ANNA UNIVERSITY, CHENNAI

NON- AUTONOMOUS COLLEGES

AFFILIATED TO ANNA UNIVERSITY

M. TECH., PHARMACEUTICAL BIOTECHNOLOGY

REGULATIONS 2025

PROGRAMME OUTCOMES (POs):

PO	Programme Outcomes
PO1	An ability to independently carry out research /investigation and development work to solve practical problems
PO2	An ability to write and present a substantial technical report/document.
PO3	Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

PROGRAMME SPECIFIC OUTCOMES(PSOs):

PSO	Programme Specific Outcomes
PSO1	Design and optimize therapeutic proteins, monoclonal antibodies, vaccines, and gene-based products using molecular biology and protein engineering.
PSO2	Apply bioprocess engineering and regulatory standards for scalable, GMP-compliant biologics manufacturing.

ANNA UNIVERSITY, CHENNAI

POST GRADUATE CURRICULUM (NON.AUTONOMOUS AFFILIATED INSTITUTIONS)

Programme: M. Tech., Pharmaceutical Biotechnology **Regulations:** 2025

Abbreviations:

BS – Basic Science (Mathematics)
ES – Engineering Science (General (**G**), Programme Core (**PC**), Programme Elective (**PE**))
SD – Skill Development
SL – Self Learning
OE – Open Elective

L – Laboratory Course
T – Theory
LIT – Laboratory Integrated Theory
PW – Project Work
TCP – Total Contact Period(s)

Semester I

S. No.	Course Code	Course Title	Type	Periods per week			TCP	Credits	Category
				L	T	P			
1.	PB25101	Bioprocess Engineering and Fermentation Technology	T	3	0	0	3	3	ES (PC)
2.	PB25102	Techniques in Pharmaceutical Biotechnology	T	3	0	0	3	3	ES (PC)
3.	PB25103	Protein and Protein Formulations	LIT	3	0	2	5	4	ES (PC)
4.	PB25104	Advanced Analytical Techniques	LIT	3	0	2	5	4	ES (PC)
5.	PB25105	Biotherapeutic Drug Delivery Systems	T	3	0	0	3	3	ES (PC)
6.	PB25106	Biomaterials and Tissue Engineering	T	3	0	0	3	3	ES (PC)
7.	PB25107	Technical Seminar	-	0	0	2	2	1	SD
Total Credits							**24**	**21**	

Semester II

S. No.	Course Code	Course Title	Type	Periods per week			TCP	Credits	Category
				L	T	P			
1.		Process Analytical Technology	T	3	0	0	3	3	ES (PC)
2.		Immunopharmacology	LIT	3	0	2	5	4	ES (PC)
3.		Programme Elective I	T	3	0	0	3	3	ES (PE)
4.		Industry Oriented Course I	T	1	0	0	1	1	SD
5.		3D Bioprinting and Organoid Engineering	T	4	0	0	4	4	ES (PC)
6.		Cell and Gene Therapy	T	4	0	0	4	4	ES (PC)
7.		Virtual Laboratory– Bioinformatics and Computational Biology	T	0	0	4	4	2	ES (PC)
8.		Self Learning Course	--	-	-	-	-	1	-
9.		Industrial Training#	L	---	---	---	---	---	SD
Total Credits							**24**	**22**	

Evaluation will be done in third semester for the summer internship.

Semester – III

S. No.	Course Code	Course Title	Type	Periods per week			TCP	Credits	Category
				L	T	P			
THEORY									
1.		Programme Elective II	T	3	0	0	3	3	ES (PE)
2.		Programme Elective III	T	3	0	0	3	3	ES (PE)
3.		Programme Elective IV	T	3	0	0	3	3	ES (PE)
4.		Open Elective	T	3	0	0	3	3	-
5.		Project Work I	---	0	0	12	12	6	SD
6.		Industry Oriented Course II	T	1	0	0	1	1	ES (PC)
7.		Industrial Training# (Evaluation)	-	---	---	---	---	2	SD
Total Credits							**25**	**21**	

Semester IV

S. No.	Course Code	Course Title	Type	Periods per week			TCP	Credits	Category
				L	T	P			
1.		Project Work II	---	0	0	24	24	12	SD
Total Credits							**24**	**12**	

Programme Elective Courses

S. No.	Course Code	Course Title	Periods			Total Contact Periods	Credits
			L	T	P		
1.		Clinical Biostatistics	3	0	0	3	3
2.		Research Methodology and IPR	3	0	0	3	3
3.		Biopharma Entrepreneurship and Innovation Management	3	0	0	3	3
4.		Clinical Trials and Bioethics	3	0	0	3	3
5.		Pharmaceutical Quality by Design (QbD)	3	0	0	3	3
6.		Biogenerics and Biopharmaceuticals	3	0	0	3	3
7.		Computational Biology and Network Pharmacology	3	0	0	3	3
8.		Nanobiotechnology	3	0	0	3	3
9.		Sterile Dosage Forms and Aseptic Processing	3	0	0	3	3
10.		Vaccine Technology and Formulation Science	3	0	0	3	3
11.		AI in Drug Discovery and Precision Medicine	3	0	0	3	3
12.		IoT in Biomanufacturing and Cold Chain Monitoring	3	0	0	3	3
13.		3D Bioprinting and Organoid Engineering	3	0	0	3	3
14.		Biosensors	3	0	0	3	3
15.		Biomedical Devices and Regulatory Affairs	3	0	0	3	3

Semester I

PB25101	Bioprocess Engineering and Fermentation Technology	L	T	P	C
		3	0	0	3

Course Objective:

The objective of this course is to provide students with an integrated foundation in bioprocess engineering, covering the essential principles of fermentation technology, microbial kinetics, bioreactor design and scale-up, and recombinant plant and animal cell culture systems. The course also emphasizes downstream processing techniques and their application in the industrial-scale production of pharmaceuticals, enzymes, and metabolites, thereby preparing students for advanced study and careers in biotechnology and biopharmaceutical industries.

Course Contents: Fermenter components, peripheral parts, accessories; control systems and sensors. Bioreactor classification and selection; control parameters; ideal reactor design. Batch, flow, and multiple reactors; non-ideal flow, RTD studies, modeling. Design and operation of CSTF, fed-batch, air-lift, and fluidized bed bioreactors. Scale-up strategies.

Bioreactor applications in pharmaceuticals and therapeutic protein production. Microbial growth kinetics in batch, continuous, and fed-batch cultures. Specific growth rate, doubling time, growth yield, metabolic quotient. Stoichiometry, carbon-nitrogen balance, redox principles, product formation.

Activity: Bioprocess Product Pitch, Virtual Bioreactor model.

Isolation, screening, and maintenance of industrial microbes. Strain improvement via mutation and genetic recombination. Directed screening for metabolic variants. Industrial strain development strategies.

Structured models for metabolism and growth. Gene expression and regulation modeling. Plasmid replication, genetic instability in recombinant systems. Host-vector interaction prediction. Process considerations: media optimization, aeration for recombinant strains.

Activity: Isolate and screen suitable microbe.

Bioreactor systems for plant and animal cell cultures. Cell immobilization and tissue culture. Monoclonal antibody production. Bioreactor design for production of therapeutic proteins and industrial recombinant applications.

Activity: Hands on practice towards design of bioreactor.

Fermentation product recovery and purification. Pretreatment, cell separation (centrifugation, filtration, clarification), removal of HCPs and viral proteins, viral inactivation. Modern techniques: electrophoresis, chromatography, ultrafiltration, reverse osmosis, cross-flow, microfiltration, isoelectric focusing, affinity separations. Production of ethanol, citric acid, lactic acid, antibiotics, vitamins, insulin, growth hormones, amylase, protease, lipase. Industrial fermentation case studies.

Activity: Conduct industrial case studies

Weightage: Continuous Assessment: 40%, End Semester Examinations: 60%

Assessment Methodology: Quiz (20%), Assignments (30%), Internal Examinations (50%)

References:

1. Carlson, R., & Morrissey, K. (2024). *Bioprocess engineering principles*. Elsevier.
2. Aguilar-López, R. (2024). *Fermentation processes: Modeling, optimization and control*. MDPI.
3. Singh, S. P., & Upadhyay, S. K. (2023). *Microbial bioreactors for industrial molecules*. Wiley.
4. Upadhyay, S. K., & Singh, S. P. (2023). *Plants as bioreactors for industrial molecules*. Wiley.
5. Saini, P., & Yadav, N. (2024). *Food and industrial bioprocessing*. Elsevier.
6. Bailey, J. E., & Ollis, D. F. (1986). *Biochemical engineering fundamentals*. McGraw-Hill International.
7. Freshney, R. I. (2021). *Culture of animal cells: A manual of basic technique and specialized applications*. Wiley-Blackwell.
8. Harrison, R. G., Todd, P. W., Rudge, S. R., & Petrides, D. P. (2015). *Bioseparations science and engineering*. Oxford University Press.
9. Shuler, M. L., & Kargi, F. (2017). *Bioprocess engineering: Basic concepts*, International. Pearson Education.
10. Waites, M. J., Morgan, N. L., Rockey, J. S., & Higton, G. (2009). *Industrial microbiology and biotechnology*. CRC Press.

	Description of CO	**PO**	**PSO1**	**PSO2**
CO1:	Design and operate batch, fed-batch, and continuous bioreactors for various applications.	PO1(3), PO2(2)	3	2
CO2:	Apply microbial growth kinetics to optimize fermentation processes.	PO3(1), PO2(2)	2	2
CO3:	Use genetic and metabolic engineering to improve industrial strains.	PO1(1), PO3(2)	2	1
CO4:	Design effective product recovery and purification methods for fermentation products.	PO3(3)	2	3

PB25102	Techniques in Pharmaceutical Biotechnology	L	T	P	C
		3	0	0	3

Course Objective:

- This course aims to enlighten students with key molecular biology and genetic engineering techniques and their practical applications in current biological research.

Course Contents: Core tools, Restriction enzymes, ligases, polymerases, Cloning Vectors: plasmids, phages, cosmids, BAC, YAC, Expression vectors, prokaryotic, PET based, yeast, baculovirus, mammalian and plant-based vectors.

Promoters, enhancers, RBS, terminators, fusion tags (e.g., His-tag, MBP, SUMO, GFP), Advances in vector design, inducible vectors, CRISPR-compatible systems. Host organisms for cloning and expression.

Activity: Vector Design & Mapping

Nuclease protection assays, Nuclease S1 mapping, Reporter assays, Mono and dual reporter assays, Electrophoretic mobility shift assay (EMSA) / Gel shift assay, Run-off transcription assay, Phage display, Ribosome display, Gene silencing, siRNAs and Morpholinos.

Activity: Quantify promoter strength

Introduction, Principles, Next generation sequencing, Sequencing Technologies, Illumina (Solexa) Sequencing, Roche 454, Ion Torrent Sequencing, Pacific Biosciences (PacBio), Oxford Nanopore Technologies (ONT), Sample preparation and library construction, DNA/RNA extraction, Fragmentation Vs Tagmentation, End repair and A-tailing, Adapter ligation, PCR amplification (Bridge and Emulsion PCR) and library enrichment, Applications of NGS.

Activity: NGS Technology "Speed Dating" or Poster Session

Gene expression and its significance. Hybridization techniques -Southern and Northern Blotting. PCR based methods: Reverse transcriptase PCR, Endpoint Vs Real time PCR (qPCR), digital PCR. High throughput expression approaches: Multiplex PCR, Microarray, Serial analysis of gene expression (SAGE) and Small Amplified RNA-SAGE (SAR-SAGE), Total analysis of gene expression (TOGA) and Ribosome profiling.

Activity: Simulate industrial models with examples

Basics and applications of genome editing methods, Zinc-finger nuclease (ZFN), Transcription activator-like effector nucleases (TALEN), Mega nucleases, CRISPR-Cas systems, Types and applications, Transposons and Cre/loxP systems.

Weightage: Continuous Assessment: 40%, End Semester Examinations: 60%

Assessment Methodology: Quiz (20%), Assignments (30%), Internal Examinations (50%)

References:

1. Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010). *Molecular biotechnology: Principles & applications of recombinant DNA*. ASM Press.
2. Head, S. R., Ordoukhanian, P., & Salomon, D. R. (Eds.). (2017). *Next generation sequencing: Methods and protocols*. Humana Press, Springer Science+Business Media, LLC.
3. Nalini, R., & Garcia-Reyero, N. (2018). *Gene expression analysis: Methods and protocols*. Humana Press.
4. Appasani, K. (2018). *Genome editing and engineering: From TALENs, ZFNs and CRISPRs to molecular surgery*. Cambridge University Press.
5. Green, M. R., & Sambrook, J. (2012). *Molecular cloning: A laboratory manual*. Cold Spring Harbor Laboratory Press.
6. Primrose, S. B., & Twyman, R. (2013). *Principles of gene manipulation and genomics*. Wiley-Blackwell.

	Description of CO	**PO**	**PSO1**	**PSO2**
CO1	Create and map vectors with promoters, enhancers, and fusion tags for gene expression.	PO1 (3), PO2(2),	2	1
CO2	Use techniques like qPCR and NGS for gene expression analysis.	PO1 (3), PO2(2), PO4(2)	3	2
CO3	Understand and utilize NGS platforms for genetic analysis.	PO1 (3), PO2(2), PO4(2)	1	2
CO4	Implement tools like CRISPR and ZFNs for gene modification in research and applications.	PO1 (3), PO2(2), PO4(2)	1	3

PB25103	Protein and Protein Formulations	L	T	P	C
		3	0	2	4

Course Objective:

- To provide advanced knowledge and hands-on training in the design, development, and characterization of protein and peptide drug formulations.

Course Contents:

Overview of therapeutic proteins and peptides: structure–activity relationship, Preformulation studies - solubility, isoelectric point, aggregation, denaturation, and degradation, Importance of pH, temperature, ionic strength, and surface interactions, Determination of Critical Quality Attributes (CQAs) for protein-based drugs.

Practical Experiments:

1. UV-Vis Spectroscopy for protein quantification
2. SDS-PAGE for purity assessment
3. HPLC for degradation product profiling
4. Thermal stress testing using water bath and cold storage

Functions of excipients, buffers, surfactants, sugars, amino acids, Stabilizers, cytoprotectants, cryoprotectants, antioxidants, Interaction studies and compatibility mapping, Excipients for aggregation inhibition and protein adsorption prevention

Practical Experiments:

1. Preparation of protein solutions with various excipient ratios
2. Turbidity/solubility assays
3. Differential Scanning Calorimetry (DSC) or Thermogravimetric Analysis (TGA)
4. Visual and colorimetric aggregation studies

Delivery challenges, enzymatic degradation, absorption barriers, Nanoparticles, liposomes, micelles, hydrogels, PEGylation, Fc-fusion proteins, protein conjugation, Delivery routes, parenteral, nasal, pulmonary, oral.

Practical Experiments:

1. Synthesis of protein-loaded PLGA nanoparticles
2. Zeta potential and particle size analysis
3. PEGylation of BSA or insulin and SDS-PAGE analysis
4. Nasal delivery simulation in ex-vivo models

Lyophilization principles and cycle design, Spray drying, spray freeze-drying, vacuum foam drying, Moisture content analysis, residual water evaluation, Impact of drying on structure and bioactivity

Practical Experiments:

1. Reconstitution study: time, clarity, pH
2. Moisture analysis via Karl Fischer titration or gravimetric method
3. Cake morphology observation using stereomicroscopy
4. Lyophilization of a protein formulation using a bench-top lyophilizer

Regulatory framework, ICH Q5C, Q6B, WHO, EMA, USFDA, Biosimilarity, comparability studies, and clinical immunogenicity, Analytical tools - ELISA, CE-SDS, FTIR, SE-HPLC, DSC, Stability-indicating assay design and degradation profiling.

Practical Experiments:

1. Potency testing using ELISA
2. Protein degradation profiling under oxidative/light stress
3. Quantification using SE-HPLC
4. QC parameters assessment and protocol documentation

Weightage: Continuous Assessment: 50%, End Semester Examinations: 50%

Assessment Methodology: Quiz (5%), Assignments (20%), Flipped Class (5%), Practical (30%), Internal Examinations (40%)

References:

1. Pearlman, R., & Wang, Y. J. (Eds.). (2002). *Formulation, characterization, and stability of protein drugs: Case histories*. Springer. https://doi.org/10.1007/b112935
2. Crommelin, D. J. A., Sindelar, R. D., & Meibohm, B. (Eds.). (2019). *Pharmaceutical biotechnology: Fundamentals and applications*. Springer. https://doi.org/10.1007/978-3-030-00710-2
3. Thompson, J. D., Ueffing, M., & Schaeffer-Reiss, C. (Eds.). (2008). *Functional proteomics: Methods and protocols*. Humana Press. https://doi.org/10.1007/978-1-59745-398-1
4. Middaugh, C. R., & Pearlman, R. (1999). Proteins as drugs: Analysis, formulation and delivery. In D. L. Oxender & L. E. Post (Eds.), *Novel therapeutics from modern biotechnology* (Handbook of Experimental Pharmacology, Vol. 137, pp. 145–194). Springer. https://doi.org/10.1007/978-3-642-59990-3_3
5. International Council for Harmonisation. (1995). *ICH Q5C: Stability testing of biotechnological/biological products*. https://database.ich.org/sites/default/files/Q5C%20Guideline.pdf
6. *Remington: The science and practice of pharmacy* (23rd ed.). (2020). Elsevier. https://www.sciencedirect.com/book/9780128200070/remington
7. Wang, W. (2005). Protein aggregation and its inhibition in biopharmaceutics. *International Journal of Pharmaceutics, 289*(1–2), 1–30. https://doi.org/10.1016/j.ijpharm.2004.11.014
8. Wang, Y. J., & Pearlman, R. (2002). *Formulation, characterization, and stability of protein drugs*. Springer. https://doi.org/10.1007/b112935

	Description of CO	PO	PSO1	PSO2
CO1	Develop stable and effective protein and peptide drug formulations.	PO1 (3), PO2(2),	2	1
CO2	Assess stability, degradation, and bioactivity of protein drugs.	PO1 (3), PO2(2), PO4(2)	3	2
CO3	Create advanced protein delivery systems for enhanced bioavailability.	PO1 (3), PO2(2), PO4(2)	2	1
CO4	Perform regulatory-compliant tests for drug quality and safety.	PO1 (3), PO2(2), PO4(2)	1	1

PB25104	Advanced Analytical Techniques	L	T	P	C
		3	0	2	4

Course Objective:

- To facilitate the students to acquire knowledge about various advanced analytical techniques used in new drug development.

Origin, Introduction, Classifications of Chromatography; Principle, Instrumentation and Applications of Thin Layer Chromatography and HPTLC; Column Chromatography; High Performance Liquid Chromatography and UPLC; Gas Chromatography; Ion Exchange Chromatography and Affinity Chromatography; Columns Parameters and Interpretation of Chromatograms; Pharmaceutical and Biological Applications.

Activity: Chromatography – TLC spotting & Rf, HPLC demo & chromatogram interpretation, group discussion on techniques.

UV-Visible Spectroscopy, Theory, Instrumentation, Sample Handling and Interpretation of Spectra; Fluorimetry, Theory, Concepts of Singlet, Doublet and Triplet Electronic States; Internal and External Conversions; Factors Affecting Fluorescence, Quenching, Instrumentation and Applications. Infrared Spectroscopy, Theory, Instrumentation, Sample Handling and Interpretation of Spectra.

Activity: Chromatography – TLC spotting & Rf, HPLC demo & chromatogram interpretation, group discussion on techniques.

Nuclear Magnetic Resonance, Theory, Instrumentation, Sample Handling, Solvent Requirement, Chemical Shift, Spin-Spin Coupling, Coupling Constant, Nuclear Magnetic Double Resonance; Principles of ^{1}H-NMR and ^{13}C NMR; Pharmaceutical and Biological Applications; Interpretation of Spectra.

Activity: NMR – Simulate spectra, interpret 1H-NMR, solvent peak mapping, spin–spin coupling examples.

Mass Spectroscopy, Theory, Instrumentation; Ionization, Atmospheric Pressure Ionization, Chemical Ionisation, Electron Impact Ionisation, Fast Atom Bombardment, Matrix Assisted Laser Desorption Ionization, Time of Flight; Quadrupole Theory and Fragmentation; Pharmaceutical and Biological Applications; Interpretation of Mass Spectra.

Activity: Mass Spec – Demo fragmentation, peak-matching exercise, ionization methods comparison, case study in drug profiling.

Electrophoresis techniques: principles, instrumentation, working conditions, and factors affecting separation in gel electrophoresis, capillary electrophoresis, zone electrophoresis, and isoelectric focusing. Applications in pharmaceutical and biological systems.

Activity: Electrophoresis – Gel run demo, virtual CE, gel image interpretation, mobility factors assignment.

Radioimmunoassay and ELISA principles and applications. Analysis of host cell proteins and DNA in biopharmaceuticals. Viable cell analysis and energy metabolism measurement in live cells. Principle and instrumentation of metabolic analyzers.

Activity: RIA & ELISA – ELISA experiment, RIA demo, case study on diagnostics. Biopharma Analysis – UV A260/A280 check, discussion on host cell DNA/protein, cell viability assay note, metabolic analyzer case study. Integrated – Mini-project comparing two techniques, student seminars, weekly quiz.

Weightage: Continuous Assessment: 50%, End Semester Examinations: 50%

Assessment Methodology: Quiz (5%), Assignments (20%), Flipped Class (5%), Practical (30%), Internal Examinations (40%)

LIST OF EXPERIMENTS

Screening of drug molecules using the listed modern analytical instruments,

1. UV/Visible Spectroscopy
2. Fluorescence Spectroscopy
3. IR Spectroscopy
4. Nuclear Magnetic Resonance Spectroscopy
5. Mass Spectroscopy
6. Thin Layer Chromatography
7. High Performance Thin Layer Chromatography
8. Column Chromatography
9. High Performance Liquid Chromatography and UPLC
10. Gas Chromatography
11. Gel Electrophoresis
12. Capillary Electrophoresis
13. Radio Immunoassay
14. Enzyme Linked Immunosorbent Assay
15. Metabolic Analyzer

References:

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L. (2014). *Spectrometric identification of organic compounds*. John Wiley & Sons Inc.
2. Skoog, D. A., Holler, F. J., & Crouch, S. R. (2017). *Principles of instrumental analysis*. Cengage Learning.
3. Willard, H. H., Merritt, L. L., Dean, J. A., & Settle, F. A. (2004). *Instrumental methods of analysis*. CBS Publishers & Distributors.
4. Beckett, A. H., & Stenlake, J. B. (2007). *Practical pharmaceutical chemistry*, Part II). CBS Publishers & Distributors.
5. Kemp, W. (2022). *Organic spectroscopy*. Bloomsbury Publishing.
6. Munson, J. W. (1984). *Pharmaceutical analysis – Modern methods, Part B* (Vol. 11). CRC Press.
7. Dyer, J. R. (1984). *Applications of absorption spectroscopy of organic compounds*. CRC Press.

	Description of CO	PO	PSO1	PSO2
CO1	Explain the principles and applications of UV/Visible, Fluorimetry, IR, NMR, and Mass Spectroscopy in pharmaceutical analysis.	PO1(3), PO2(2),	2	1
CO2	Demonstrate proficiency in chromatographic, electrophoretic separations, and molecular assays for pharmaceutical analysis.	PO1(3), PO2(2), PO4(2)	3	2
CO3	Apply theoretical knowledge to develop and validate analytical methods in pharmaceutical research and quality control.	PO1(3), PO2(2), PO4(2)	2	1
CO4	Interpret analytical data from spectrometric and chromatographic techniques and engage in chemical and biological screening of pharmaceutical products.	PO1 (3), PO2(2), PO4(2)	1	1

PB25105	Biotherapeutics Drug Delivery Systems	L	T	P	C
		3	0	0	3

Course Objective:

- The objectives of the course is to learn advanced biotherapeutics delivery systems

Course Contents:

Classification of biologics: Peptides, proteins, monoclonal antibodies, nucleic acids, and cell-based products. Structure-function relationships and physicochemical properties. Stability challenges and common barriers to delivery including enzymatic degradation, immunogenicity, and poor permeability.

Monoclonal antibodies: Pharmacokinetics and therapeutic delivery strategies. Antibody-drug conjugates including radioimmunoconjugates, immunotoxins, and drug immunoconjugates. ADEPT (Antibody-Directed Enzyme Prodrug Therapy). Emerging strategies: intracellular delivery via protein transduction domains, liposomal carriers, antibody-mediated translocation, and novel intracellular targets.

Activity: Case studies on biologic stability and design antibody – drug conjugate

Vaccine delivery systems: Oral, single-shot, mucosal, and transdermal delivery. Role of delivery systems and absorption enhancers to improve vaccine uptake. Design considerations for enhancing immune response through novel delivery platforms.

Activity: Case studies on mucosal vaccine design and development

Gene therapy: Definition, scope, and therapeutic goals—gene replacement, silencing, and editing. Viral vectors (Adenovirus, AAV, Lentivirus, Retrovirus): structure, mechanism, advantages, and limitations. Non-viral vectors: liposomes, cationic polymers (PEI), dendrimers, and nanoparticles. Physiological barriers to gene delivery.

Activity: Design Nanoparticle to Overcome Delivery Barriers

Preformulation considerations for biologics: Physicochemical factors and key initial variables. Experimental design for early-stage preformulation studies. Requirements for novel parenteral formulations and delivery platforms.

Selection criteria for innovative delivery systems. Challenges in development and implementation. Strategies to overcome biological and technological barriers in advanced drug delivery of complex biotherapeutics.

Activity: Conduct preformulation stability investigation

Weightage: Continuous Assessment: 40%, End Semester Examinations: 60%

Assessment Methodology: Quiz (20%), Assignments (30%), Internal Examinations (50%)

References:

1. Wang, B., Siahaan, T., & Soltero, R. (2005). *Drug delivery: Principles and applications*. Wiley-Interscience.
2. Jørgensen, L., & Nielsen, H. (2021). *Delivery technologies for biopharmaceuticals*. Wiley.
3. Walsh, G. (2018). *Biopharmaceuticals: Biochemistry and biotechnology*. Wiley.

	Description of CO	**PO**	**PSO1**	**PSO2**
CO1	Understand and explain the challenges and opportunities in delivering biotherapeutics effectively.	PO1(3), PO2(2),	2	3
CO2	Describe and apply formulation strategies for antibody-based therapeutics, focusing on stability and efficacy.	PO1(3), PO2(2), PO4(2)	2	2
CO3	Evaluate and compare delivery technologies for vaccines and gene therapies, addressing their respective advantages and limitations.	PO1(3), PO2(2), PO4(2)	2	1
CO4	Analyze and interpret the latest trends in biotherapeutic product development, including innovations in formulation and delivery technologies.	PO1(3), PO2(2), PO4(2)	3	1

PB25106	Biomaterials and Tissue Engineering	L	T	P	C
		3	0	0	3

Course Objective:

- To introduce the fundamental principles of biomaterials and their interaction with biological systems. To impart understanding of tissue engineering concepts, including scaffolds, cells, and signalling mechanisms. To develop skills in designing materials for regenerative medicine and biomedical applications.

Definition, classification, and key properties of biomaterials—mechanical, surface, chemical, and biological. Concepts of biocompatibility and biodegradation. Applications in medical devices and implants. Overview of historical development and future directions.

Types of biomaterials: metallic (e.g., stainless steel, titanium alloys), polymeric (biodegradable and non-biodegradable), ceramic (bioinert, bioactive, resorbable), and composites. Biomaterial-based drug delivery systems and controlled release mechanisms.

Activity: Identify and categorize biomaterials in their everyday environment

Tissue engineering principles. Cell sources: stem cells, primary cells. Scaffolds—material selection, properties, and fabrication methods. Bioreactors and mechanical stimulation for tissue development. Host integration and vascularization.

Activity: Compare and Contrast – Cell Sources and Scaffold Materials

Engineering of tissues: skin, cartilage, bone, and blood vessels. Role of growth factors and gene therapy. Advances in 3D bioprinting and organoid technology. Clinical case studies and translational applications. Immunological challenges and ethical considerations.

Activity: Real-world applications and ethical considerations of tissue engineering by examining a clinical case.

Biomaterials testing: in vitro and in vivo methods. Sterilization techniques and packaging standards. Overview of regulatory frameworks and standards—ISO, FDA, CE.
Risk analysis and quality control in biomaterials development. Intellectual property, technology transfer, and commercialization strategies for medical biomaterial products.

Activity: Case studies on commercialization of biomaterials lab to market.

Weightage: Continuous Assessment: 40%, End Semester Examinations: 60%

Assessment Methodology: Quiz (20%), Assignments (30%), Internal Examinations (50%)

References:

1. Ratner, B. D., et al. (2020). *Biomaterials science: An introduction to materials in medicine* (4th ed.). Academic Press.
2. Palsson, B. O., & Bhatia, S. N. (2016). *Tissue engineering*. Pearson Education, Inc.

3. Ramalingam, M., et al. (2023). *Biomaterials and tissue engineering: Integration and regeneration* (2nd ed.). CRC Press.
4. Pal, S. (2022). *Fundamentals of biomedical engineering* (2nd ed.). PHI Learning.
5. Park, J. B., & Bronzino, J. D. (2021). *Biomaterials: Principles and applications* (4th ed.). CRC Press.
6. Lanza, R., Langer, R., & Vacanti, J. (2020). *Principles of tissue engineering* (5th ed.). Academic Press.

	Description of CO	**PO**	**PSO1**	**PSO2**
CO1	Describe the properties, types, and medical applications of biomaterials.	PO1(3), PO2(2),	2	3
CO2	Explain the principles behind tissue engineering and scaffold design for regenerative medicine.	PO1(3), PO2(2), PO4(2)	3	2
CO3	Evaluate biomaterial performance using standard testing methods.	PO1(3), PO2(2), PO4(2)	2	1
CO4	Apply knowledge of biomaterials to develop and improve tissue-engineered products for medical use.	PO1(3), PO2(2), PO4(2)	1	1