Syllabus
Third Semester Courses in
MSc
Biotechnology
(2024-2025)

Contents:

APPROVED SYLLABUS

ST. XAVIER'S COLLEGE AUTONOMOUS MUMBAI 400 001

PRINCIPAL
ST. XAVIER'S COLLEGE
AUTONOMOUS
MUMBAI - 400 001.

MSc II Biotechnology	
Course Title: CLINICAL DRUG DEVELOPMENT Course Code: PSBTY6501EL1	
Credits 4: (Theory and Practical) 60 hr. **COLLABORATOR:** ***Tata Consultancy Services*- under the TCS-driven Academic Interface programme (under MOU)**	
No.	**Course Objectives** **The industry oriented and curated course aims to provide the learners with the following**
	• Gain a deep understanding of the domains in drug development process, from early-stage clinical research to Clinical data management. • Gain insights into the process of drug safety surveillance and its documentation process. • Regulatory Proficiency by attaining knowledge about regulatory affairs and in navigating the complex regulatory landscape governing pharmaceuticals and biotechnology. • Learn the importance of ethical considerations, and data integrity in clinical research. • Acquire practical skills and knowledge directly applicable to careers in pharmaceutical companies, clinical research organizations (CROs) and regulatory bodies

CO	Course Outcomes *On completing the course, the learner will be able to*	Bloom's Taxonomy Level (BT level)
1	Comprehend about the domains involved in Clinical Research. Understand and demonstrate proficiency in the fundamental principles and techniques of clinical data management.	Remembering, Understanding
2	Comprehend important aspects of pharmacovigilance, and gain a deep understanding of the regulatory framework governing pharmaceuticals and healthcare products	Understanding Applying, Evaluating
3	Implement data collection tools and ensure data accuracy and integrity throughout the trial	Applying, Analyzing, Evaluating
4	Implement the technical writing skills in creating compliant documents for diverse scientific needs in the pharmaceutical industry.	Applying, Analyzing, Creating

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UNIT I		**Introduction to Clinical Drug Development**	**(15)**
	1.	Overview of Drug Discovery & Development , Overview of Clinical Research .	
	2.	Overview of Clinical Trial Process	
	3.	Overview of GxP guidelines; Overview of Ethical considerations and ICH GCP Guidelines .	
UNIT II		**Clinical Data Management**	**(15)**
	1.	Overview of Clinical Data Management	
	2.	Clinical Database programming and Management Plan	
	3.	Medical Coding Dictionaries and other tools for CDM	
UNIT III		**Pharmacovigilance and Regulatory Affairs**	**(18)**
	1.	Overview to Pharmacovigilance	
	2.	Overview to Regulatory Authorities and Regulations	
	3.	Adverse events and reporting methods.	
	4.	ICH guidelines	
	5.	Global Regulatory requirements	
UNIT IV		**Communication Formats**	**(12)**
	1.	Essentials in communication of complex data	
	2.	Scientific Communication formats	
	3.	Formats of Clinical trial documents	
	4.	Ethical practices in medical writing	

List of Recommended resources :

- Centre, U. M. (n.d.). *WHODrug global*. Uppsala Monitoring Centre | UMC. https://who-umc.org/whodrug/whodrug-global/
- *ClinicalTrials.gov*. (n.d.). ClinicalTrials.gov. https://clinicaltrials.gov/study-basics/glossary
- *Comisión federal para la Protección contra Riesgos Sanitarios | Gobierno | gob.mx*. (n.d.). El portal único del gobierno. | gob.mx. https://www.gob.mx/cofepris/en

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- *Data management in clinical research: An overview*. (2012, March). PubMed Central (PMC). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3326906/
- *GCDMP©*. (n.d.). Society for Clinical Data Management (SCDM). https://scdm.org/gcdmp/
- Good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf. (n.d.). In *https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf*.
- Health Canada. (2022, May 2). *Pharmaceutical drugs directorate*. Canada.ca. https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/therapeutic-products-directorate.html
- *Home*. (n.d.). CDSCO. https://cdsco.gov.in/opencms/opencms/en/Home/
- *Homepage*. (n.d.). European Medicines Agency. https://www.ema.europa.eu/en/homepage
- *ICH official web site : ICH*. (n.d.). ICH Official web site : ICH. https://www.ich.org/page/efficacy-guidelines
- (n.d.). MedDRA. https://www.meddra.org/
- (2023, September 26). U.S. Food and Drug Administration. https://www.fda.gov/

Evaluation (PSBTY6501EL1): Total marks per course – 100.

- Formative Assessment 'for' Learning.
  CIA- 40 marks (Project assignment)
- Summative Assessment 'of' Learning
  End Semester Examination – 60 marks.
  One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

Distribution of Bloom's Taxonomy levels for the course assessment

Learning Levels	Remembering	Understanding	Analyzing and Application	Evaluation And creation
*Percentage	NA	30-35%	40-45%	20-30%

Course Title: APPLICATIONS OF INFORMATICS IN BIOTECHNOLOGY

Course Code: PSBTY6501ELI

Credits 4: Theory 30 hrs and Practical 30 hrs

No.	Course Objectives	
1.	The course aims to familiarize learners with the applications of informatics in various domains of Biotechnology.	
CO	**Course Outcomes** **On completing the course, the learner will be able to**	**Bloom's Taxonomy Level (BT level)**
1	Gain proficiency in using informatics tools and software applications relevant to immunological research	Understanding, Applying
2	Apply the principles of vaccine design and be able to apply informatics approaches to identify potential vaccine candidates, predict antigenic epitopes, and assess vaccine efficacy.	Understanding, Applying
3	Develop proficiency in using bioinformatics tools and software applications relevant to plant biology research	Applying
4	Gain a thorough understanding of the principles and concepts of nutrigenomics, including the interaction between nutrients and genes, and the impact of individual genetic variations on nutrient metabolism, absorption, and utilization.	Analyzing
5	Proficient in applications of AI and ML in healthcare settings, including disease diagnosis, medical imaging analysis, drug discovery, personalized treatment planning, predictive analytics, and health monitoring.	Analyzing Evaluating, Creating

MSc II BIOTECHNOLOGY		
Course Title: APPLICATIONS OF INFORMATICS IN BIOTECHNOLOGY **Course Code: PSBTY6501ELI**		
Credits 4: Theory 30 hrs and Practical 30 hrs		
No.	**Course Objectives**	
1.	The course aims to familiarize learners with the applications of informatics in various domains of Biotechnology.	
CO	**Course Outcomes** **On completing the course, the learner will be able to**	**Bloom's Taxonomy Level (BT level)**
1	Gain proficiency in using informatics tools and software applications relevant to immunological research	Understanding, Applying
2	Apply the principles of vaccine design and be able to apply informatics approaches to identify potential vaccine candidates, predict antigenic epitopes, and assess vaccine efficacy.	Understanding, Applying
3	Develop proficiency in using bioinformatics tools and software applications relevant to plant biology research	Applying
4	Gain a thorough understanding of the principles and concepts of nutrigenomics, including the interaction between nutrients and genes, and the impact of individual genetic variations on nutrient metabolism, absorption, and utilization.	Analyzing
5	Proficient in applications of AI and ML in healthcare settings, including disease diagnosis, medical imaging analysis, drug discovery, personalized treatment planning, predictive analytics, and health monitoring.	Analyzing Evaluating, Creating

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UNIT I		**Data Resources for Immunoinformatics**	**16(T+P)**
	1.	Basic concept of immunology - Types of immunity, cells of immune system, epitope, paratope, Antigenicity, allergenicity	
	2.	Concept of Immunoinformatics, current trends in Immunoinformatics	
	3.	Immunological databases - Antibody databases, Allergenic Databases, Pathogen antibody databases, Monoclonal antibody databases, organism / pathogen specific immunology databases, Epitope databases, IMGT, IEDB, Databases related to molecule evolution of immune gene and proteins and other related resources.	
	4.	Computational tools in Immunoinformatics - Online tools for analysis of gene, and proteome data related to immune system.	
	5.	Immunomics - concept and applications	
UNIT II		**Vaccine Designing**	**16 (T+P)**
	1.	Epitope prediction - T and B cell	
	2.	Epitope analysis	
	3.	Allergenicity prediction	
	4.	Computational vaccine designing - Epitope prediction, docking, population coverage studies, Mapping of Vaccine Construct, Codon optimization and In Silico Cloning, Immune simulation, MD simulation.	
	5.	Structural studies - Antigen and antibody structural studies, modelling, and interaction studies	
	6.	Practical case studies on vaccine designing.	
UNIT III		**Plant Bioinformatics**	**14 (T+P)**
	1.	Bioinformatics databases and tools for plant biotechnology. Bioinformatics for plant breeding - examples - Rice, Maize. Bioinformatics for studying stress resistance in plants, Bioinformatics approaches to study resistance to plant pathogen (Case studies)	
	2.	Network pharmacology and applications - Network Biology to Network Pharmacology, Network Ethnopharmacology, Network pharmacology common databases network construction, case studies and applications.	

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	3.	Nutrigenetics and Nutrigenomics: Concept of nutrigenetics, Nutrient- gene interactions, Nutrigenomics, Nutraceuticals, Natural bioactive compounds	
	4.	Biodiversity informatics: Biodiversity informatics: Concepts, practices, and challenges, Indian Biodiversity Information System (IBIS), Global Biodiversity Information Facility, Biodiversity Information Management, India Biodiversity Portal	
UNIT IV		**ML and AI in Biotechnology**	**14 (T+P)**
	1.	AI and ML concepts and models	
	2.	Overview of applications in biological sciences and biotechnology	
	3.	AI in Agricultural Biotechnology - AI-based algorithms in the agricultural sector	
	4.	Health Informatics • AI in medical Biotechnology - AI in disease detection, Framework for AI in disease detection modelling, medical imaging for diseases diagnosis • AI in disease monitoring • AI and ML in Drug discovery - ML and AI in drug discovery, Role of ML in Predicting Drug Efficacy and Toxicity, Case Studies of Successful AI-Aided Drug Discovery, Challenges and Limitations	

Reference Books:

1. Edwards, D. (Ed.). (2008). *Plant bioinformatics: methods and protocols* (Vol. 406). Springer Science & Business Media.
2. Flower, D. R. (Ed.). (2008). *Immunoinformatics: Predicting immunogenicity in silico* (Vol. 409). Springer Science & Business Media.
3. Krane, D. E. (2002). *Fundamental concepts of bioinformatics*. Pearson Education India.
4. Pevsner, J. (2015). *Bioinformatics and functional genomics*. John Wiley & Sons.
5. Tomar, N. (Ed.). (2020). *Immunoinformatics*. Humana Press.
6. Yang, Z. R. (2010). *Machine learning approaches to bioinformatics* (Vol. 4). World scientific.

Research Articles:

1. Bhardwaj, A., Kishore, S., & Pandey, D. K. (2022). Artificial intelligence in biological sciences. Life, 12(9), 1430.
2. Blanco-Gonzalez, A., Cabezon, A., Seco-Gonzalez, A., Conde-Torres, D., Antelo-Riveiro, P., Pineiro, A., & Garcia-Fandino, R. (2023). The role of ai in drug discovery: challenges, opportunities, and strategies. Pharmaceuticals, 16(6), 891.
3. Chandran, U., Mehendale, N., Patil, S., Chaguturu, R., & Patwardhan, B. (2017). Network pharmacology. Innovative approaches in drug discovery, 127.
4. Hopkins, A. L. (2008). Network pharmacology: the next paradigm in drug discovery. Nature chemical biology, 4(11), 682-690.
5. Johnson N. F. (2007). Biodiversity informatics. Annual review of entomology, 52, 421–438. https://doi.org/10.1146/annurev.ento.52.110405.091259
6. Noor, F., Tahir ul Qamar, M., Ashfaq, U. A., Albutti, A., Alwashmi, A. S., & Aljasir, M. A. (2022). Network pharmacology approach for medicinal plants: review and assessment. Pharmaceuticals, 15(5), 572.
7. Oli, A. N., Obialor, W. O., Ifeanyichukwu, M. O., Odimegwu, D. C., Okoyeh, J. N., Emechebe, G. O., & Ibeanu, G. C. (2020). Immunoinformatics and vaccine development: an overview. ImmunoTargets and therapy, 13-30.
8. Thomas, S., Abraham, A., Baldwin, J., Piplani, S., & Petrovsky, N. (2022). Artificial intelligence in vaccine and drug design. Vaccine Design: Methods and Protocols, Volume 1. Vaccines for Human Diseases, 131-146.

Evaluation (PSBTY6502EL1):
Total marks per course – 100.

- Formative Assessment 'for' Learning (continuous internal assessment - CIA to improve learning).
  CIA- 40 marks (Mini Project/ Assignment)
- Summative Assessment 'of' Learning (focus on outcomes, quantitative data for outcomes of instruction).
  End Semester Examination – 60 marks.
  One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

Distribution of Bloom's Taxonomy levels for the course assessment

Learning Levels	Remembering	Understanding	Analyzing and Application	Evaluation	Creation
*Percentage	10%	25-35%	20-25%	15-20%	10-15%

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