatory Requirements for nutraceuticals in
CO 4	To Understand the regulation for registration and labeling of nutraceuticals and food supplements in USA
CO 5	To analyze the regulatory requirement of nutraceutical in Europe
Regulatory aspects of Herbal & Biologicals [Theory | Regular]	
CO ID.	**Course Outcome**
CO1	Know the regulatory Requirements for Biologics and Vaccines
CO2	Understand the regulation for newly developed biologics and biosimilars
CO3	Know the pre-clinical and clinical development considerations of biologics
CO4	Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements
Regulatory affairs practicals-II [Practical | Regular]	
CO ID.	**Course Outcome**
CO1	This course is designed to impart fundamental knowledge on studies on Change Management/ Change control. Deviations, Corrective & Preventive Actions (CAPA) , Documentation of raw materials analysis as per official monographs, Preparation of audit checklist for various agencies , Preparation of submission to FDA using eCTD software , Preparation of submission to EMA using eCTD software , Preparation of submission to MHRA using eCTD software, Preparation of Biologics License Applications (BLA),Preparation of documents required for Vaccine Product Approval, Comparison of clinical trial application requirements of US, EU and India of Biologics.
CO2	This course is designed to impart fundamental knowledge of Preparation of Checklist for Registration of Blood and Blood Products, Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization, Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization, Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization, Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization, Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization, Checklists for 510k and PMA for US market, Checklist for CE marking for various classes of devices for EU, STED Application for Class III Devices , Audit Checklist for Medical Device Facility, Clinical Investigation Plan for Medical Devices
MRA 201 T Regulatory aspects of Drug and cosmetics [Theory | Regular]	
CO ID.	**Course Outcome**
CO1	Process of drug discovery and development and generic product development
CO2	Regulatory approval process and registration procedures for API and drug products in US, EU
CO3	Cosmetics regulations in regulated and semi-regulated countries
CO4	A comparative study of India with other global regulated markets
MRA 203 T Regulatory aspects of medical devices [Theory | Regular]	

CO ID.	Course Outcome
CO 1	CO1: Know the basics of medical devices and IVDs, process of development, ethical and quality considerations.
CO 2	CO 2: Know Harmonization initiatives for approval and marketing of medical devices and IVDs.
CO 3	CO 3: Understand regulatory approval process for medical devices and IVDs in China, Japan and ASEAN countries.
CO 4	CO 4: Know clinical evaluation and investigation of medical devices and IVDs.