

**ANNA UNIVERSITY, CHENNAI**  
**NON- AUTONOMOUS COLLEGES**  
**AFFILIATED TO ANNA UNIVERSITY**  
**M. TECH., PHARMACEUTICAL BIOTECHNOLOGY**  
**REGULATIONS 2025**

**PROGRAMME OUTCOMES (POs):**

| <b>PO</b>  | <b>Programme Outcomes</b>  |
|------------|--|
| <b>PO1</b> | An ability to independently carry out research /investigation and development work to solve practical problems   |
| <b>PO2</b> | An ability to write and present a substantial technical report/document.   |
| <b>PO3</b> | 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):**

| <b>PSO</b>  | <b>Programme Specific Outcomes</b>  |
|-------------|---|
| <b>PSO1</b> | Design and optimize therapeutic proteins, monoclonal antibodies, vaccines, and gene-based products using molecular biology and protein engineering. |
| <b>PSO2</b> | 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

**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       |
| <b>Total Credits</b> |             |  |      |                  |   |   | <b>24</b> | <b>21</b> |          |

### Semester II

| S. No.               | Course Code | Course Title   | Type | Periods per week |     |    | TCP       | Credits   | Category |
|----------------------|-------------|--|------|------------------|-----|----|-----------|-----------|----------|
|                      |             |  |      | L                | T   | P  |           |           |          |
| 1.                   | PB25201     | Process Analytical Technology                                | T    | 3                | 0   | 0  | 3         | 3         | ES (PC)  |
| 2.                   | PB25202     | 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.                   | PB25203     | 3D Bioprinting and Organoid Engineering                      | T    | 4                | 0   | 0  | 4         | 4         | ES (PC)  |
| 6.                   | PB25204     | Cell and Gene Therapy  | T    | 4                | 0   | 0  | 4         | 4         | ES (PC)  |
| 7.                   | PB25205     | Virtual Laboratory– Bioinformatics and Computational Biology | L    | 0                | 0   | 4  | 4         | 2         | ES (PC)  |
| 8.                   | ---         | Self-Learning Course   | --   | -                | -   | -  | -         | 1         | -        |
| 9.                   | PB25206     | Industrial Training <sup>#</sup>                             | L    | ---              | --- | -- | ---       | ---       | SD       |
| <b>Total Credits</b> |             |  |      |                  |     |    | <b>24</b> | <b>22</b> |          |

# 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   |           |           |          |
| 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.                   | --          | Programme Elective V             | T    | 3                | 0   | 0   | 3         | 3         | ES (PE)  |
| 5.                   | PB25301     | Project Work I                   | ---  | 0                | 0   | 12  | 12        | 6         | SD       |
| 6.                   | ---         | Industry Oriented Course II      | T    | 1                | 0   | 0   | 1         | 1         | ES (PC)  |
| 7.                   | PB25206     | Industrial Training <sup>#</sup> | -    | --               | --- | --- | ---       | 2         | SD       |
| <b>Total Credits</b> |             |                                  |      |                  |     |     | <b>25</b> | <b>21</b> |          |

### Semester IV

| S. No.               | Course Code | Course Title    | Type | Periods per week |   |    | TCP       | Credits   | Category |
|----------------------|-------------|-----------------|------|------------------|---|----|-----------|-----------|----------|
|                      |             |                 |      | L                | T | P  |           |           |          |
| 1.                   | PB25401     | Project Work II | ---  | 0                | 0 | 24 | 24        | 12        | SD       |
| <b>Total Credits</b> |             |                 |      |                  |   |    | <b>24</b> | <b>12</b> |          |

### PROGRAMME ELECTIVE COURSES

| S. No. | Course Code | Course Title   | Periods |   |   | Total Contact Periods | Credits |
|--------|-------------|--|---------|---|---|-----------------------|---------|
|        |             |  | L       | T | P |                       |         |
| 1.     | PB25001     | Clinical and Non-clinical Statistics                 | 3       | 0 | 0 | 3                     | 3       |
| 2.     | PB25002     | Research Methodology and IPR                         | 3       | 0 | 0 | 3                     | 3       |
| 3.     | PB25003     | Biopharma Entrepreneurship and Innovation Management | 3       | 0 | 0 | 3                     | 3       |
| 4.     | PB25004     | Clinical Trials and Bioethics                        | 3       | 0 | 0 | 3                     | 3       |
| 5.     | PB25005     | Pharmaceutical Quality by Design                     | 3       | 0 | 0 | 3                     | 3       |
| 6.     | PB25006     | Biogenerics and Biopharmaceuticals                   | 3       | 0 | 0 | 3                     | 3       |
| 7.     | PB25007     | Computational Biology and Network Pharmacology       | 3       | 0 | 0 | 3                     | 3       |
| 8.     | PB25008     | Nanobiotechnology                                    | 3       | 0 | 0 | 3                     | 3       |
| 9.     | PB25009     | Sterile Dosage Forms and Aseptic Processing          | 3       | 0 | 0 | 3                     | 3       |
| 10.    | PB25010     | Vaccine Technology and Formulation Science           | 3       | 0 | 0 | 3                     | 3       |
| 11.    | PB25011     | AI in Drug Discovery and Precision Medicine          | 3       | 0 | 0 | 3                     | 3       |
| 12.    | PB25012     | IoT in Biomanufacturing and Cold Chain Monitoring    | 3       | 0 | 0 | 3                     | 3       |
| 13.    | PB25013     | mRNA Therapeutics and Vaccine Platforms              | 3       | 0 | 0 | 3                     | 3       |
| 14.    | PB25014     | Biosensors   | 3       | 0 | 0 | 3                     | 3       |
| 15.    | PB25015     | Omics Technologies                                   | 3       | 0 | 0 | 3                     | 3       |
| 16.    | PB25016     | Advances in Molecular Medicine                       | 3       | 0 | 0 | 3                     | 3       |
| 17.    | PB25017     | Molecular Diagnostics and Biosensor Technology       | 3       | 0 | 0 | 3                     | 3       |
| 18.    | PB25018     | Metabolic Engineering                                | 3       | 0 | 0 | 3                     | 3       |

| S. No. | Course Code | Course Title            | Periods |   |   | Total Contact Periods | Credits |
|--------|-------------|-------------------------|---------|---|---|-----------------------|---------|
|        |             |                         | L       | T | P |                       |         |
| 19.    | PB25019     | Bioconjugate Technology | 3       | 0 | 0 | 3                     | 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),<br>PO2(2) | 3    | 2    |
| CO2: | Apply microbial growth kinetics to optimize fermentation processes.                       | PO3(1),<br>PO2(2) | 2    | 2    |
| CO3: | Use genetic and metabolic engineering to improve industrial strains.                      | PO1(1),<br>PO3(2) | 2    | 1    |
| CO4: | Design effective product recovery and purification methods for fermentation products.     | PO3(3)            | 2    | 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),<br>PO2(2),           | 2    | 1    |
| CO2 | Use techniques like qPCR and NGS for gene expression analysis.                           | PO1 (3),<br>PO2(2),<br>PO4(2) | 3    | 2    |
| CO3 | Understand and utilize NGS platforms for genetic analysis.                               | PO1 (3),<br>PO2(2),<br>PO4(2) | 1    | 2    |
| CO4 | Implement tools like CRISPR and ZFNs for gene modification in research and applications. | PO1 (3),<br>PO2(2),<br>PO4(2) | 1    | 3    |

**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](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>
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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>

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

**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  $^1\text{H-NMR}$  and  $^{13}\text{C NMR}$ ; Pharmaceutical and Biological Applications; Interpretation of Spectra.

**Activity:** NMR – Simulate spectra, interpret  $^1\text{H-NMR}$ , 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.

|     | <b>Description of CO</b>  | <b>PO</b>                     | <b>PSO1</b> | <b>PSO2</b> |
|-----|---|-------------------------------|-------------|-------------|
| CO1 | Explain the principles and applications of UV/Visible, Fluorimetry, IR, NMR, and Mass Spectroscopy in pharmaceutical analysis.                          | PO1(3),<br>PO2(2),            | 2           | 1           |
| CO2 | Demonstrate proficiency in chromatographic, electrophoretic separations, and molecular assays for pharmaceutical analysis.                              | PO1(3),<br>PO2(2),<br>PO4(2)  | 3           | 2           |
| CO3 | Apply theoretical knowledge to develop and validate analytical methods in pharmaceutical research and quality control.                                  | PO1(3),<br>PO2(2),<br>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),<br>PO2(2),<br>PO4(2) | 1           | 1           |

**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),<br>PO2(2),           | 2    | 3    |
| CO2 | Describe and apply formulation strategies for antibody-based therapeutics, focusing on stability and efficacy.                                 | PO1(3),<br>PO2(2),<br>PO4(2) | 2    | 2    |
| CO3 | Evaluate and compare delivery technologies for vaccines and gene therapies, addressing their respective advantages and limitations.            | PO1(3),<br>PO2(2),<br>PO4(2) | 2    | 1    |
| CO4 | Analyze and interpret the latest trends in biotherapeutic product development, including innovations in formulation and delivery technologies. | PO1(3),<br>PO2(2),<br>PO4(2) | 3    | 1    |

**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.

**Introduction:** 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.

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

# **SEMESTER II**

**Course Learning Objective:**

To understand the principles and importance of PAT in pharmaceutical manufacturing. To understand importance of validation in pharmaceutical industries to ensure the quality, safety, and compliance of products and processes.

**Course Contents:**

Definition, need, historical evolution, FDA and ICH Guidelines on PAT- PAT and Quality by Design (QbD) - Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs)-Regulatory expectations and compliance.

Guidance development process and scope, process understanding-principles and tools – PAT tools-Risk based approach-Integrated systems approach-Real time release – strategy for implementation- PAT regulatory approach.

Spectroscopic Methods - NIR FTIR, UV-Vis. Chromatographic Techniques- Online HPLC- Particle Size Analysis: Laser Diffraction - Imaging and Microscopy: In-line microscopy, Multivariate image analysis- Chemometrics and Multivariate Data Analysis (MVDA): PCA, PLS- Sensor Technologies- pH, conductivity, temperature, pressure, AI-ML applications in PAT.

Purpose of Validation-Validation Strategy-Validation Concept -Validation Life Cycle - Determination of Quality Attributes-The Validation Protocol –Steps of Validation-Control During Routine Operation, Qualification of water systems-Required Quality for Water for Pharmaceutical Purposes-Selection of Water for Pharmaceutical Purposes -Design Qualification of Water Systems -Qualification of Equipment and Components for Water System -Sanitization -Sampling Considerations -Microbial Considerations - Continuous Automatic Monitoring of Water.

Qualification of Air Handling Systems- Purposes of an Air Handling System - Validation of Air Handling Systems- Classification of Air Quality and Design Qualification- Performance Qualification and Parameters of Cleanliness.

Microbiological Evaluation Program for Controlled Environments- Training of Personnel-Sampling and Test of Air Quality- Microbiological Environmental Control Program-Establishment of Microbiological Alert and Action Levels - Quantitation of Viable Airborne Microorganisms – Continuous Automatic Monitoring of Air.

**Course Outcomes:**

1. To Identify CPPs and CQAs and their impact on product quality and the rationale behind of PAT implementation
2. Understand the principle and process involved in the process analytical technology
3. Select appropriate analytical tools for specific unit operations.
4. To understand, design, and validate pharmaceutical water systems in compliance with regulatory standards.
5. To understand the design, function, and validation of Air Handling Units (AHUs) to maintain controlled environments and ensure compliance with cleanroom and regulatory requirements in pharmaceutical manufacturing.
6. Understand the various process and procedure to ensure and assurance of consistent product quality in pharmaceutical manufacturing.

**References:**

1. Bakeev, K. A. (Ed.). (2010). Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. Wiley.
2. Rathore, A. S., & Mhatre, R. (Eds.). (2009). Process Validation and Analytical Technology. CRC Press.
3. ICH Guidelines: Q8- Pharmaceutical Development
4. ICH-Q9 - Quality Risk Management
5. ICH-Q10 - Pharmaceutical Quality System
6. ICH-Q11-Development and Manufacture of Drug Substances
7. FDA Guidance for Industry: PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance (2004).
8. Developments in Surface Contamination and Cleaning. Rajiv Kohli, KL. Mithal, Elsevier, Oxford, U.K.
9. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter, Marcel Dekker Inc, 2003.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 3   |     |     |     | 2   | 3   |     |     |      |      | 2    | 3    | 2    |
| CO2 | 3   | 3   | 2   |     | 2   |     |     |     |     |      |      | 2    | 3    | 2    |
| CO3 | 2   | 2   | 2   | 3   | 3   |     |     |     |     |      | 1    | 2    | 3    | 3    |
| CO4 | 3   |     |     | 2   | 2   | 3   | 3   |     |     |      |      | 2    | 2    | 2    |
| CO5 | 3   |     | 1   | 2   |     | 3   | 3   |     |     |      |      | 2    | 2    | 1    |
| CO6 | 3   | 3   | 3   | 2   | 2   | 3   | 3   | 2   | 2   | 2    | 2    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

The course aims to make students to understand the applications of immunology for the development of diagnostics and vaccines and make use of the knowledge of immunopharmacology for clinical applications.

**Course Contents:**

Review on Cells and Organs of immune system and their development, Humoral immune response, Cell mediated immune responses, Complement pathways, Cytokine classification and activation, Molecular targets and therapeutic pathways of immune system, Principles of basic and clinical pharmacokinetics; Overview of discovery and development of immuno-drugs.

T and B epitopes classification, Adjuvant and hapten classification, Immuno-screening of antigens, Vaccine formulation technology, Vaccine production and validation, Recombinant vaccines, Peptide vaccines, DNA vaccines, Reverse vaccinology. Immunodiagnosics – Antigen detection assay – ELISA and IFT, Development of Rapid immuno diagnostic tests- Immuno-lateral flow / flow through assays; Agglutination tests; Plaque Forming Cell Assay, Flow cytometry – Instrumentation and applications.

Auto immunity: Introduction, Auto recognition, Auto immuno diseases – Type 1 diabetes, Systemic lupus erythematosus, Haemolytic anaemia, Rheumatoid arthritis; Laws of transplantation, Immunological basis of transplantation reactions, HLA Classification and HLA typing; Drugs used in immunosuppressive therapy: Corticosteroids, DMARDs, Antimetabolites and Calcineurin inhibitors.

(WHO) Anatomical Therapeutic Chemical (ATC) Classification of drugs affecting the immune system (L, L01, L02, L03, L04), Therapeutic uses of cytokines, Monoclonal antibodies - Therapeutic mAbs - Classification and formulation.

Engineered antibodies – Catalytic and Idiotypic antibodies, Cancer vaccines, customized therapeutic cancer vaccines, scFv antibodies, CAR T-cell therapy, Dendritic cells-based immunotherapy, Immune checkpoint inhibitors.

Classification of hypersensitivity reactions, Diagnosis of hypersensitivity reactions, Classification of allergens, Drug Hypersensitivity – pharmacologic perspective, immunologic perspective, Off target toxicity, Cellular Basis, Chemical Basis – The Hapten/pro hapten hypothesis, The Danger theory, The pi concept, Therapy and Prevention of allergies, Pharmacology of antihistamines, Mast cell stabilizers.

**LIST OF EXPERIMENTS:**

1. Preparation of antigen and Routes of immunization (Intraperitoneal, Sub-cutaneous, Intramuscular, Intra- nasal, Oral – VIRTUAL DEMO).
2. Methods of bleeding (Tail bleeding, Intravenous, intraorbital - VIRTUAL DEMO).
3. Collection of serum, storage and purification of total IgG (salt precipitation).
4. Blood smear identification of leucocytes by Giemsa stain.
5. Separation of mononuclear cells by Ficoll-Hypaque
6. Demonstration of agglutination inhibition by latex beads (Pregnancy test).
7. Direct Agglutination – Widal test Salmonella detection.
8. Methods for prototype development of Immunodiagnosics (ICT card).
9. Evaluation of Antibody titre by direct ELISA.
10. Evaluation of Antigen by Sandwich ELISA.
11. Characterization of antigens by SDS-PAGE and immunoblotting.
12. Gene amplification by PCR.

**Course Outcomes:**

1. Understand the basic concepts of immunology and pharmacology.
2. Comprehend the importance of immunoassays.
3. Perform experiments on immunoassays for identifying drugs and vaccines.
4. Evaluate vaccines and immunotherapeutics for emerging diseases.
5. Apply knowledge on development of immunological agents
6. Apply the knowledge and skills on immunology for the development of Immunotherapeutics and immunodiagnosics

**References:**

1. Edward A. Greenfield. Antibodies: A Laboratory Manual. 2<sup>nd</sup> edition, Cold Spring Harbor Laboratory Press, 2013.
2. Mary Louise Turgeon. Immunology & Serology in Laboratory Medicine. Eighth edition, Elsevier, 2024.
3. Jonathan Brostoff, Ivan M. Roitt, G. K. Scadding, David K. Male. Clinical Immunology. Mosby, 1994.
4. John E. Coligan, Ethan M. Shevach, Ada M. Kruisbeek, Warren Strober, David H. Margulies. Current Protocols in Immunology. John Wiley & Sons Inc, 1991.
5. David Male, Jonathan Brostoff, David Roth, Ivan Roitt (Editors). Immunology. 8<sup>th</sup> edition, Saunders, 2012.
6. Jenni Punt, Sharon Stranford, Patricia Jones, Judith A. Owen. Kuby Immunology. Eighth edition, Macmillan Learning, 2022.
7. Kenneth Murphy, Casey Weaver, Leslie Berg, Gregory Barton. Janeway's Immunobiology. 10<sup>th</sup> edition, W. W. Norton & Co Inc, 2022.
8. Laurence L. Brunton, Bjorn C. Knollmann (Editors). Goodman & Gilman's The Pharmacological Basis of Therapeutics. 14<sup>th</sup> edition, McGraw Hill, 2023.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 3   |     |     |     | 2   | 2   |     |     |      |      | 2    | 2    |      |
| CO2 | 3   | 2   | 2   |     | 2   |     |     |     |     |      | 1    | 2    | 3    | 2    |
| CO3 | 2   | 2   | 3   | 3   | 3   |     |     |     |     |      |      | 3    | 3    | 2    |
| CO4 | 2   | 3   | 2   | 2   | 2   | 2   | 3   |     |     | 1    |      | 3    | 3    | 3    |
| CO5 | 3   | 2   | 2   | 2   |     | 3   | 3   |     |     |      |      | 2    | 2    | 2    |
| CO6 | 3   | 3   | 3   | 2   | 2   | 3   | 3   | 2   | 2   | 2    | 2    | 3    | 3    | 3    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

|                |  |        |        |        |        |
|----------------|--|--------|--------|--------|--------|
| <b>PB25203</b> | <b>3D Bioprinting and Organoid Engineering</b> | L<br>4 | T<br>0 | P<br>0 | C<br>4 |
|----------------|--|--------|--------|--------|--------|

### **Course Learning Objective:**

To introduce students to the fundamentals and advancements in 3D bioprinting technologies and organoid engineering, focusing on their applications in pharmaceutical and biomedical research. The course aims to develop student expertise in tissue modelling, stem cell-based organoid development, and ethical, regulatory, and translational aspects.

### **Course Contents:**

Additive Manufacturing Fundamentals - Principles of bioprinting – Biomaterials used in bioprinting such as hydrogels, scaffolds, and bioinks – Bioprinting techniques: inkjet, extrusion, and laser-assisted methods

Tissue Bioprinting and Engineering - Bioprinting of tissues like skin, bone, cartilage, and vascular structures – Crosslinking mechanisms – Structural integrity challenges and vascularization strategies

Organoids: Biology and Types - Fundamentals of organoid development – Classification: intestinal, liver, kidney, neural organoids – Derivation from pluripotent and adult stem cells

Design, Tools, and Characterization - Computer-aided design (CAD) for tissue and organ structures – Role of microfluidics and scaffold engineering – Imaging, functional assays, and characterization of organoids

Applications in Biomedicine - Organoids and bio-printed tissues in drug screening – Applications in toxicity testing, disease modelling

Ethics and Regulatory Perspectives - Regulatory frameworks from FDA, ICMR – Ethical implications of neural organoids and human-animal chimeras – Oversight in translational research

### **Course Outcomes:**

1. Understand the principles and materials used in 3D bioprinting
2. Demonstrate knowledge on various tissue constructs fabricated using bioprinting
3. Describe organoid formation and its biological basis
4. Apply software tools and microfabrication in organoid modeling
5. Evaluate regulatory and ethical frameworks for organoid applications
6. Analyze pharmaceutical applications in translational research using bioprinted tissues and organoids

### **Laboratory/Software/Consumable Requirements:**

1. CAD/CAM software for scaffold design (Autodesk Fusion 360, BioCAD)
2. Bioprinter (Inkjet or Extrusion type) or access to simulation tools (Cellink GoHani)
3. Cell culture facility (biosafety cabinet, CO<sub>2</sub> incubator)
4. Matrigel and ECM substitutes
5. High-resolution microscopy & image analysis software

**References:**

1. Al-Rubeai, M., Cell Engineering, Springer, 2020.
2. Davies, J., & Lawrence, M., Organoids and Mini-Organs, Elsevier, 2018.
3. Turksen, K. (Ed.), Organoids: Stem Cells, Structure, and Function, Springer, 2019.
4. National Academies of Sciences, The Emerging Field of Human Neural Organoids, NAP, 2021.
5. Jamie Davies, Chapter 1: Introduction to Organoids, in Organoids and Mini-Organs, Elsevier, 2018, pp. 3–18.
6. Sutcliffe & Lancaster, “Generating Brain Organoids,” in Organoids: Stem Cells, Structure, and Function, Springer, 2019, pp. 1–12.
7. Ghaedi & Niklason, “Lung Organoids from Stem Cells,” in Methods in Molecular Biology, Springer, 2019, pp. 55–92.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   |     |     |     |     |     |     |     |     |      | 1    | 3    | 2    | 1    |
| CO2 | 3   | 2   | 3   | 2   | 2   |     |     |     |     |      | 1    | 3    | 3    | 2    |
| CO3 | 3   | 3   |     |     |     |     |     |     |     | 1    | 2    | 3    | 2    | 2    |
| CO4 | 2   | 2   | 2   | 3   | 3   |     |     |     | 1   | 1    | 2    | 3    | 3    | 3    |
| CO5 |     |     | 1   | 1   |     | 3   | 3   | 2   |     | 2    | 3    | 2    | 2    | 2    |
| CO6 | 3   | 2   | 3   | 3   | 2   | 2   | 2   | 1   | 1   | 3    | 3    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

PB25204

**Cell and Gene Therapy**

|   |   |   |   |
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**Course Learning Objective:**

To impart an in-depth understanding of the principles, techniques, and applications of cell and gene therapy. This course covers the therapeutic potential, regulatory challenges, and clinical development of advanced cell- and gene-based therapies. Students will explore both scientific innovations and manufacturing practices vital to translating therapies from lab to clinic.

**Course Contents:**

Overview and evolution of gene and cell therapy, Genetic basis of human diseases: monogenic, polygenic, multifactorial disorders; Concept of DNA, RNA, and protein-based therapeutics – principles and mechanism; Sources of therapeutic cells: bone marrow, peripheral blood, cord blood, adipose tissue; Evolution of ATMPs: first–fourth generation gene therapies; Somatic vs germline gene therapy; Barriers to *in vivo* and *ex vivo* gene/cell therapy; Multi-omic datasets for target discovery; Regulatory elements for therapeutic gene expression: enhancers, silencers, UTR engineering, codon optimization.

Stem cell technology - Autologous vs allogeneic therapies; Hematopoietic stem cell transplantation; MSC therapy: immunomodulation and tissue repair; iPSCs: generation, genetic correction, directed differentiation; Safety concerns: tumorigenicity, genomic instability, immune rejection; CAR-T cell therapy- design, generations, manufacturing workflow; Armored CAR-T, universal/allogeneic CAR-T, logic-gated CAR circuits, CAR-NK, CAR-macrophage, and CAR-dendritic cell therapies.

Viral Vectors - Adenovirus, AAV, Lentivirus, Retrovirus, HSV, Poxvirus; Advanced viral vector engineering - AAV capsid engineering, integration-deficient lentivirus. Non-Viral Vectors -Lipid nanoparticles, polymeric carriers, nanoparticles; Physical delivery: electroporation, microinjection, sonoporation; Exosomes, biomimetic vesicles, DNA nanostructures; mRNA, saRNA, circRNA delivery platforms, mitochondrial gene delivery.

Genome editing techniques - Programmable nucleases, CRISPR–Cas systems: Cas9, Cas12, Cas13; Base editing and prime editing systems; CRISPRa/CRISPRi and epigenome editing; RNA editing tools (ADAR-based systems); Off-target assessment, computational design tools, genome integrity assays; Applications in correcting genetic diseases, oncology, metabolic and neuromuscular disorders

GMP manufacturing of viral vectors (HEK293, Sf9/baculovirus systems), continuous processing, perfusion reactors; Automated closed-system manufacturing for cell therapies; Analysis and quality control - Release testing: potency, purity, identity, vector copy number, integration site analysis; ddPCR for vector genome quantification; Long-read sequencing for vector integration analysis, Release criteria for CAR-T and stem cell products.

Preclinical models: humanized mice, PDX, organoids; Biodistribution, toxicity, immunogenicity, vector shedding; Clinical trial phases for cell and gene therapies; Long-term follow-up requirements for gene therapy recipients; Regulatory frameworks: FDA, EMA, PMDA, CDSCO for ATMPs; CMC requirements for IND/IMPd; Case studies: Zolgensma, Luxturna, Roctavian, Hemgenix, approved CAR-T therapies.

**TOTAL HOURS: 60 PERIODS**

### Course Outcomes:

- CO1: Describe the principles of gene and cell therapy and the genetic basis of human diseases.
- CO2: Distinguish major stem-cell and engineered immune-cell therapies and evaluate their safety and therapeutic applications.
- CO3: Analyze viral and non-viral vector systems and their suitability for targeted gene delivery.
- CO4: Explain genome-editing technologies and assess their precision, limitations, and therapeutic relevance.
- CO5: Interpret GMP manufacturing workflows and quality-control assays used in ATMP production.
- CO6: Evaluate preclinical models, clinical translation steps, regulatory requirements in gene and cell therapy.

### TEXT BOOKS:

1. Clévio Nóbrega , Liliana Mendonça , Carlos A. Matos, *A Handbook of Gene and Cell Therapy*. Schaffer DV, Tortorella MD, editors. Cham (Switzerland): Springer; 2020.
2. Gee, A. P., editor. *Cell Therapy: cGMP Facilities and Manufacturing*. 2nd ed. Cham (Switzerland): Springer; 2022.
3. Stacey, G., Zhao, T., editors. *Cell Therapy Manufacturing: Current Developments and Future Directions*. Cham (Switzerland): Springer; 2025.
4. Lanza R, Atala A, editors. *Handbook of Stem Cells*. 2nd ed. San Diego: Academic Press; 2021.
5. Swiech K, Malmegrim KCR, Picanço-Castro V, editors. *Chimeric Antigen Receptor T Cells: Development and Production*. *Methods in Molecular Biology*, vol. 2086. New York, NY: Humana/Springer; 2020. DOI: 10.1007/978-1-0716-0146-4.
6. Nancy Smyth Templeton, editor. *Gene Therapy: Therapeutic Mechanisms and Strategies*. 4th ed. CRC Press; 2015.
7. J M Le Doux (Editor), Humana Press, 2008 *Methods in Molecular Biology*, Volume 433, Gene Therapy Protocols, 3rd edn. Volume 1: *Production and In Vivo Applications of Gene Transfer Vectors*, ISBN: 978-1-58829-903-1; Volume 2: *Design and Characterization of Gene Transfer Vectors* ISBN: 978-1-60327-247-6.
8. Kiran Musunuru, *Genome Editing: A Practical Guide to Research and Clinical Applications*, Academic Press, 2021.
9. María Cristina Galli, *Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective*, 2nd edition, Springer cham, 2023, <https://doi.org/10.1007/978-3-031-34567-8>.
10. Review articles from *Nature Reviews Genetics*, *Nature Reviews Drug Discovery*, *Trends in Biotechnology*, *Annual Review of Genetics*, *Molecular Therapy* (Springer Nature), and *Gene Therapy* (Nature Publishing Group).

|     | <b>Description of CO</b>  | <b>PO</b>                     | <b>PSO1</b> | <b>PSO2</b> |
|-----|---|-------------------------------|-------------|-------------|
| CO1 | Describe the principles of gene and cell therapy and the genetic basis of human diseases.                               | PO1 (1)<br>PO2 (1)<br>PO3 (3) | 2           | 2           |
| CO2 | Distinguish major stem-cell and engineered immune-cell therapies and evaluate their safety and therapeutic applications | PO1 (2)<br>PO3 (3)            | 2           | 2           |
| CO3 | Analyze viral and non-viral vector systems and their suitability for targeted gene delivery.                            | PO1 (2)<br>PO3 (3)            | 3           | 3           |
| CO4 | Explain genome-editing technologies and assess their precision, limitations, and therapeutic relevance                  | PO1 (2)<br>PO3 (3)            | 2           | 2           |
| CO5 | Interpret GMP manufacturing workflows and quality-control assays used in ATMP production.                               | PO1 (2)<br>PO2 (1)<br>PO3 (3) | 2           | 3           |
| CO6 | Evaluate preclinical models, clinical translation steps, regulatory requirements in gene and cell therapy.              | PO1 (2)<br>PO2 (1)<br>PO3 (3) | 3           | 3           |

**PB25205**

**VIRTUAL LABORATORY -  
BIOINFORMATICS AND  
COMPUTATIONAL BIOLOGY  
LABORATORY**

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**Course Learning Objective:**

Introduce biopharma related databases, 3D structures of drugs, small molecules and targets. Get familiarized with Next Generation Sequencing Data analysis in a disease context. Perform Quantitative Structure Activity Relationship, Molecular Docking and simulations.

**LIST OF EXPERIMENTS**

1. Basics of Linux Operating System – Syntaxes and Commands.
2. Biological and Small molecular structure Databases – Nucleic acid databases; Protein databases, Databases of RNA sequences, Small Molecule Databases.
3. Computing molecular properties of drugs/compounds using online tools and standalone softwares.
4. Molecular modeling of small molecules: Obtaining 3D structures and understanding data formats.
5. Retrieval of disease targets and drug targets from data resources, PDB structures, and identification of active sites.
6. Homology modeling of protein targets and model evaluation.
7. Pharmacophore and toxicophore identification using online tools.
8. Quantitative Structure–Activity Relationship (QSAR) modeling
9. Drug-like property evaluation of compounds and ADMET analysis.
10. Molecular docking, visualization and interpretation: Protein–protein, protein–small molecule docking using online tools and standalone softwares.
11. Molecular Dynamics Simulation using GROMACS & MM-PBSA/GBSA Energy Analysis.
12. Designing of Primers for PCR using online tools
13. Pharmacogenomics: Effect of SNPs / mutations on drug binding using docking approaches.
14. Basic R Scripting & Next Generation Sequencing Data Analysis: Bioconductor R Package for Differential gene expression analysis using a disease related dataset.

**Course outcomes:**

1. Classify various types of biological databases.
2. Retrieve and analyze data related to small molecules, drugs, and their targets using appropriate computational tools.
3. Explain the structure of biological macromolecules and describe methods for structure prediction and validation.
4. Perform basic analyses of next-generation sequencing (NGS) data.
5. Design primers for the genes of interest using computational tools.
6. Conduct computational structural studies such as QSAR, molecular docking, and molecular dynamics simulations, and interpret the results.

**References:**

1. Arthur M. Lesk. Introduction to Bioinformatics. 5th edition, Oxford University Press, 2019.
2. Richard Durbin, Sean R. Eddy, Anders Krogh, Graeme Mitchison. Biological Sequence Analysis: Probabilistic Models of Proteins and Nucleic Acids. Cambridge University Press, 1998.
3. Dan Gusfield. Algorithms on Strings, Trees and Sequences: Computer Science and Computational Biology. Cambridge University Press, 1997.
4. David W. Mount. Bioinformatics: Sequence and Genome Analysis. Second edition, Cold Spring Harbor Laboratory Press, 2004.
5. Pierre Baldi, Søren Brunak. Bioinformatics: The Machine Learning Approach. Second edition, Bradford Books, 2001.
6. Eija Korpelainen, Jarno Tuimala, Panu Somervuo, Mikael Huss, Garry Wong. RNA-seq Data Analysis: A Practical Approach. First edition, Chapman and Hall/CRC, 2014.
7. Xinkun Wang. Next-Generation Sequencing Data Analysis. First edition, CRC Press, 2016.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     | 2   |     |     |     |     |      | 1    | 2    | 1    | 3    |
| CO2 | 3   | 3   | 2   |     | 3   |     |     |     |     |      | 1    | 3    | 2    | 3    |
| CO3 | 3   | 2   | 3   | 2   | 2   |     |     |     |     |      | 1    | 3    | 2    | 2    |
| CO4 | 2   | 2   | 1   | 3   | 3   |     |     |     |     |      | 2    | 2    | 1    | 3    |
| CO5 | 2   | 2   |     | 2   | 2   |     |     |     |     |      | 2    | 2    | 1    | 3    |
| CO6 | 3   | 3   | 3   | 2   | 3   |     |     |     |     |      | 1    | 3    | 2    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

## PROGRAMME ELECTIVE – I

**PB25001**

**Clinical and Nonclinical Statistics**

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### **Course Learning Objectives:**

To provide students with an understanding of biostatistical principles and methods used in clinical research and healthcare. To develop skills in applying statistical techniques to analyse clinical data, interpret results, and make informed decisions in medical settings.

### **Course Contents:**

Definition and scope of statistics. Types of data: nominal, ordinal, interval, and ratio scales. Data collection methods: cross-sectional, cohort studies, and clinical trials. Descriptive statistics: mean, median, mode, range, variance, and standard deviation. Role of statistics in quality control, formulation, analysis, and clinical research.

Basic probability concepts and distributions: Normal, Binomial, and Poisson. Sampling techniques: random, stratified, and systematic. Sampling distributions and the Central Limit Theorem. Estimation: point and interval estimates, confidence intervals.

Hypothesis testing: null and alternative hypotheses, p-value, type I and type II errors. Application of statistical tests in pharmaceutical and clinical practice.

Parametric tests: one-sample, two-sample, and paired t-tests, ANOVA, and Chi-square test. Non-parametric tests: Mann-Whitney U test, Wilcoxon signed-rank test, and Kruskal-Wallis test.

Statistical power and sample size determination in QC, formulation, analytical, preclinical, and clinical studies. Importance of appropriate test selection and design robustness.

Regression analysis: simple and multiple linear regression. Logistic regression for binary outcomes. Cox proportional hazards regression for survival analysis. Model evaluation using R-squared and residual analysis.

### **Course outcomes:**

1. Describe fundamental statistical concepts and data types used in clinical and epidemiological research.
2. Apply appropriate descriptive and inferential statistical techniques to analyze clinical and biomedical data.
3. Interpret results from statistical analyses and draw valid conclusions relevant to clinical decision-making and public health.
4. Evaluate different study designs including randomized controlled trials, cohort, and case-control studies for clinical research.
5. Perform and interpret regression models (linear, logistic, and Cox) in the context of clinical and epidemiological data.
6. Assess sample size requirements, statistical power, and ethical considerations in the planning and execution of clinical trials.

### **Reference Books:**

1. Friis, R. H., & Sellers, T. A. (2014). Epidemiology for public health practice (5th ed.). Jones & Bartlett Learning.
2. Norman, G. R., & Streiner, D. L. (2014). Biostatistics: The bare essentials (5th ed.). BC Decker Inc.
3. Wright, D. B., & London, M. (2018). Applied biostatistics in public health practice (2nd ed.). Oxford University Press.

4. Higgins, J. P. T., & Green, S. (2011). Cochrane handbook for systematic reviews of interventions (Version 5.1.0). Wiley-Blackwell.
5. Armitage, P., Berry, G., & Matthews, J. N. S. (2002). Statistical methods in medical research (4th ed.). Wiley-Blackwell.
6. Sullivan, L. M. (2012). Essentials of biostatistics in public health (2nd ed.). Jones & Bartlett Learning.
7. Kirkwood, B. R., & Sterne, J. A. C. (2003). Essential medical statistics (2nd ed.). Blackwell Science.
8. Sachs, L. (2013). Applied statistics: A handbook of techniques (3rd ed.). Springer-Verlag.
9. Rosner, B. (2015). Fundamentals of biostatistics (8th ed.). Cengage Learning.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     | 1   |     |     |     |     |      |      | 3    | 2    |      |
| CO2 | 3   | 3   | 2   | 2   | 2   |     |     |     |     |      | 1    | 3    | 3    | 2    |
| CO3 | 2   | 3   | 2   | 2   | 2   |     | 1   |     | 1   | 1    | 2    | 3    | 3    | 2    |
| CO4 | 2   | 3   | 2   | 2   | 1   | 1   | 2   | 1   |     |      | 1    | 2    | 2    | 1    |
| CO5 | 3   | 3   | 2   | 3   | 2   |     |     |     |     |      | 1    | 3    | 3    | 3    |
| CO6 | 3   | 3   |     | 2   |     | 1   | 2   |     |     | 1    | 3    | 3    | 2    | 2    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To enable students to understand the foundational principles and practices of research methodology as applicable to pharmaceutical sciences and to introduce intellectual property rights (IPR) and their regulatory importance. This course aims to develop scientific reasoning and ethical research practices with a focus on IPR management for innovation protection.

**Course Contents:**

Meaning, objectives, and types of research. Research approaches and stages in the research process. Characteristics of good research. Common challenges faced by researchers.

Elements of effective research design. Types of research designs: exploratory, descriptive, diagnostic, and experimental. Research ethics, plagiarism, informed consent, and approval protocols.

Data types and collection methods: surveys, observations, and experiments. Sampling techniques. Statistical analysis using software tools. Interpretation and presentation of research findings.

Definition and scope of Intellectual Property Rights (IPR). Types of IPR: patents, trademarks, copyrights, and industrial designs. Patentable vs. non-patentable subject matter. Filing procedures in India and abroad.

Overview of WIPO, TRIPS, and the Indian Patent Act. Commercialization strategies for intellectual property. Patent infringement and litigation processes.

Role of IPR in academia and industry. Technology transfer, licensing, and innovation protection. Strategic importance of IP management in research and development.

**Course Outcomes:**

1. Understand the fundamental principles and types of research.
2. Design ethically sound and scientifically robust research studies.
3. Apply data collection and analysis techniques in research.
4. Explain the basics of IPR and patent systems in India and abroad.
5. Evaluate the importance of IPR management in pharmaceutical innovation.

**References:**

1. Hazari, A. (2023). \*Research Methodology for Allied Health Professionals: A Comprehensive Guide to Thesis and Dissertation\*. Springer.
2. Saharan, V. A., Kulhari, H., & Jadhav, H. R. (2025). \*Principles of Research Methodology and Ethics in Pharmaceutical Sciences\*. CRC Press.
3. Kothari, C. R., & Garg, G. (2019). \*Research Methodology: Methods and Techniques\* (4th ed.). New Age International Publishers.
4. Tiwari, B. (2016). \*Intellectual Property Rights: Text and Cases\*. PHI Learning.
5. Theisz, V. (2015). \*Medical Device Regulatory Practices: An International Perspective\*. CRC Press
6. Subbaram, N. R. (2013). \*Handbook of Indian Patent Law and Practice\*. S. Chand Publishing.
7. Kumar, A. (2018). \*Fundamentals of Intellectual Property\*. LexisNexis.
8. Kumar, P. (2020). \*Research Ethics in Pharmaceutical Sciences\*. Himalaya Publishing House.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     |     |     |     |     |      | 2    | 2    |      |      |
| CO2 | 3   | 3   | 2   | 2   |     | 2   | 3   |     |     | 2    | 3    |      |      |      |
| CO3 | 3   | 3   |     | 3   | 2   |     |     |     |     | 1    | 3    | 2    |      | 2    |
| CO4 | 2   |     |     |     |     |     | 3   |     |     |      | 2    |      | 2    |      |
| CO5 | 2   |     |     |     |     | 2   | 3   | 1   | 2   | 3    | 2    |      | 3    |      |
| CO6 | 3   | 2   | 2   | 2   |     | 3   | 3   | 2   | 2   | 3    | 3    | 2    | 2    | 2    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To Enable the students to understand the sources of innovation opportunities and development of the skills to identify and analyze these opportunities for biopharma entrepreneurship and innovation. To Develop personal skills set for creativity, innovation and entrepreneurship and specific Concepts and tools for combining and managing creativity in organization.

**Course Contents:**

Introduction to biopharma entrepreneurship – Biopharma technology in a global scale, Scope in Biopharma entrepreneurship, Importance of entrepreneurship. Meaning of entrepreneur, function of an entrepreneur, types of entrepreneurs, and advantages of being entrepreneur.

Innovation – types, out of box thinking, opportunities for Biopharma entrepreneurship. Entrepreneurship development programs of public and private agencies (MSME, DBT, BIRAC, Startup and Make in India).

Management principles of Henry Fayol. Portfolio selection - Business plan preparation: business feasibility analysis by SWOT, socio-economic costs benefit analysis, business canvas, Sources of financial assistance – making a business proposal, approaching loan from bank and other financial institutions, budget planning and cash flow management, basics in accounting practices - balance sheet, P&L account, double entry book keeping, and estimation of income, expenditure, GST, Income tax, EBITA & PAT.

Knowledge centers - Universities, innovation centre, research institutions and business incubators. R&D - technology development and upgradation, assessment of technology development, managing technology transfer, industry visits to successful bio-enterprises, regulations for transfer of foreign technologies, quality control, technology transfer agencies.

Definition, characteristics, need and rationale, objectives, scope and advantages of small-scale industries. Types of bioindustries – Pharma, Agri and Industry. Biofertilizers production - Azospirillum, Azolla, Cyanobacteria and its applications. Biopesticides production - Bacterial, fungal, viral and plant insecticides, Sericulture, Apiculture, Dairy farming. Single Cell Protein Production and applications.

Assessment of market demand for potential product(s) of interest, Market conditions, segments, prediction of market changes, identifying needs of customers including gaps in the market. Branding issues, developing distribution channels – franchising policies, promotion, advertising, branding and market linkages. Marketing of agro products. Recruitment and selection process, leadership skills, managerial skills, organization structure, training, team building and teamwork.

**TOTAL HOURS:45 PERIODS****COURSE OUTCOMES:**

1. Know the legal and financial conditions for starting a business venture
2. Explain the importance of marketing and management in small businesses venture and can interpret their own business plan
3. Identify the elements of success of biopharma entrepreneurial scheme and projects
4. Specify the basic performance indicators of various entrepreneurial activities.
5. Summarise the regulations for transfer of foreign technologies
6. Analyse the business environment in order to identify business opportunities.

**REFERENCES:**

1. P.C. Tripathi, P.N. Reddy, Ashish Bajpai (2021), Principles of Management, 7th Edition, McGraw Hill Education, New Delhi.
2. Robert N. Lussier (2023), Management Fundamentals: Concepts, Applications, and Skill Development, 10th Edition, SAGE Publications, Inc., California, USA.
3. S. S. Khanka (2020), Entrepreneurial Development, Revised Edition, S. Chand & Co. Ltd., New Delhi.
4. Vasant Desai (2025), Dynamics of Entrepreneurial Development & Management, 6th Edition, Himalaya Publishing House, Mumbai.
5. Biotech Consortium India Limited. Bioentrepreneurship Development: A Resource Book. Compiled by Shreya Sanghvi Malik and Shiv Kant Shukla, Biotech Consortium India Limited, 2018.
6. Vinnie Jauhari & Sudhanshu Bhushan, "Innovation Management". Oxford University Press, 2014.
7. Chelladurai, G., S. Iruthaya Kalai Selvam, and Priya Sundarrajan. Bio Entrepreneurship. Bilaspur, Chhattisgarh: Authors Click Publishing, 2025.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 2   |     | 2   |     |     |     | 3   |     |     | 3    | 2    |      | 2    |      |
| CO2 | 2   |     | 3   |     |     |     |     | 2   | 2   | 3    | 2    |      | 2    |      |
| CO3 |     | 2   | 2   |     |     | 3   |     | 3   |     | 3    | 2    | 2    | 2    |      |
| CO4 |     | 2   |     |     |     |     |     |     |     | 3    | 3    |      |      |      |
| CO5 |     |     |     |     |     | 3   | 3   |     |     |      | 2    |      | 3    |      |
| CO6 | 2   | 2   |     |     |     | 2   |     | 3   | 2   | 3    | 3    |      | 2    | 2    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To facilitate the students to acquire knowledge about the basic principles of clinical trials with respect to ethics and handling of quality data management.

**Course Contents:**

Brief History of Clinical Trials; Who can be in Clinical Trials? Need of Clinical Trials, Glossary of Common Terms in Clinical Trials: Clinical Research, Healthy Volunteer, Inclusion/Exclusion Criteria, Informed Consent, Patient Volunteer, Phases of Clinical Trials, Placebo, Protocol, Principal Investigator, Randomization, Single-Double-Blind Studies, Types of Clinical Trials; Diagnostic Trials, Natural History Studies, Prevention Trials, Quality of Life Trials, Screening Trials, Treatment Trials. Clinical Trial Protocol and its Components. Type of Analyses: ITT, mITT and PP.

Comparison Structure: Parallel, Crossover and Group Allocation Designs; Extensions of the Parallel Design: Factorial and Large Simple Designs; Superiority, Equivalency and Non-Inferiority Designs; Adaptive Design; Randomized Controlled Trial (RCT): Reasons for Randomization, Features of RCT; Who sponsors and runs Clinical Trials? How should an RCT be designed?, How should an RCT be conducted?: Random Allocation, Allocation Concealment, Blinding, Conduct, Outcome Ascertainment, Sample Size, Power of a Study; How should an RCT be reported? Randomization and Masking, Overview of Clinical Study Design.

Clinical Trial Design: Randomized controlled trials (RCT), Observational studies, Cross-sectional studies, Epidemiology concepts: Measures of disease frequency (prevalence, incidence), Measures of association (relative risk, odds ratio), Bias and confounding factors in clinical research, Ethical considerations in clinical trials. Case studies on clinical trials.

General Ethical Issues in Clinical Trials; Historical Guidelines in Clinical Research: Nuremberg Code - Declaration of Helsinki-Belmont Report; Brief History of ICH – Structure - Harmonization Process, Responsible Conduct of Research, Ethical Review Procedures, Informed Consent Process, Vulnerability; The Principles of ICH GCP - Institutional Review Board/Independent Ethics Committee - Investigator, Sponsor; Clinical Trial Protocol and Protocol Amendment(s); Essential Documents for the conduct of a Clinical Trial; Biological Materials; Research during Humanitarian Emergencies and Disasters.

Introduction of Clinical Trial Regulation, Aims and Key benefits of the Regulations, Regulatory and Data Strategy, Evolution of Regulatory Changes in India, Regulatory Requirements for the conduct of Clinical Trials in India, Regulatory Bodies, Framework and Procedures (INDIA), Regulatory Bodies, Framework and Procedures (Foreign), Central Drugs Standard Control Organization (CDSCO), Initiatives and Priorities of CDSCO. Food and Drug Administration (USFDA), advances the FDA's mission, Drug and Cosmetic Act - Schedule Y- ICMR Guideline – Data Safety Monitoring Board (DSMB) Regulations: Roles and Responsibilities, Membership, Meetings, Study Reports for DSMB Meetings, Reports from the DSMB, Relationship Between DSMBs and IRBs, Reimbursement.

Project Management, Protocol development in Clinical Research, Case Report Form, Investigator's Brochure (IB), Selection of an Investigator and Site; Clinical Trial Stakeholders, Contract Research Organization (CRO), Site Management Organizations (SMO), Ethical and Regulatory Submissions, Recruitment Techniques, Retention of Clinical Trial Subjects; Monitoring Visits, Investigator Meeting, Documentation in Clinical Trials, Regulatory Binder, Record Retention – Pharmacovigilance, Training in Clinical Research, Project Auditing, Inspection, Fraud and Misconduct, Roles and Responsibilities of Clinical Research Professionals.

**Course Outcomes:**

1. Explain the basic concepts of clinical trials.
2. Demonstrate the clinical trial designs.
3. Understand the importance of ethics in clinical research.
4. Discuss the regulations in clinical research.
5. Develop the ability to involve in data safety monitoring and clinical trial management.
6. Apply the theoretical knowledge in conduction of clinical trials for screening of biological and pharmaceutical products.

**References:**

1. Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, David M. Reboussin, Christopher B. Granger, "Fundamentals of Clinical Trials", 5<sup>th</sup> Edition, Springer Cham, 2016.
2. Tom Brody, Clinical trials, Elsevier, 2016.
3. Roli M, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR.
4. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, Fortaleza: World Medical Association, 2013.
5. International Ethical Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences; 2016.
6. WHO, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
7. WHO, Handbook for Good Clinical Research Practice: Guidance for Implementation, WHO Library Cataloguing-in-Publication Data, 2002.
8. Josef K, Paul M, Graeme S, Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Wiley, 2000.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     | 1   |     |     |     |      | 2    | 3    |      | 2    |
| CO2 | 3   | 3   | 2   | 2   | 2   |     |     |     |     |      | 2    | 3    | 2    | 3    |
| CO3 |     |     |     |     |     | 3   | 3   |     |     |      | 2    | 2    | 3    |      |
| CO4 |     | 2   |     |     |     | 2   | 3   |     |     |      | 2    | 2    | 3    |      |
| CO5 | 2   | 2   | 3   | 2   | 2   | 2   |     |     |     | 2    | 2    | 3    | 3    | 2    |
| CO6 | 3   | 3   | 3   | 3   | 3   |     |     | 2   |     | 2    | 3    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Objective:**

Understand the fundamental principles of Quality by Design (QbD) to pharmaceutical product and process development, including formulation design, risk assessment, and process optimization. Design and implement robust analytical and process control strategies, including Process Analytical Technology (PAT), quality risk management, and regulatory-compliant documentation for lifecycle management and regulatory submissions.

**Course Contents:**

Introduction to Quality by Design (QbD): evolution, core concepts, and benefits. Comparison between traditional and QbD approaches. Regulatory background and overview of ICH guidelines (Q8, Q9, Q10, Q11, Q15). Role of QbD across the pharmaceutical development lifecycle.

Application of QbD in drug and product development. Risk assessment and management during formulation and process development. Use of Design of Experiments (DoE) for process optimization. Key elements: Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs). Selection and role of excipients.

Process Analytical Technology (PAT): vision, components, and real-world application. Development of control strategies including monitoring, control, and continuous improvement. Concepts of real-time release testing and regulatory expectations. Analytical QbD (AQbD): principles and practical uses.

Tools and methodologies for quality risk assessment. Regulatory guidance from global agencies: FDA, EMA, MHRA, TGA, Health Canada, GCC. Interpretation of ICH Q8 to Q12. Documentation standards and knowledge management practices.

QbD applications in regulatory submissions: NDAs, ANDAs, CTD, and eCTD. Handling post-approval changes and fostering continuous improvement. Technology transfer and knowledge management in QbD implementation.

Industry case studies illustrating QbD implementation and regulatory acceptance. Types of variation filings and global expectations. Best practices for integrating QbD into development and regulatory workflows.

**Course Outcomes:**

1. Distinguish between traditional and QbD approaches in pharmaceutical development and articulate the regulatory framework governing QbD
2. Design pharmaceutical products and processes using QbD methodology, including defining Quality Target Product Profiles (QTPP), identifying Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs), and selecting appropriate excipients.
3. Conduct and interpret risk assessments and design experiments (DoE) to optimize formulation and manufacturing processes, supported by relevant case studies.
4. Develop and implement robust analytical and process control strategies using PAT and real-time monitoring.
5. Analyze case studies to evaluate QbD implementation in regulatory filings, post-approval changes, and continuous improvement initiatives in the pharmaceutical industry

**References:**

1. Gintaras V. Reklaitis, Christine Seymour, Salvador García-Munoz Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture, American Institute of Chemical Engineers, Inc. 2017.
2. Sarwar Beg and Md Saqib Hasnain, Pharmaceutical Quality by Design: Principles and Applications, Academic press, 2019.
3. Anurag S. Rathore & Rohin Mhatre Quality by Design for Biopharmaceuticals: Principles and Case Studies, Wiley, 2009.
4. Walkiria S. Schlindwein, Mark Gibson, Pharmaceutical Quality by Design: A Practical Approach, John Wiley & Sons Ltd.2018.
5. Andrew Teasdale, David Elder, Raymond W. Nims, **ICH Quality Guidelines: An Implementation Guide**, Wiley, 2017.
6. Douglas C. Montgomery, Design and Analysis of Experiments, 80<sup>th</sup> Edition, John Wiley & Sons, Inc, 2013.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     | 2   | 3   |     |     |      | 2    | 3    | 2    | 2    |
| CO2 | 3   | 3   | 3   |     | 3   |     |     |     |     | 1    | 2    | 3    | 3    | 3    |
| CO3 | 3   | 3   | 3   | 3   | 3   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |
| CO4 | 3   | 2   | 3   | 2   | 3   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO5 | 3   | 2   |     | 2   | 2   | 2   | 2   |     |     |      | 2    | 2    | 3    | 3    |
| CO6 |     |     |     |     |     |     |     |     |     |      |      |      |      |      |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

Introduce the students about manufacturing processes and characterisation of biosimilars.

**Course Contents:**

Definition: Generics and its advantages; Biogenerics and Biosimilars; Why biosimilars are not (bio) generics; The advent of Biosimilars; The role of patents in the drug industry; Protein-based biopharmaceuticals; Manufacturing processes; Global market; International Non-proprietary Names (INN) nomenclature system biosimilars regulation (EU position, US pathways, Government initiatives).

Approved follow-on proteins/Biosimilars; Characteristics of high selling peptides and proteins, Products with expired patents; Challenging originator's patents; Target products for FOB (follow-on biologics) /Biosimilars development peptides; Recombinant Non-Glycosylated proteins; Recombinant glycosylated proteins; Industries dealing with biogenerics and its market value; World scenario; Indian scenario.

Approaches to the characterization of biosimilars; Problems in characterizing biologics (Types of biologic, Peptides, Non-glycosylated proteins, Glycosylated proteins, Monoclonal antibodies); Equivalence issues; Post-translational modifications; Effect of microheterogeneity; Pharmacokinetics; Pharmacodynamics; and Clinical efficacy;

Analytical Methods for the characterization of biosimilars (Chromatography, Protein sequencing, Mass Spectrometry, UV absorption, Circular dichroism, X-ray techniques, Nuclear magnetic resonance, Electrophoresis, Western blotting, Bioassays, ELISA, Immunoprecipitation and other procedures).

Computing to immunogenicity (product-related factors and host-related factors), consequence of immunogenicity to biopharmaceuticals; Measurement of immunogenicity.

Case studies: Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon Granulocyte-macrophage-CSF, DNase, Factor VIIa, Factor IX, Factor VIII, activated protein C, Tissue plasminogen activator, Monoclonal antibodies etc., Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing.

**TOTAL HOURS: 45 PERIODS****Course Outcomes:**

1. Acquire knowledge about basic concepts of biogenerics and biosimilars
2. List the industries dealing with biosimilars and its market value
3. Carry out various analytical methods for the characterisation of biosimilars..
4. Acquire knowledge of the factors contributing immunogenicity to biopharmaceuticals
5. Summarise the biopharmaceutical concepts using case studies
6. Acquire knowledge about biogenerics and biosimilars, their market, analytical technique, and immunogenicity.

**REFERENCES:**

1. Niazi, Sarfaraz K. "Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues". CRC Press, 2006.
2. Ho, Reedney J. Y., MiloGibaldi. "Biotechnology & Biopharmaceuticals Transforming Proteins and Genes into Drugs", 2nd edition, 2013.
3. Gary Wash, "Biopharmaceuticals: Biochemistry and Biotechnology" 2<sup>nd</sup> edition, 2013
4. Sarfaraz K. Niazi "Biosimilars and Biologics: Implementation and Management" , First edition, 2017
5. Shayne Cox Gad "Handbook of Pharmaceutical Biotechnology", First edition, 2007

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     | 2   |     |     |     |      | 2    | 2    | 2    | 2    |
| CO2 | 2   | 1   |     |     | 1   | 2   |     |     |     |      | 2    | 2    | 3    | 2    |
| CO3 | 3   | 2   | 2   | 2   | 3   |     |     |     |     |      | 1    | 3    | 2    | 3    |
| CO4 | 3   | 2   |     | 2   | 2   | 3   |     |     |     |      | 2    | 3    | 2    | 2    |
| CO5 | 2   | 3   | 2   |     | 2   | 2   |     |     |     |      | 2    | 2    | 3    | 3    |
| CO6 | 3   | 3   | 3   | 2   | 3   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To introduce students to computational modeling and systems-level analysis in biology, and to apply these techniques in network pharmacology for drug discovery, with a particular focus on natural products and multi-target systems.

**Course Contents:**

Overview and evolution of computational biology. Introduction to sequence databases and biological data formats. Modeling approaches: deterministic, stochastic, and logical models. Applications in genomics, transcriptomics, and proteomics.

Basics of graph theory and construction of biological networks. Analysis of protein-protein interaction, gene regulatory, and metabolic networks. Network metrics: centrality, motifs, and modularity. Visualization and interpretation using tools like Cytoscape.

Drug repurposing workflows and databases. Machine learning in drug target identification. Retrosynthesis and generative design for natural product discovery.

Transition from one-drug-one-target to network-target paradigms. Construction and interpretation of disease-gene-target-drug interaction networks.

Tools and platforms in network pharmacology: STITCH, BATMAN-TCM. Integration of multi-omics data for pharmacological analysis.

AI and big data in herb-drug interaction prediction. Frameworks for designing network-based pharmacological studies on natural products. Future directions in computational systems pharmacology.

**Total Hours: 45 Periods**

**Course Outcomes:**

1. Explain the foundational concepts and tools of computational biology.
2. Interpret biological networks and apply network modeling techniques
3. Analyze biological data for drug discovery and repurposing using computational methods
4. Evaluate the principles and frameworks of network pharmacology
5. Apply computational approaches to study multi-target and multi-component drug interactions
6. Design network-based strategies to investigate herbal medicines and natural products.

**References:**

1. Li, Shao (Ed.). (2021). Network Pharmacology. Springer.
2. Raman, Karthik. (2021). An Introduction to Computational Systems Biology. CRC Press.
3. Sharma, R. et al. (2025). Computational Biology in Drug Discovery and Repurposing. Apple Academic Press.
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| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     | 2   |     |     |     |     |      | 1    | 3    | 2    |      |
| CO2 | 3   | 3   | 2   | 2   | 2   |     |     |     |     |      | 1    | 3    | 3    | 2    |
| CO3 | 3   | 3   | 2   | 3   | 3   |     |     |     |     | 1    | 2    | 3    | 3    | 3    |
| CO4 | 2   | 3   | 3   | 2   | 2   | 1   | 1   |     |     |      | 1    | 3    | 3    | 2    |
| CO5 | 3   | 2   | 2   | 3   | 2   |     |     |     |     |      | 1    | 3    | 3    | 3    |
| CO6 | 2   | 2   | 3   | 3   | 3   | 1   | 1   |     | 1   | 1    | 2    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To enable students to comprehend the principles of nanobiotechnology and apply interdisciplinary knowledge to design, synthesize, and characterize nanomaterials for biomedical, agricultural, and environmental applications

**Course Contents:**

Evolution and historical context of nanoscience and nanotechnology, Principles of nanoscale phenomena - Quantum confinement, surface-to-volume ratio, and surface energy, Scope and convergence of nanotechnology with biotechnology, Bottom-up self-assembly vs. top-down nanofabrication, Key milestones - Carbon nanotubes, fullerenes, DNA nanotechnology, nanoparticle-based diagnostics

Synthesis Methods - Top-down (mechanical milling, lithography), Bottom-up (chemical vapor deposition, sol-gel, hydrothermal, microemulsion) Green synthesis using microbial and plant extracts, Characterization Techniques - Spectroscopy: UV-Vis, FTIR, Structural: XRD, DLS, Microscopy: SEM, TEM, Cryo-TEM, AFM, Surface charge & porosity: Zeta potential, BET analysis

Optical properties - Plasmon resonance, fluorescence, photonic crystals, quantum dots, Electrical and magnetic properties - Conductivity, magnetoresistance, tunneling effects, Mechanical properties - Nanoindentation, elasticity at nanoscale, Spectroscopic and analytical tools - Raman, FTIR, EDX, Surface/interface characterization: Contact angle, AFM force mapping, Biosensors - FRET, SPR, cantilever-based detection.

Nanoscale structure and function of biological macromolecules (DNA, proteins, enzymes), Cytoskeletal nanosystems and molecular motors, Biofunctionalization techniques - PEGylation, antibody conjugation, avidin-biotin chemistry, DNA origami, scaffolded nanostructures, Nano bioconjugates in biosensing, drug delivery, and diagnostics, Nanopore sequencing, single-molecule tracking techniques.

Drug Delivery - Liposomes, dendrimers, carbon nanotubes, stimuli-responsive nanocarriers, Cancer Nanotherapeutics - Theranostic nanoparticles, nanorobots, tumor-targeting ligands, Nanotoxicology- Mechanistic toxicology, dose-response models, ecotoxicity.

Environmental Nanotech - Nanosensors for heavy metals, pesticides, Nanocomposites for water purification, Agricultural Applications - Nano-fertilizers, nano-pesticides, crop monitoring nanosensors.

**TOTAL HOURS: 45 PERIODS****Course Outcomes:**

1. Integrate fundamental principles of nanoscience with biological systems to explore biomedical and environmental applications.
2. Synthesize and characterize diverse nanomaterials using physical, chemical, and biological methods.
3. Analyze nanomaterial properties using advanced analytical and spectroscopic techniques.
4. Design and engineer bioconjugates and nanobiostructures for drug delivery and biosensing applications.
5. Evaluate the safety, toxicity, and ecological impacts of nanotechnology-based innovations.
6. Apply interdisciplinary knowledge of nanobiotechnology in solving real-world problems in healthcare, agriculture, and environmental sustainability.

## REFERENCES:

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7. Roco, M. C., & Bainbridge, W. S. (2002). Converging technologies for improving human performance: Nanotechnology, biotechnology, information technology and cognitive science. National Science Foundation.
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| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   | 2   |     |     | 2   |     |     |     |      | 2    | 3    | 2    | 3    |
| CO2 | 3   | 3   | 3   | 2   | 3   |     |     |     |     |      | 2    | 3    | 2    | 3    |
| CO3 | 2   | 3   |     | 3   | 3   |     |     |     |     |      | 2    | 2    | 2    | 2    |
| CO4 | 2   | 2   | 3   | 2   | 3   | 2   |     | 2   |     | 2    | 2    | 3    | 3    | 3    |
| CO5 | 2   |     |     |     |     | 3   | 3   |     |     |      | 2    | 2    | 3    | 3    |
| CO6 | 3   | 2   | 3   | 3   | 2   | 2   | 2   | 2   |     | 2    | 3    | 3    | 3    | 3    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

**PB25009 Sterile Dosage Forms and Aseptic Processing**

|   |   |   |   |
|---|---|---|---|
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| 3 | 0 | 0 | 3 |

**Course Learning Objective:**

To impart comprehensive knowledge on the development, manufacture, and quality assurance of sterile pharmaceutical products. To equip students with aseptic techniques, sterilization methods, contamination control, and validation approaches. To familiarize students with regulatory requirements and Good Manufacturing Practices (GMP) applicable to sterile dosage forms.

**Course Contents:**

Overview and classification of sterile dosage forms. Importance, scope, and formulation considerations based on route of administration. Regulatory and pharmacopeial requirements (IP, USP, BP, Ph. Eur). Key challenges in sterile product development.

Sterilization methods: physical (moist heat, dry heat, filtration, ionizing radiation) and chemical (ethylene oxide, formaldehyde). Method selection based on formulation type. Sterilization validation, use of biological indicators, and dehydrogenation techniques.

Aseptic processing principles. Facility design: cleanroom layout, HVAC systems, airflow patterns. Use of laminar airflow cabinets, isolators, and RABS. Cleanroom classifications (ISO 14644, EU GMP). Personnel hygiene and gowning protocols.

Sources and types of contamination: microbial, particulate, pyrogen. Cleaning and disinfection protocols for contamination control. Environmental monitoring: surface, air, and personnel—use of settle plates, contact plates, and active air samplers.

Quality control tests for sterile products: sterility test, bacterial endotoxin test, particulate matter test. Media fill validation and aseptic process simulation. Filter integrity testing procedures.

Regulatory requirements for sterile manufacturing: USFDA, EMA, WHO, Schedule M. Good Manufacturing Practice (GMP) and Quality Risk Management (QRM). Documentation practices and deviation handling in sterile product manufacturing.

**Course Outcomes:**

1. Classify and formulate different sterile dosage forms.
2. Choose appropriate sterilization techniques and validate them.
3. Design aseptic manufacturing areas with controlled environments.
4. Implement contamination control and monitoring systems.
5. Apply regulatory and quality control strategies to sterile products.
6. Interpret sterile dosage forms and aseptic processing

**REFERENCES:**

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2. Remington: The Science and Practice of Pharmacy, 23rd Edition, Pharmaceutical Press, 2021
3. Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th Edition, Elsevier, 2023
4. Hugo and Russell's Pharmaceutical Microbiology, 9th Edition, 2022, Wiley-Blackwell
5. Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice, USFDA, Revised 2020
6. WHO Good Manufacturing Practices for Sterile Pharmaceutical Products, WHO TRS No. 1019, 2023

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   | 2   |     |     | 1   |     |     |     |      |      | 3    | 2    | 2    |
| CO2 | 3   | 3   | 2   | 2   |     | 2   |     |     |     |      |      | 3    | 2    | 2    |
| CO3 | 3   | 2   | 3   |     | 3   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |
| CO4 | 3   |     | 2   | 2   | 2   | 3   | 2   |     |     |      | 2    | 3    | 3    | 3    |
| CO5 | 3   |     | 2   |     |     | 2   | 3   |     |     |      | 2    | 3    | 3    | 3    |
| CO6 | 3   |     | 2   | 2   |     | 2   |     |     |     |      | 2    | 3    | 2    | 2    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

|                |   |   |   |   |   |
|----------------|---|---|---|---|---|
| <b>PB25010</b> | <b>Vaccine Technology and Formulation Science</b> | L | T | P | C |
|                |   | 3 | 0 | 0 | 3 |

### **COURSE LEARNING OBJECTIVE:**

To provide students with a comprehensive understanding of the scientific, technological, and regulatory aspects of vaccine development, enabling them to analyse immunological mechanisms, apply bioengineering tools, and evaluate vaccine efficacy.

### **COURSE CONTENTS:**

Milestones in vaccinology - Jenner's smallpox work, Pasteur's contributions, eradication success stories, Timeline of development for key vaccines: BCG, Polio, MMR, Influenza, COVID-19, Vaccine classifications - Live attenuated, Inactivated, Subunit, Toxoid, Conjugate, DNA/RNA-based, Recombinant.

Strategies of vaccination: Preventive, Therapeutic, Herd immunity, Ring vaccination, Global health initiatives - WHO EPI, GAVI, COVAX collaboration, Vaccine delivery routes - Intramuscular, Subcutaneous, Oral, Nasal, Importance of cold chain logistics in vaccine transport and storage.

Innate and adaptive immune responses post-vaccination, Antigen-presenting cells (APCs) and T/B cell crosstalk, Memory T and B cells, central vs. effector memory, Correlates of protection, immune biomarkers, Vaccine-induced tolerance and immunopathological responses, Adverse immune responses, special considerations for elderly and immunocompromised individuals.

Types of immunity - Active, Passive, Herd immunity concepts, Vaccine adjuvants - Mechanisms and examples (Alum, MF59, MPLA, QS-21, CpG), Antigen delivery systems - Nanoparticles, Liposomes, Virosomes, ISCOMs, Mucosal immunity and oral vaccine design, Immunomodulation via vaccination - Th1/Th2/Th17 axis, Case studies - HPV, Influenza, and COVID-19 vaccines.

Overview of traditional vaccines - Inactivated, Toxoids, Live attenuated, Recombinant and subunit vaccine platforms - VLPs, protein conjugates, DNA/RNA vaccines: Design, expression, and delivery tools, Tools of immunoinformatics - IEDB, VaxiJen, NetMHC, reverse vaccinology approaches, Case study - Design and rollout of mRNA-based COVID-19 vaccines, Synthetic biology approaches for programmable vaccines.

Clinical development stages - Preclinical, Phase I-IV trials, Parameters of vaccine efficacy, safety, and immunogenicity endpoints, Role of regulatory bodies: FDA, EMA, CDSCO, WHO Prequalification, Pharmacovigilance - VAERS, VSD, and global monitoring, Vaccine hesitancy: Sociocultural, psychological, and misinformation aspects, Emerging technologies - Thermostable vaccines, Needle-free delivery, Cancer/Neoantigen vaccines, Ethical and IPR considerations in vaccine deployment.

### **Course Outcomes:**

1. Analyze the historical progression of vaccinology and classify various vaccine types and delivery strategies.
2. Explain the immunological mechanisms involved in vaccine response, including innate and adaptive immunity, immune memory, and the implications for different population groups.
3. Evaluate the role of adjuvants and antigen delivery systems in modulating immune responses and apply knowledge to the development of mucosal and oral vaccines.
4. Compare traditional and next-generation vaccine platforms and utilize bioinformatics tools like IEDB and reverse vaccinology in the rational design of synthetic and mRNA-based vaccines.
5. Interpret clinical trial phases, assess vaccine safety and efficacy, and understand global regulatory frameworks, including post-marketing surveillance and sociocultural barriers.
6. Comprehensive knowledge and applied competencies in the principles, design, immunology, engineering, and regulatory aspects of modern vaccine development, enabling them to contribute meaningfully to vaccine research and public health.

**References:**

1. Rappuoli, R., Aderem, A. (2011). Vaccines for the 21st Century. Springer.
2. Singh, M. (Ed.). (2015). Vaccine Adjuvants and Delivery Systems. Wiley. <https://doi.org/10.1002/9781118678063>
3. Abbas, A.K., Lichtman, A.H., & Pillai, S. (2021). Cellular and Molecular Immunology, Elsevier.
4. Plotkin, S.A., Orenstein, W.A., Offit, P.A. (2022). Plotkin's Vaccines (8th Ed.). Elsevier.
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| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   | 2   |     |     | 1   |     |     |     |      |      | 3    | 2    | 2    |
| CO2 | 3   | 3   |     | 2   |     | 2   |     |     |     |      |      | 3    | 2    | 2    |
| CO3 | 3   | 2   | 2   |     | 3   | 2   |     |     |     |      |      | 3    | 3    | 3    |
| CO4 | 3   | 2   | 3   | 2   | 3   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |
| CO5 | 2   | 2   | 2   |     | 2   | 3   | 3   |     |     |      | 2    | 3    | 3    | 3    |
| CO6 | 3   | 3   | 3   | 2   | 2   | 3   | 2   |     |     | 2    | 2    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To provide an in-depth understanding of how artificial intelligence (AI) and machine learning (ML) techniques are revolutionizing the fields of drug discovery and precision medicine. The course will equip students with knowledge to analyse biomedical datasets, design predictive models for drug efficacy, and explore personalized therapeutic strategies.

**Course Contents:**

Foundations of AI in Drug Discovery - Historical background – Definitions of AI, ML, and DL – Comparison: AI vs traditional statistics – Types of biomedical data – Common ML algorithms: SVM, Random Forest, KNN, CNN

AI in Early-Stage Drug Discovery - AI-assisted target identification and lead optimization

AI in Clinical Development - Adaptive clinical trial designs – Predictive biomarkers – Use of digital twins – AI for patient recruitment and clinical trial simulation

AI in Omics and Precision Medicine - Applications in genomics, transcriptomics, and proteomics – AI for personalized therapy recommendations

Model Robustness and Ethics - Interpretability of AI models – Fairness and algorithmic bias – Transparency in model decision-making – Regulatory perspectives from FDA and EMA – Ethical considerations in AI-enabled healthcare

Integration and Implementation - Data curation and preprocessing – Model validation and performance metrics - Future trends in AI for pharmaceutical innovation

**Course Outcomes:**

1. Apply machine learning algorithms to biomedical data relevant to drug discovery
2. Analyze the utility of AI in target identification, drug design, and virtual screening
3. Evaluate how AI models enhance precision in clinical trial design and execution
4. Integrate multi-omics data for personalized therapy prediction using AI
5. Interpret ethical and regulatory frameworks related to AI-based drug and diagnostic systems
6. Propose AI-based solutions for real-world pharmaceutical and healthcare problems

**RESOURCES REQUIRED:**

1. High-performance computing lab with Python/R (TensorFlow, Scikit-learn, DeepChem).
2. Access to public datasets (e.g., ChEMBL, TCGA, PubChem, DrugBank).
3. Software: KNIME, Galaxy, Bioconductor.
4. AI model development environment: Jupyter, Colab, GitHub classroom integration

**References:**

1. Chang, M. (2020). Artificial Intelligence for Drug Development, Precision Medicine, and Healthcare. CRC Press.
2. Thompson, S. (2025). Artificial Intelligence in Medicine. CRC Press.
3. Kumar, A. et al. (2025). Artificial Intelligence in Medicine and Healthcare. CRC Press.
4. Oshida, Y. (2022). Artificial Intelligence for Medicine: People, Society, Pharmaceuticals, and Medical Materials. De Gruyter.
5. Raz, M. et al. (2022). Artificial Intelligence in Medicine: Applications, Limitations, and Future Directions. Springer.
6. NIH/NCI: AI and ML in Cancer Research and Precision Oncology.
7. NPTEL & Coursera courses on AI in Healthcare and Deep Learning for Genomics.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     | 2   | 3   |     |     |     |     |      | 2    | 3    | 3    | 2    |
| CO2 | 3   | 3   | 2   | 2   | 3   |     |     |     |     | 1    | 2    | 3    | 3    | 2    |
| CO3 | 2   | 3   |     | 3   | 2   | 2   |     |     |     | 2    | 2    | 3    | 3    | 2    |
| CO4 | 3   | 3   | 2   | 2   | 3   | 1   |     |     |     | 1    | 3    | 3    | 3    | 3    |
| CO5 | 2   | 2   |     |     |     | 2   | 3   |     |     | 2    | 2    | 2    | 3    | 2    |
| CO6 | 3   | 3   | 3   | 2   | 3   | 2   | 3   | 2   | 2   | 3    | 3    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To equip students with fundamental knowledge and practical insights into the role of the Internet of Things (IoT) in biomanufacturing and pharmaceutical cold chain management, with emphasis on sensor integration, data acquisition, process optimization, and quality compliance in the pharmaceutical supply chain.

**Course Contents:**

IoT Fundamentals and Pharma 4.0 Integration - Core concepts of IoT – System architecture and key components (sensors, actuators, gateways) – Transition from Industry 4.0 to Pharma 4.0 – Real-time data acquisition and feedback mechanisms in pharmaceutical operations

Bioprocess Monitoring and Embedded Systems - Sensor networks in bioreactors – Parameters: temperature, pH, dissolved oxygen, agitation – Role of embedded platforms like Arduino and Raspberry Pi – Data acquisition, logging, and SCADA system connectivity

IoT in Cold Chain and Logistics - IoT applications in cold storage and biological transport – Technologies: RFID, GPS, NFC – Wireless monitoring of temperature and humidity – Integration with cloud for alerts and compliance

Communication Protocols and IoT Platforms - IoT communication protocols: MQTT, CoAP, LoRa, ZigBee, NB-IoT – Cloud services: Azure IoT Hub, AWS, Blynk – Dashboards, visual analytics, and AI/ML-driven predictive insights

Compliance, Quality, and Security - Regulatory frameworks: 21 CFR Part 11, GAMP 5, WHO GDP – Data integrity and compliance in IoT systems – Cybersecurity challenges and risk mitigation strategies

Emerging Technologies and Sustainable Innovation - Digital twins for virtual modeling and process optimization – Sustainable practices in biomanufacturing through smart systems

**Course Outcomes:**

1. Describe IoT components and their applications in smart pharmaceutical manufacturing
2. Implement sensor-based data acquisition and process control in bioprocessing
3. Analyze cold chain logistics using real-time tracking and remote monitoring tools
4. Integrate communication protocols and cloud platforms for secure data handling
5. Interpret regulatory standards and ethical implications in IoT-enabled pharma systems
6. Propose sustainable IoT frameworks for pharma process and distribution optimization

**Resources Required:**

1. Embedded systems: Arduino/ESP32/Raspberry Pi kits.
2. IoT sensors (temperature, humidity, CO<sub>2</sub>, pressure).
3. Cold box/cooler for simulated cold chain.
4. Wi-Fi/GSM modules, RFID/GPS kits.
5. Cloud platforms: Blynk, ThingSpeak, Google Firebase

**References:**

1. Raj, P., & Raman, C., The Internet of Things: Enabling Technologies, Platforms, and Use Cases, CRC Press, 2017.
2. Madakam, S., Internet of Things (IoT): Applications in Smart Industries, Springer, 2023.
3. Ghosh, T.K., & Saha, R., Pharmaceutical Supply Chains and the Cold Chain, Wiley, 2021.
4. IEC & WHO. Guidelines on the International Cold Chain, WHO Technical Report Series.
5. Debasis Bagchi et al., Smart Pharmaceutical Industrial Applications of IoT and Blockchain, Academic Press, 2022.
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7. US FDA. Guidance for Industry: Data Integrity and Compliance with CGMP, 2018.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     | 3   |     |     |     |     |      | 2    | 3    | 2    | 2    |
| CO2 | 3   | 2   | 3   | 3   | 3   |     |     |     |     | 1    | 2    | 3    | 3    | 3    |
| CO3 | 2   | 2   | 2   | 2   | 3   | 1   |     |     |     | 1    | 2    | 3    | 3    | 2    |
| CO4 | 2   | 3   | 2   | 3   | 3   | 1   |     |     |     | 2    | 3    | 3    | 3    | 3    |
| CO5 | 2   |     |     |     |     | 2   | 3   |     |     | 2    | 3    | 2    | 2    | 2    |
| CO6 | 3   | 2   | 2   | 2   | 3   | 2   | 2   | 2   | 2   | 3    | 3    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

|                |  |          |          |          |          |
|----------------|--|----------|----------|----------|----------|
| <b>PB25013</b> | <b>mRNA Therapeutics and Vaccine Platforms</b> | <b>L</b> | <b>T</b> | <b>P</b> | <b>C</b> |
|                |  | 3        | 0        | 0        | 3        |

**Course Learning Objective:**

To provide a thorough understanding of the principles, development, delivery, and clinical application of mRNA-based therapeutics and vaccine platforms, integrating molecular biology, nanotechnology, immunology, and regulatory science.

**Course Contents:**

RNA Biology and Modifications - RNA structure and types – Transcription and translation mechanisms – Post-transcriptional modifications – Codon optimization and untranslated regions (UTRs) – RNA stability, degradation, and nucleotide modifications such as pseudouridylation

RNA-Based Therapeutics and Applications - Therapeutic RNA categories: protein replacement, immunotherapy, and rare diseases – Coding versus noncoding RNA modalities – In vitro transcription (IVT) methods – Role of immune modulators and adjuvants in RNA therapeutics

mRNA Vaccines: Design and Case Studies - Antigen selection principles – Strategies for mRNA vaccine construction – Applications in infectious diseases and cancer – Case studies including COVID-19, Zika, Influenza, and cancer neoantigen vaccines – Immunogenicity and antigen presentation mechanisms

Delivery Systems and Pharmacokinetics - Lipid nanoparticles (LNPs), polymeric carriers, and exosome-mediated delivery – Cellular uptake, endosomal escape – Stability profiles, biodistribution, and cold-chain storage requirements – Pharmacokinetics and safety evaluation

Advanced RNA Platforms and Regulatory Aspects - Self-amplifying RNA (saRNA), circular RNA (circRNA) technologies – GMP-compliant manufacturing and scale-up strategies – Regulatory approval processes including Emergency Use Authorization (EUA), biosimilars, and global guidelines

Emerging Trends and Innovations - Personalized RNA therapy approaches – Artificial intelligence-driven vaccine design – Next-generation RNA vaccine platforms – Future directions in mRNA-based drug development

**Course Outcomes:**

1. Explain the structure and function of mRNA and the principles of its synthesis.
2. Describe the design and development of mRNA therapeutics and vaccines.
3. Analyze delivery systems such as lipid nanoparticles (LNPs) for mRNA transport.
4. Evaluate mRNA vaccine clinical applications, safety, and manufacturing.
5. Discuss emerging trends like circular RNA, self-replicating RNA, and AI tools.

**PEDAGOGICAL TOOLS:**

1. Interactive lectures and group discussions
2. Journal article analysis (e.g., SARS-CoV-2 vaccine platforms)
3. Mini project on mRNA design or delivery simulation
4. Guest lectures from industry/regulatory experts

**REFERENCES:**

1. Niazi, S. K. (2023). mRNA Therapeutics: Fast-to-Market Strategies. CRC Press.
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5. Singh, M. (2023). Therapeutic Platform of Bioactive Lipids. Apple Academic Press.
6. Malviya, R. et al. (2025). Cancer Vaccination and Challenges. CRC Press.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   |     |     |     |     |     |     |     |     |      | 1    | 3    | 2    | 1    |
| CO2 | 3   | 3   | 3   | 2   |     |     | 1   |     |     | 1    | 1    | 3    | 3    | 2    |
| CO3 | 3   | 2   | 2   | 3   | 3   | 1   |     |     |     | 1    | 2    | 3    | 3    | 3    |
| CO4 | 2   | 2   | 3   | 3   | 2   | 2   | 2   |     |     | 2    | 2    | 3    | 3    | 3    |
| CO5 | 2   |     | 2   | 1   | 1   | 3   | 3   |     |     | 2    | 3    | 2    | 2    | 3    |
| CO6 | 3   | 2   | 3   | 3   | 3   | 2   | 2   | 2   | 2   | 3    | 3    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

|                |                   |          |          |          |          |
|----------------|-------------------|----------|----------|----------|----------|
| <b>PB25014</b> | <b>Biosensors</b> | <b>L</b> | <b>T</b> | <b>P</b> | <b>C</b> |
|                |                   | 3        | 0        | 0        | 3        |

### **Course Learning Objective:**

To introduce students to the principles, components, design, and applications of biosensors, with a focus on their role in medical diagnostics, environmental monitoring, and food safety.

### **Course Contents:**

Fundamentals of Biosensors - Definition, historical evolution, and classification of biosensors – Core components: biorecognition element, transducer, signal processor – Working principles and key performance parameters such as sensitivity, specificity, and response time

Biorecognition Elements and Immobilization - Types of recognition elements: enzymes, antibodies, nucleic acids, aptamers, molecularly imprinted polymers (MIPs) – Immobilization techniques including adsorption, covalent bonding, and entrapment – Factors influencing recognition efficiency

Biosensor Types and Transduction Mechanisms - Electrochemical sensors: amperometric, potentiometric, conductometric – Optical sensors: fluorescence, colorimetric, SERS, SPR – Mass-sensitive and piezoelectric biosensor technologies

Applications in Medical Diagnostics - Biosensors for disease diagnosis – Glucose monitoring – Detection of cancer biomarkers – Point-of-care testing applications

Environmental and Food Monitoring Applications - Biosensors in environmental monitoring for pollutant and pathogen detection – Applications in food and water safety for identifying toxins, allergens, and contaminants

Advanced Biosensor Technologies and Regulation - Emerging biosensor platforms: wearable and implantable devices, microfluidics, lab-on-chip – Use of nanomaterials and AI integration – Commercialization pathways, regulatory frameworks, and associated challenges

### **Course Outcomes:**

1. Understand the fundamental principles and classifications of biosensors
2. Describe the types and roles of biorecognition elements and transducers.
3. Apply knowledge of biosensor fabrication techniques and materials
4. Evaluate the performance of biosensors for various biomedical and industrial applications.
5. Interpret the challenges and future prospects in biosensor development

### **References:**

1. Sibel A. Ozkan, Bengi Uslu, Mustafa Kemal Sezgintürk. (2023). Biosensors: Fundamentals, Emerging Technologies, and Applications. CRC Press.
2. Seamus Higson. (2012). Biosensors for Medical Applications. Woodhead Publishing.
3. Baljinder Kaur et al. (2025). Biosensors: Nanomaterials, Approaches, and Performance-Enhancement Strategies. IEEE Press & Wiley.
4. Relevant scientific publications and recent journal articles in Biosensors and Bioelectronics.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     |     |     |     |     |      | 1    | 3    | 2    | 1    |
| CO2 | 3   | 3   | 2   |     |     |     |     |     |     |      | 1    | 3    | 2    | 1    |
| CO3 | 2   | 2   | 3   | 2   | 3   |     |     |     |     |      | 1    | 3    | 3    | 2    |
| CO4 | 2   | 2   | 3   | 3   | 2   | 2   |     |     | 1   | 1    | 2    | 3    | 3    | 3    |
| CO5 | 1   | 2   | 2   | 2   | 2   | 3   | 2   | 1   | 1   | 2    | 2    | 2    | 2    | 3    |
| CO6 |     |     |     |     |     |     |     |     |     |      |      |      |      |      |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To impart the Knowledge of theory, tools and application of omics technology in the field of biotechnology. To develop the skills in the area of genomics, proteomics and metabolomics and learn advanced techniques in protein separation and analysis.

**Course Contents:**

Major genome sequencing projects, Introduction to different tools and algorithms, Data repositories and databases, Choice of sequencing platforms, Designing and producing microarrays; types of microarrays; cDNA microarray technology; Oligonucleotide arrays; Sample preparation, labelling, hybridization, generation of microarray data. Transcriptomics using cDNA and oligonucleotide arrays.

Over-view of Next Generation Sequencing (NGS) technologies; Principles of NGS by Roche/454, Illumina, Life Technologies, File formats, Basic pipeline for data analysis – quality check, adaptor trimming, Genome assembly, Genome annotation, Pacific Biosciences, Ion Torrent technologies; Applications of NGS to disease diagnosis and personalized medicine.

Types of protein arrays; Protein microarray fabrication; Experimental analysis of proteins arrays. Data acquisition and processing; Applications of protein microarray types. Principles and methods in yeast two-hybrid system, Advances in yeast two hybrid system and its applications.

Sample preparation, First-dimension IEF with IPG; Second dimensional separation of proteins; Image analysis of 2-DE gels; DIGE, Protein expression profiling and comparative proteomics of complex proteomes using 2-DE.

Basics of Mass-spectrometry (MS) and bimolecular analysis; Common ionization methods for peptide/protein analysis; Principles of Time of Flight (TOF), Ion Trap (IT), and Orbitrap mass analyzers; Mass spectrometry-based proteomics: MALDI-TOF, Nano-LC-MS; Gas chromatography coupled to Mass spectrometry; Mass-spectrometry analysis of Post Translational Modifications of proteins.

Clinical proteomics, biomarker discovery, Medical proteomics-disease diagnosis, pharmaceutical proteomics, proteomics and plant biotechnology. Applications in cancer biology, cell biology, immunology, diseases and drug discovery. Applications of genomics, metabolomics, proteomics using case studies.

**TOTAL HOURS: 45 PERIODS**

**Course Outcomes:**

1. Explain some of the current genomics technologies and illustrate how these can be used to study gene function.
2. Apply interdisciplinary knowledge (e.g. chemistry, biophysics) to solve problems in genomics
3. Analyse the interaction and functions of protein using protein microarray technology.
4. Apply suitable proteomic techniques for identification, purification and modifications of Proteins.
5. Identify the biomarkers for the chronic diseases for drug discovery and development.
6. Critically review the recent updates in genomics and proteomics research.

**References:**

1. Brown T.A., "Genomes", BIOS Scientific Publishers Ltd, Oxford, 4th Edition, 2018.
2. Ali Masoudi-Nejad, Zahra Narimani , Nazanin Hosseinkhan , Next Generation Sequencing and Sequence Assembly: Methodologies and Algorithms, 1st edn,2013, Springer
3. Muller H. J. and Roder T. Microarrays. 1st edn, 2006, Elsevier Academic Press
4. Daniel C. Liebler, "Introduction to Proteomics: Tools for the New Biology", 1st edn, 2002, Humana Press, Totowa, New Jersey.
5. Hoffman E. D. and Stroobant V. Mass Spectrometry – Principles and Applications. 3<sup>rd</sup> edn, 2007, John Wiley & Sons Ltd.
6. Sandor Suhai, "Genomics and Proteomics- Functional and computational Aspects", 1st edn, Springer, New York, 2007.
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| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     |     |     |     |     |      | 2    | 3    |      | 3    |
| CO2 | 3   |     |     |     |     |     |     |     |     |      | 2    | 3    |      | 3    |
| CO3 | 2   | 2   | 3   |     | 3   |     |     |     |     |      | 1    | 3    | 2    | 3    |
| CO4 | 2   | 2   | 3   | 2   | 3   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO5 | 2   |     | 3   |     | 2   |     |     |     |     |      | 1    | 3    | 3    | 2    |
| CO6 | 3   | 3   | 2   | 2   | 2   | 2   |     |     |     | 1    | 3    | 3    | 3    | 3    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

**PB25016**

**Advances in Molecular Medicine**

| L | T | P | C |
|---|---|---|---|
| 3 | 0 | 0 | 3 |

**Course Learning Objectives:**

To understand molecular mechanisms underlying human diseases and to explore the use of molecular biology in diagnosis, prognosis, and therapy. Analyse emerging therapeutic modalities including RNA therapeutics, gene editing, and immunotherapies.

**Course Contents:**

Molecular mechanisms of genetic and acquired diseases, Overview of omics technologies (genomics, transcriptomics, proteomics, metabolomics). Role of non-coding RNAs and epigenetic regulation, gene-environment interactions in disease manifestation, genetic and physical mapping of human genome and identification of diseases gene.

Single-Gene Disorders, Autosomal Dominant Disorders -Polycystic Kidney Disease, Huntington's Disease. Autosomal Recessive Disorders-Cystic Fibrosis, Tay–Sachs Disease. PCR-Based Methods for Mutation Detection, Alternative Methods for Mutation Detection and DNA Sequencing for Disease Association, Microarray Approaches to Gene Expression Analysis, Methods for Analysis of DNA Methylation.

Clinical Diagnostic Technologies: Flow Cytometry, Medical Cytogenetics, Fluorescence In-Situ Hybridization, Immunohistochemistry, Laser Capture Microdissection (FFPE).

Molecular basis of infection and pathogenesis of Bacillus anthracis, Mycobacterium spp., Dengue infection, HIV Infection, Influenza Virus, Measles, Mumps, Chicken Pox, Poliomyelitis, Human Papilloma virus (HPV), Mechanism of bacterial persistence and survival, Antibiotic action and resistance mechanisms, Drug resistance - origin (genetic and non-genetic), mechanisms. Anti-viral chemotherapy and viral vaccines.

RNA-based therapeutics (mRNA, siRNA, antisense oligos), Monoclonal antibodies, bispecifics, and ADCs, CRISPR-Cas systems and genome editing in therapy, Regulatory and ethical considerations in gene editing.

Molecular targets in oncology and inflammation, CAR-T cell therapy and immune checkpoint inhibitors, Organoids, iPSCs, and regenerative therapeutics, Synthetic biology in therapeutic development, Nanoparticles and targeted drug delivery.

**TOTAL HOURS: 45 PERIODS**

**Course Outcomes:**

1. Explain the molecular processes involved in genetic and acquired diseases and apply omics technologies.
2. Recognize and explain the molecular basis of single-gene disorders and mutation detection methods.
3. Understand bacterial/viral infections and antibiotic resistance, applying this knowledge in diagnostics.
4. Evaluate RNA-based therapeutics, gene editing techniques and understand and evaluate the ethical, legal, and regulatory aspects of genetic technologies.
5. Assess the significance and potential of molecular targets in developing novel immunotherapies, regenerative therapeutics and tissue engineering.
6. Perform an in-depth analysis of molecular biology in the diagnosis and advanced development of therapeutics.

**REFERENCES:**

1. Alberts, B., Johnson, A., Lewis, J., Raff, M., Roberts, K., & Walter, P. (2014). Molecular biology of the cell (6th ed.). Garland Science.
2. Reddy, P., & Kalluri, R. (2018). Molecular genetics of single-gene disorders. Springer.
3. Sande, M. A., & Mandell, G. L. (2015). Mandell, Douglas, and Bennett's principles and practice of infectious diseases (8th ed.). Elsevier.
4. Carroll, D., & Koretke, D. (2020). Gene editing technologies: CRISPR and beyond (2nd ed.). Academic Press.
5. Elles, R., Mountfield, R. (2011). Molecular Diagnosis of Genetic Diseases. Springer Publication
6. Strachan, T., & Read, A. P. (2018). Human molecular genetics (4th ed.). Garland Science.
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8. Tashiro, K., & Hayashi, T. (2019). Cystic fibrosis and other genetic disorders. Springer.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     | 2   | 2   |     |     |     |     |      | 1    | 3    | 3    | 2    |
| CO2 | 3   | 3   |     | 2   | 1   |     |     |     |     |      |      | 2    | 3    | 1    |
| CO3 | 2   | 2   |     | 2   | 1   | 2   |     |     |     |      |      | 3    | 2    | 2    |
| CO4 | 2   | 3   | 2   |     | 2   | 2   | 3   |     |     |      | 2    | 2    | 3    | 3    |
| CO5 | 2   | 2   | 3   | 2   | 2   |     |     |     |     |      | 1    | 3    | 3    | 3    |
| CO6 | 3   | 3   | 2   | 3   | 2   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |

**Legend:** **3** – Strong correlation, **2** – Moderate correlation, **1** – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To Sensitize students about molecular biology and various facets of molecular medicine. To Familiarize students with emerging trends in medical devices.

**Course Contents:**

DNA, RNA and Protein: An overview; chromosomal structure & mutations; DNA polymorphism: human identity; clinical variability and genetically determined adverse reactions to drugs. PCR: Real-time; ARMS; Multiplex; ISH; FISH; ISA; RFLP; DHPLC; DGGE; CSCE; SSCP; Nucleic acid sequencing: new generations of automated sequencers; Microarray chips; EST; SAGE; microarray data normalization & analysis; molecular markers: 16S rRNA typing; Diagnostic proteomics: SELDI-TOF MS; Bioinformatics data acquisition & analysis.

Direct detection & identification of pathogenic-organisms that are slow growing or currently lacking a system of in vitro cultivation as well as genotypic markers of microbial resistance to specific antibiotics.

Exemplified by two inherited diseases for which molecular diagnosis has provided a dramatic improvement of quality of medical care: - Fragile X Syndrome: Paradigm of the new mutational mechanism of the unstable triplet repeats, von-Hippel Lindau disease: recent acquisition in the growing number of familial cancer syndromes.

Rationale of electronic biosensors; Essence of three types of electronic biosensors (i.e., potentiometric, amperometric, and cantilever-based sensors); Three essential metrics that define modern electronic sensors; detection time, sensitivity, and selectivity; Physics of detection time that allows one to organize every available sensor in a systematic way; Fundamental limits of detection of various classes of sensors; Opportunities and challenges of integrating sensors in a system platform.

Principles and applications of Calorimetric, Piezoelectric, semiconductor, impedimetric, based transducers; Biochemical Transducers: Electrode theory: electrode-tissue interface, metal-electrolyte interface, electrode-skin interface, electrode impedance, electrical conductivity of electrode jellies and creams

Photo detectors, optical fiber sensors, indicator mediated transducers; General principles of optical sensing, optical fiber temperature sensors; Pulse sensor: photoelectric pulse transducer, strain gauge pulse transducer Enzymes; Oligonucleotides Nucleic Acids; Lipids (Langmuir-Blodgett bilayers, Phospholipids, Liposomes); Membrane receptors and transporters; Immunoreceptors; Chemoreceptors.

**Course Outcomes:**

The student will be able to

1. Acquire knowledge on basics of genomics, proteomics and metabolomics that could be employed in early diagnosis and prognosis of human diseases and biomarker detection in body fluids.
2. Identify and detect pathogenic micro-organisms
3. Design the biomedical tool for the detection of inherited diseases
4. Understand the principles of biosensors classification and construction..
5. Apply the knowledge to analyse the configuration/distinction of optical sensors and bio-recognition systems
6. Acquire basic knowledge on molecular biology, molecular medicine and sensors

**REFERENCES:**

1. Campbell, A. M., & Heyer, L. J. (2006). *Discovering Genomics, Proteomics, and Bioinformatics* (2nd ed.). San Francisco: Benjamin Cummings.
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3. Patrinos, G. P., Ansorge, W., & Danielson, P. B., "Molecular Diagnostics", 3rd ed., Academic Press, 2016.
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6. F.Schellr,F.Schubert,J.Fedrowitz,(1997),FrontiersinBiosensors,Birkhauser.
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8. Webster, J. G. (Ed.). (2006). *Encyclopedia of Medical Devices and Instrumentation* (2nd ed., Volumes I–VI). New York, NY: John Wiley & Sons.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     | 2   |     | 2   |     |     |     |      | 2    | 3    | 2    | 3    |
| CO2 | 3   | 3   | 2   | 3   | 3   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO3 | 3   | 3   | 3   | 3   | 3   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO4 | 2   | 3   | 3   | 2   | 3   |     |     |     |     |      | 2    | 3    | 2    | 3    |
| CO5 | 2   | 2   | 2   | 2   | 3   |     |     |     |     |      | 2    | 2    | 2    | 3    |
| CO6 | 3   | 2   |     | 2   | 2   |     | 2   |     |     | 2    | 3    | 3    | 2    | 3    |

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| PB25018   | Metabolic Engineering | L | T | P | C |
|---|-----------------------|---|---|---|---|
|   |                       | 3 | 0 | 0 | 3 |
| <p><b>Course Learning Objective:</b><br/>To familiarize the student with quantitative approaches for analysing cellular metabolism. To make the students aware of the use of theoretical and experimental tools that can give insights into the structure and regulation of metabolic networks. To identify the optimal strategy for introducing directed genetic changes in the microorganisms with the aim of obtaining better production strains using case studies.</p>   |                       |   |   |   |   |
| <p><b>Course Contents:</b><br/>Introduction to metabolic engineering, comprehensive models of cellular reactions with stoichiometry and reaction rates; metabolic flux analysis of exactly/over/under determined systems. Shadow price, sensitivity analysis.</p> <p>Monitoring and measuring the metabolome, Methods for the experimental determination of metabolic fluxes by isotope labelling metabolic fluxes using various separation-analytical techniques. GC-MS for metabolic flux analysis.</p> <p>Genome wide technologies: DNA /phenotypic microarrays and proteomics. Development of Genomic scale metabolic model, Insilico Cells: studying genotype-phenotype relationships using constraint-based models, case studies in E. coli, S.cerevisiae metabolic network reconstruction methods.</p> <p>Optimization of metabolic network, Identification of targets for metabolic engineering; software and databases for genome scale modelling.</p> <p>Fundamental of Metabolic Control Analysis, control coefficients and the summation theorems, Determination of flux control coefficients. Multi-substrate enzyme kinetics, engineering multifunctional enzyme systems for optimal conversion, and a multi scale approach for the predictive modeling of metabolic regulation.</p> <p>Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis. Study of genome scale model in various systems for the production of green chemicals using software tools. Validation of the model with experimental parameters.</p> |                       |   |   |   |   |
| <p><b>Course Outcomes:</b></p> <ol style="list-style-type: none"> <li>1. Comprehend modern biology with engineering principles.</li> <li>2. Analyze metabolic fluxes using advanced analytical tools and interpret experimental metabolomics data.</li> <li>3. Construct and simulate genome-scale metabolic models and identify metabolic engineering targets using relevant software and databases.</li> <li>4. Apply Metabolic Control Analysis and enzyme kinetics for metabolic regulation.</li> <li>5. Validate metabolic engineering strategies for the production of biofuels, bioplastics, and green chemicals.</li> <li>6. Compare the potential metabolic engineering strategies using quantitative metabolic modelling.</li> </ol>  |                       |   |   |   |   |

## REFERENCES:

1. Stephanopoulos, G.N. "Metabolic Engineering: Principles and Methodologies." 1st edition, Academic Press / Elsevier, 1998.
2. Nielsen, J. and Villadsen, J. "Bioreaction Engineering Principles". 2011, 3rd edition, Springer, New York
3. Smolke, Christiana D., "The Metabolic Pathway Engineering Handbook Fundamentals", CRC Press Taylor & Francis, 1st edition 2010.
4. Voit, E.O. "Computational Analysis of Biochemical Systems: A Practical Guide for Biochemists and Molecular Biologists". Cambridge University Press, 1st edition 2000.
5. Scheper, T. "Metabolic Engineering" Vol.73 (Advances in Biochemical Engineering & Biotechnology) Springer, 1st edition, 2010.
6. Cortassa, S. et al, " An Introduction to Metabolic and Cellular Engineering", World Scientific Publishing, 2nd edition, 2012.
7. Kholodenko, Boris N and H. V. Westerhoff "Metabolic Engineering in the Post Genomic Era", Horizon Bioscience, 1st edition, 2004.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     |     |     | 2   |     |     |     |      |      | 3    | 2    | 2    |
| CO2 | 3   | 3   | 2   | 3   | 2   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO3 | 3   | 3   | 3   | 2   | 3   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO4 | 3   | 3   | 3   | 2   | 2   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |
| CO5 | 3   | 2   | 2   | 2   | 2   | 3   | 2   |     |     |      | 2    | 3    | 3    | 3    |
| CO6 | 3   | 3   | 3   | 2   | 2   | 2   |     |     |     | 2    | 2    | 3    | 3    | 3    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation

**Course Learning Objective:**

To introduce the principles, strategies, reagents, and methodologies used in bioconjugation and explore their applications in diagnostics, therapeutics, and biotechnology.

**Course Contents:**

Introduction to bioconjugation: scope, significance, and applications in diagnostics, imaging, and therapeutics. Overview of biomolecule structures—proteins, nucleic acids, and carbohydrates. Crosslinking strategies: covalent vs. non-covalent interactions.

Reactive chemistries targeting amine, carboxyl, thiol, hydroxyl, and aldehyde groups. Types of crosslinkers: zero-length, homobifunctional, heterobifunctional, and cleavable linkers. Applications of PEGylation and click chemistry in bioconjugation.

Conjugation techniques: antibody–enzyme conjugates, fluorescent probes, and oligonucleotide labeling. Methods for glycoprotein, liposome, and nanoparticle conjugation. Site-specific labeling and enzymatic modification strategies (e.g., transglutaminase).

Advanced systems: nanocarriers, polymer-drug conjugates, and quantum dot labeling. Streptavidin–biotin systems, enzyme-targeted nanoconjugates. Techniques for characterization: dynamic light scattering and related analytical tools.

Assay development and quality control for bioconjugates. Evaluation of toxicity, stability, and biological activity. Standard testing parameters and validation procedures.

Recent developments and challenges in bioconjugate engineering. Innovations in site-specific labeling, multifunctional conjugates, and smart delivery systems. Future trends and translational considerations.

**Course Outcomes:**

1. Explain the principles and strategies behind bioconjugation reactions.
2. Describe functional groups and reactive chemistries used in bioconjugation.
3. Analyze methods of protein, nucleic acid, and polysaccharide modifications.
4. Apply conjugation techniques in drug delivery, diagnostics, and nanotech.
5. Evaluate bioconjugation approaches for site-specificity and functional utility.
6. Design bioconjugation strategies for biomolecular systems with desired traits.

**REFERENCES:**

1. Hermanson, G. T. (2008). *Bioconjugate Techniques* (2nd ed.). Academic Press.
2. Mark, S. S. (Ed.). (2011). *Bioconjugation Protocols: Strategies and Methods* (2nd ed.). Springer.
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8. Sapsford, K. E., et al. (2006). Functionalizing Nanoparticles with Biological Molecules. Analytical Chemistry.

| COs | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 | PSO1 | PSO2 | PSO3 |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|
| CO1 | 3   | 2   |     | 1   |     |     |     |     |     |      | 1    | 3    | 2    | 2    |
| CO2 | 3   | 2   | 2   | 1   |     |     |     |     |     |      | 1    | 3    | 2    | 3    |
| CO3 | 3   | 3   | 3   | 2   | 2   |     |     |     |     |      | 2    | 3    | 3    | 3    |
| CO4 | 3   | 2   | 3   | 2   | 3   | 2   |     |     |     |      | 2    | 3    | 3    | 3    |
| CO5 | 3   | 3   | 2   | 3   | 2   | 2   | 2   |     |     |      | 2    | 3    | 3    | 3    |
| CO6 | 3   | 2   | 3   | 3   | 3   | 2   |     |     | 1   | 2    | 3    | 3    | 3    | 3    |

**Legend:** 3 – Strong correlation, 2 – Moderate correlation, 1 – Low correlation, Blank – No significant correlation