Gyanmanjari Innovative University

Course Syllabus

Gyanmanjari Pharmacy College

Semester-7 (B. Pharm)

Subject: Industrial Pharmacy-II (BPHBP17334)

Type of course: Major

Prerequisite: B. Pharmacy

Rationale: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
				Theory Marks		Practical Marks		CA	
CI	T	P	C	ESE	MSE	V	P	ALA	
3	1	-	4	75	25	-	-	50	150

Legends: CI-Classroom Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

Course Content:

Chapter No.	Course content	Hrs	% Weightage
1.	**Pilot plant scales up techniques:** General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	10	25
2.	**Technology development and transfer:** WHguideO lines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipment, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies,	10	25

	Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues		
3.	**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies	10	25
4.	**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	08	15
5.	**Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	07	10

Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1.	**Pilot Plant Scale-Up Flow Diagram** The Faculty will assign students to prepare a stepwise flow diagram for the scale-up of any dosage form (tablet/liquid/semi-solid), including key considerations and documentation, and submit it on the GMIU Web portal.	10
2.	**Technology Transfer Case Study** Faculty will assign za case study on technology transfer from R&D to production, including protocol, risks, and challenges. Students will analyze the case study and submit it on the GMIU Web portal.	10
3.	**Regulatory Approval Process Chart** The Faculty will assign students to prepare a chart showing the drug approval process (IND, NDA, clinical trials) along with the roles of regulatory authorities and submit it on the GMIU Web portal.	10
4.	**Quality Management System Report** The Faculty will assign students to prepare a report on quality concepts such as QbD, Six Sigma, ISO standards, and OOS with applications in the pharmaceutical industry and submit it on the GMIU Web portal.	10

5.	**Indian Regulatory Framework Assignment** **The Faculty will assign** students to explain the structure and role of CDSCO and state authorities, along with drug approval procedures in India, and submit the assignment on the GMIU Web portal.	10
	Total	50

Suggested Specification table with Marks

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	**Remembrance (R)**	**Understanding (U)**	**Applicatio n (A)**	**Analyze (N)**	**Evaluat e (E)**	**Create (C)**
Weightage	15%	30%	25%	15%	10%	05%

Course Outcome:

After learning the course, the students should be able to:	
CO1	Understand pilot plant scale-up techniques and related documentation.
CO2	Explain technology transfer process, protocols and regulatory requirements.
CO3	Describe drug approval process, clinical studies and regulatory affairs roles.
CO4	Analyze quality management systems including QbD, ISO and Six Sigma.
CO5	Understand Indian regulatory framework including CDSCO and drug approval procedures.

Instructional Method:

The course delivery method will depend upon the requirement of content and the need of students. The teacher, in addition to the conventional teaching method by blackboard, may also use any of the tools such as demonstration, role play, quiz, brainstorming, MOOCs, etc. From the content, 10% topics are suggested for flipped mode instruction. Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory. The internal evaluation will be done on the basis of Active Learning Assignment. Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.

Reference Books:

[1] Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http, //en.wikipedia.org/wiki/Regulatory_ Affairs

[2] International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php

[3] Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition

[4] Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.