Subject Description Form

Subject Code	ABCT5102
Subject Title	Pharmacology and Toxicology inBiotherapeutics
Credit Value	3
Level	5
Pre-requisite	Nil
Co-requisite	Nil
Exclusion	Nil
Objectives	1. Equip students with a comprehensive understanding of modern pharmacology, emphasizing the distinctions and integrations between traditional drug development and biopharmaceutical innovations. 2. Offer a deep dive into the entire drug development pipeline, from initial discovery and clinical trials to final market approval, emphasizing regulatory, quality control, and manufacturing challenges. 3. Foster expertise in biopharmaceutical expression systems, manufacturing processes, and downstream processing, ensuring students grasp the intricacies of biopharmaceutical production from gene expression to drug delivery. 4. Provide insights into the clinical implications of drug development, covering topics like immunogenicity, personalized medicine, and advanced cell therapies, preparing students for future innovations in the field. 5. Through case studies and practical examples, ensure students can apply theoretical knowledge to real-world scenarios, understanding the challenges and successes in drug and biopharmaceutical development.
Intended Learning Outcomes	Upon completion of the subject, students will be able to: a) demonstrate a thorough understanding of both traditional pharmacology and the innovations in biopharmaceuticals, bridging foundational concepts with modern advancements. b) recognize the key concepts of drug development, from pharmacokinetics to regulatory approval, showcasing their ability to navigate the complexities of drug and biopharmaceutical development in real-world contexts. c) possess the ability to critically evaluate the challenges and implications of immunogenicity in biologics, toxicological concerns, and the advancements in cell and stem cell therapies. d) demonstrate a clear understanding of the regulatory landscape from IND applications to market entry, paired with insights into analytical strategies, quality control, and assurance in drug development. e) apply the knowledge on personalized medicine and pharmacogenomics,

	students will be prepared to anticipate and contribute to the future directions of pharmacology, ensuring their readiness for the evolving landscape of drug development and therapeutics.
Subject Synopsis/ Indicative Syllabus	**1. Introduction to Pharmacology:** - Exploring pharmacology's scope and significance. - Branches and roles in modern medicine. - The trajectory of drug discovery. **2. Pharmacokinetics (ADME):** - Grasping pharmacokinetics fundamentals. - Processes of absorption, distribution, metabolism, and excretion. - ADME's impact on drug efficacy. **3. Immunogenicity and Toxicology in Biologics:** - Delving into biologics and immunogenicity challenges. - Toxicological concerns and their implications. - Case-based exploration of biologic mysteries. **4. IND-Enabling and Drug Approval Process:** - Traversing the regulatory landscape. - Clinical trial phases and the New Drug Application. - Regulatory checks and balances. **5. Biopharmaceutical Expression, Manufacturing, and Downstream Processing:** - From biopharmaceutical expression to production. - Manufacturing intricacies and challenges. - Ensuring biopharmaceutical quality. **6. Analytical Strategies and Quality Control & Assurance:** - Role of analytical strategies in drug development. - Quality control versus assurance. - The tenets of Good Manufacturing Practices. **7. Advanced Cell and Stem Cell Therapies:** - Potential of cell therapies in medicine. - Insights into stem cell treatments. - Future horizons in cellular therapeutics. **8. Overview of Clinical Trial Phases:** - The realm of clinical trials. - Objectives and outcomes of trial phases. **9. Personalized Medicine and Pharmacogenomics:** - The revolution of personalized medicine. - Genetics in drug responses. - The promise of tailored treatments.
Teaching/Learning Methodology	Lectures, tutorial, written assignments presentations, examination 1. Presentation –Students are assigned specific topics related to pharmacology. They delve deeply into these subjects, conducting independent research, and

then present their findings. This exercise not only allows the presenting students to gain a deeper understanding of their assigned topic but also enriches the listeners with insights that extend beyond regular lectures.

2. Attendance – Students are expected to attend at least 80% of both the lecture and tutorial classes.

3. Written Assignments – Students will be asked to write an essay on a selected topic. They will be assessed on their understanding of the topic's content. In their essays, students must also express their own opinions to demonstrate their problem-solving skills and critical thinking abilities.

4. Final Examination - Written exams assess how much students have learned about the concepts of modern pharmacology and drug development, as well as the challenges and successes in drug and biopharmaceutical development. Writing skills will be assessed in all the assessment methods.

Assessment Methods in Alignment with Intended Learning Outcomes

Specific assessment methods/tasks	% (weighting)	Intended subject learning outcomes to be assessed (Please tick as appropriate)				
		a	b	c	d	e
1. Attendance	10		√		√	
2. Presentation	25	√	√	√		√
3. Written Assignments	20	√		√	√	√
4. Final Examination	45	√			√	
Total	100 %					

Explanation of the appropriateness of the assessment methods in assessing the intended learning outcomes:

Students are allowed to use GenAI tools to support their writing of and essays. If GenAI tools are used to support their essay writings, students must declare the use of such tools and how they have been used in the assessments. It should be noted that submitting a work generated by GenAI, in part or in whole, as your own (even in paraphrased form) constitutes an act of academic dishonesty; it is no different from asking another person to write your assignment or claiming others' ideas as yours.

Student Study Effort Expected

Class contact:	
▪ Lecture	26 Hrs.
▪ Tutorial	13 Hrs.
Other student study effort:	

	▪ Assignment and presentation	15 Hrs.
	▪ Self study	63 Hrs.
	Total student study effort	117 Hrs
Reading List and References	1. Katzung, B. (2021). Basic & Clinical Pharmacology (15th ed.). McGraw-Hill. ISBN: 9781260452310. 2. Stine, K. E., & Brown, T. M. (2015). Principle of toxicology (3rd ed.). ISBN: 9781466503427. 3. Di, L. (2016). Drug-like properties: Concepts, structure design, and methods from ADME to toxicity optimization (2nd ed.). Elsevier. ISBN: 0128010762.	