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Geethanjali

Geethanjali College of Pharmacy

Approved by AICTE, PCI New Delhi, Permanently Affiliated to JNTUH & B. Pharmacy Accredited by NBA
Recognized Under UGC Section 2F & 12B of UGC Act, 1956, by DSIR-SIRO & HI/BI of MSME, Certified by ISO 9001:2015
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PROGRAM: M. PHARMACY (PHARMACEUTICAL REGULATORYAFFAIRS)

BATCH (2019-2021) REGULATION R19

COURSE OUTCOMES WITH KNOWLEDGE LEVEL & ITSRELEVANCE TO PROGRAM OUTCOMES

Program: Master of Pharmacy (PHARMACEUTICAL REGULATORY AFFAIRS)/ First Year/ I Semester					
Course Name	**Code**	**Course Outcome No**	**CO Statement**	**Knowledge Level**	**Relevance to PO's**
Drug regulatory affairs	M.PR/R19 C112	C112.1	Discuss the rationale behind regulatory requirements and ways and means of complying with them in India.	K4	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C112.2	Point out the important aspects of GMP.	K4	
		C112.3	List various laws, legislation and guidance related to safety, efficacy ethical conduct and regulatory approval of drugs in USA & Brazil.	K4	
		C112.4	Handle documentation and general principles involved in regulatory writing and submission to agencies.	K4	
		C112.5	Organize the submission of Drug Master Files to regulatory authorities as per their specific requirements in USA, Europe and Canada.	K4	

Intellectual property rights	M.PR/R19 C113	C113.1	Differentiate types of intellectual properties (IPs) and their roles in contributing to organizational competitiveness.	K4	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10
		C113.2	Identify activities and constitute IP infringements and the remedies available to the IP owner and describe the precautious steps to be taken to prevent infringement of	K4	

			proprietary rights in productsand technology development.		PO11
		C113.3	List the impact of International Treaties / Conventions related to IPR.	K4	
		C113.4	Discuss the applicationprocedure of patent in USA & EU.	K4	
		C113.5	Identify the claims in a given document and draft it.	K4	
Drug regulation and writing	M.PR/R19 C118	C118.1	Discuss the types of documents in pharmaceuticalindustry.	K4	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C118.2	Organize the modules of dossier preparation and CTD submission.	K4	
		C118.3	List the basics of internal and external audits& focus on ISO standards and guidelines on audits.	K4	
		C118.4	Structure the inspection systems in pharmaceutical companies and follow up actions.	K4	
		C118.5	Prioritize the regulatory aspects of product life-cycle management and product recalls.	K4	
Good regulatory practice	M.PR/R19 C111	C111.1	Analyze Current good manufacturing practices introduction to cGMP part 210 and part 211 WHO c GMP guideline ,Global Harmonization Task Force Guidance docs	K4	PO1 PO3 PO4 PO6 PO7 PO9 PO10 PO11
		C111.2	Survey Introduction to USFDA good laboratory practice regulation inspection process documentation audits future regulations quality Council of India standards	K4	

		C111.3	Award Good automated laboratory practice introduction principles requirements sop's training documentation checklist software evaluation checklist element ISO and QCI standards	K5	
		C111.4	Determine Good distribution practice introduction requirements principles documentation process and equipments delivery to customer return self inspection stability testing elemental CDSCO guidance and ISO standards	K5	
		C111.5	Evaluate Quality management system concept of quality, quality by design Six Sigma concept out of specification validations type of validation, validation master plan analytical method validation heat ventilation and air conditioning and cleaning validation ICH guidelines to establish the quality safety efficacy of drug substances on product and CDSCO regulatory guidance document	K5	
Value education	M.PR/R19 C1115	C1115.1	Understand human values, their significance and role in life.	K3	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C1115.2	Promote self-reflection and critical inquiry that foster critical thinking of one's valueand the values of others.	K3	
		C1115.3	Practice respect for human rights and democratic principles.	K3	
		C1115.4	Emerge as responsible citizens with clear conviction to practice values and ethics in life.	K3	

		C1115.5	Develop the overall personality.	K3	
Drug regulation and registration lab	M.PR/R19 C1111	C1111.1	Motivate Case study on Change management change control deviation and corrective and preventive action. Import of drugs for research and development development activity .GMP audit requirement as per CDSCO	K4	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C1111.2	Classify preparation of checklist for registration of IND as per ICH CTD formatPreparation of checklist for registration of NDA as per ICH CTD formatPreparation of checklist for registration of NDA as per ICH CTD format	K4	
		C1111.3	Comparative study of DMF system in US ,Europe and JapanPreparation of regulatory submission using e CTD software	K5	
		C1111.4	Estimate Documentation of raw materials analysis as per official monographs Preparation of audit checklist for various agencies	K5	
		C1111.5	Determine Preparation of the submission to FDA using e CTD softwarePreparation of submission to EMA using e CTD softwarePreparation of submission to MHRA using e CTD software	K5	
Regulatory practice and documention lab	M.PR/R19 C1110	C1110.1	Categorise Introduction on Good Pharmaceutical Practices, Case study: Facilities and equipment system, Case study: Packaging and labelling system ,Case study: Production system, Case	K4	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8

			study: Laboratory system,		PO9 PO10 PO11
		C1110.2	Analyze Regulatory Documentation in Pharmaceutical industry, Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.	K4	
		C1110.3	Criteria Preparation of Standard Operating Procedures , Preparation of analytical report ,preparation of BMR MFR ,DR labeling comparison between brand &generics ,preapartion of regulatory dossier as per Indian CTD format	K5	
		C1110.4	Influence Submission in Sugamsystem of CDSCO , USFDA Warning Letter Case study 1 and 2 on Response with scientific rationale to USFDA warning letter Preparation of submission checklist of IMPD for EU	K5	
		C1110.5	Importance submission Study of marketing authorization procedures in EU ,ISO:13485:-Medical devices - Quality management systems ,ISO : 31000:- Quality Risk Management	K5	
Research methodology &IPR	MPR/R19. C119	C119.1	Select the meaning of research problem , source of research problem ,criteria characteristics of a good research problem .errors in selecting a research problem, data collection, analysis, interpretation ,necessary	K3	PO3 PO9 PO10 PO11

			instruments		
		C119.2	Develop effective literature studies approaches, analysis, plagiarism, research ethics	K3	
		C119.3	organize effective technical writing, how to write report, paper developing a research proposal, format of research proposal ,a presentation and assessment by review committee	K3	
		C119.4	Construct the nature ofintellectual propriety ,process of patenting and development international scenario international co operation on IP .patenting under PCT.	K3	
		C119.5	Identify patent rights new development in IPR and administration in IPR, tradition knowledge case study IPR AND IIT'S.	K3	
M. Pharmacy/ First Year/ II Semester					
Regulatory aspects of herbals biologics	MPR/R19C122	C122.1	Explain the regulations & guidelines, principles for development of similar biologics & data requirements for preclinical studies, clinical trial application, market authorization application & pharmacovigilance, GMP & GDP	K1	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C122.2	Summarize the introduction to biologics; biologics, biological& biosimilars, different biological products, difference between generic drug &biosimilars, laws, regulations& guidance on biologics/biosimilars, development & approval of biologics, preclinical & clinical development considerations,	K2	

			advertising, labeling & packingof biologics		
		C122.3	Illustrate the introduction to biologics; derivatives, scientific guidelines & guidance related to biologics in EU, comparability/ biosimilarity assessment, plasma master file,TSE/BSE evaluation, development & regulatory approval of biologics, preclinical & clinical development considerations; stability, safety, advertising, labeling & packing of biologicsin EU	K4	
		C122.4	Describe Vaccine regulations in India, US & European union: clinical evaluation, marketing authorization, registration or licensing, quality assessment, pharmacovigilance, additional requirements blood & blood products regulations in India, US & European union: regulatory requirements of blood or its components including blood products, label requirements, ISBT & IHN	K1	
		C122.5	Summarize Quality, safety & legislation for herbal products in India, US & European union.	K2	
Regulatory aspects of medical devices	MPR/R19C121	C121.1	Group the basics of medical devices and IVDs, process of development, ethical and quality considerations.	K3	PO1 PO3 PO4 PO6 PO7 PO9 PO10 PO11
		C121.2	Present the quality system regulations and quality risk management of medical devices.	K3	
		C121.3	Classify the medical devices and IVDs regulations in USA.	K3	

		C121.4	Summarize the medical devicesand IVDs directives in European Union.	K3	
		C121.5	Explain the regulatory approval process for medical devices and IVDs in China, Japanand ASEAN countries and Understand organizational structure, regulatory guidelines and functions of IMDRF/GHTF.	K3	
Regulatory aspects of neutraceuticals	MPR/R19C123	C123.1	Campare Nutraceuticals introduction history of food and nutraceuticals regulation meaning of nutraceuticals dietary supplements functional foods medical for scope and opportunities in nutraceutical market	K4	PO1 PO3 PO4 PO6 PO7 PO8 PO9 PO10 PO11
		C123.2	List Global aspects WHO guidelines on nutrition and international its role in dietary supplements and nutraceuticals industries certification and Standards for food and dietary supplements good manufacturing practices for nutraceuticals	K4	
		C123.3	Conclude India food safety and Standards act and Standards Authority of India organisation and functions regulations for important manufacture and sale of nutraceutical products in India vitamin dietary allowance in India	K5	
		C123.4	Determine USA food safety modernization act dietary supplement health and Education Act US regulation for manufacture and sale of nutraceuticals and dietary supplements labelling requirements and label claims	K5	

			and dietary supplements recommended dietary allowance in USA		
		C123.5	Explain European Union European food safety authorityorganisation and functions youEuropean directives and regulations for manufacturing and sale of nutraceuticals and dietary supplements nutrition labelling European regulationson novel food and normal foodingredients recommended dietary allowance in Europe	K5	
Regulatory aspects of herbals biologics lab	MPR/R19C129	C129.1	Demonstrate biological license applications(BLA) & documents required for vaccineproduct approval	K3	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C129.2	Make use of clinical trial application requirements of US, EU, & INDIA of biologics	K3	
		C129.3	Identify the checklist for registration of blood & blood products	K3	
		C129.4	Analyze registration requirement comparison study in 5 emerging markets (WHO, BRICS, CHINA & SOUTH COREA, ASEAN & GCC) & preparing checklist for market authorization	K4	
		C129.5	Construct document required for the approval of herbal products of diverse dosage forms (3 products) as per regulations requirements	K3	
Regulatory aspects of medical devices lab	MPR/R19C1210	C1210.1	GMP of medical devices and quality requirements	K4	PO1 PO3 PO4 PO6 PO7
		C1210.2	Checklist for 510K and PMAfor US market	K4	

		C1210.3	Clinical investigation of medical devices: regulations of investigational medical devices	K4	PO9 PO10 PO11
		C1210.4	Check list for CE marking for various classes of devices forEU	K4	
		C1210.5	Audit checklist for medical device facility	K4	
Clinical research and pharmacovigilance	MPR/R19C126	C126.1	Explain the regulatory requirements for conducting clinical trails	K2	PO1 PO3 PO4 PO6 PO7 PO8 PO9 PO10 PO11
		C126.2	Classify the types of clinical trial designs	K3	
		C126.3	Discuss the responsibilities of key players involved in clinical trials	K2	
		C126.4	Explain the priniciples of pharmacovigilance	K2	
		C126.5	Give examples adverse drug reactions and their management	K2	
Disaster management	MPR/R19C1113	C1113.1	Understand key concepts of disasters and its relationships with development and disaster prone areas in India.	KL 3	
		C1113.2	Explain repercussions of disasters and hazards.	KL 3	
		C1113.3	Promote prevention and preparedness for disaster.	KL 3	
		C1113.4	Understand the techniques of risk reduction	KL 3	
		C1113.5	Enhance awareness of disaster risk management and build skills to respond to disasters.	KL 3	
M. Pharmacy/ Second Year/ I Semester					
Audits& regulatory compliance	MPR/R19C218	C218.1	Discuss briefly about audit objectivesand their management.	KL 4	PO1 PO3 PO4 PO6
		C218.2	Understand the role of quality systems and audits in pharmaceutical	KL 4	

			manufacturing environment.		PO7 PO9 PO10 PO11
		C218.3	Prepare checklist of auditing of vendors and production department.	KL 4	
		C218.4	Organize the auditing of a microbiological laboratory.	KL 4	
		C218.5	List the basics of auditing various engineering systems in a manufacturing plant.	KL 4	
Pharmaceutic al production technology	MPR/R19.C 213	C213.1	Summarize Pilot plant scale-up techniques used in pharmaceutical manufacturing	K3	PO1 PO2 PO3 PO4 PO5 PO6 PO7 PO8 PO9 PO10 PO11
		C213.2	Elaborate formulation development of parenteral dosage forms.	K5	
		C213.3	Elaborate about formulation, manufacture and quality control of pharmaceutical aerosols.	K5	
		C213.4	Classify cosmetics and nutraceuticals based on preparation, manufacturing aspects, specific properties and prevention.	K4	
		C213.5	Distinguish the principles of Aseptic processing operations.	K4	