| Biomolecular Engineering and Biological Systems Design + Lab | | | |
|---|---|---|---|
| Course Code | 1MBBC201 | Scheme | 2026 |
| Type of course | **IPCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 : 2 | CIE Marks | 50 |
| Total Hours of Pedagogy L:T:P:SL:TW | 42: 0: 28 : 48 | SEE Marks | 50 |
| Credits | **4** | Total Marks | 100 |
| Type of Examination (IPCC): | Theory- CIE +SEE, and Lab- CIE only. | Exam Hours | 3 |

**Course outcome (Course Skill Set)**

At the end of the course, the student will be able to:

1. CO1 (L2 – Understand): Explain fundamental programming concepts, computational thinking, and the role of programming in biological and life-science research.
2. CO2 (L3 – Apply): Apply Python and R programming concepts to process, manipulate, and analyze biological data.
3. CO3 (L3 – Apply): Develop programs for biological sequence analysis, data processing, statistical analysis, and visualization using appropriate programming libraries and packages.
4. CO4 (L4 – Analyze): Analyze biological datasets using Python, R, Biopython, and Bioconductor and interpret computational results.
5. CO5 (L5 – Evaluate): Design and evaluate computational workflows for biological problems, integrating programming, statistical analysis, visualization, and reproducible data analysis.

**Module-1**

Advanced Molecular Biology and Gene Organization

Structure and organization of prokaryotic and eukaryotic genomes; DNA replication, repair and recombination; transcriptional and post-transcriptional regulation; translation and post-translational modifications; gene regulation in prokaryotes and eukaryotes; operon concept; epigenetic regulation; molecular basis of gene expression; molecular tools used in biological systems engineering.

Number of Hours: 8

**Module-2**

Recombinant DNA Technology and Genetic Engineering

Restriction enzymes and DNA modifying enzymes; cloning vectors; plasmids, bacteriophages and artificial chromosomes; gene cloning strategies; PCR and advanced PCR techniques; recombinant DNA construction; transformation and transfection methods; selectable and reporter markers; blue-white screening; expression vectors; recombinant protein production; molecular cloning workflow.

Number of Hours: 8

**Module-3**

Genome Engineering and Synthetic Biology

Genome editing technologies; CRISPR-Cas systems; TALENs and Zinc Finger Nucleases; site-directed mutagenesis; synthetic gene circuits; promoter engineering; pathway engineering; metabolic engineering; directed evolution; synthetic biology principles; engineering biological systems using modular genetic components.

Number of Hours: 8

**Module-4**

Molecular Engineering of Biological Systems

Engineering microbial cell factories; microbial strain improvement; mutagenesis and selection strategies; auxotrophic mutants; adaptive laboratory evolution; recombinant protein expression systems; enzyme engineering; pathway optimization; systems metabolic engineering; engineering microorganisms for industrial enzymes, metabolites, vaccines and therapeutic proteins.

Number of Hours: 9

**Module-5**

Biological Systems Design and Industrial Biotechnology

Design-Build-Test-Learn (DBTL) cycle; engineering biological systems for industrial applications; systems biology approaches in strain design; bioprocess integration; biosensors and synthetic biological circuits; biosafety and biosecurity; regulatory considerations; case studies on engineered microbial systems for pharmaceuticals, biofuels, biochemicals and precision fermentation.

Number of Hours: 9

**PRACTICAL COMPONENTS OF IPCC**

**List of experiments**

1. Generation of auxotrophic mutants
2. Replica plating and mutant screening
3. Mutant characterization and complementation studies
4. Chemical/UV mutagenesis and mutation analysis
5. Blue–white screening for recombinant clone identification
6. Plasmid transformation and selection
7. Recombinant protein expression analysis
8. Strain improvement for bioprocess applications
9. Enzyme/metabolite production using engineered strains
10. Phenotypic and biochemical characterization of improved strains

Textbooks

1. Brown, T. A., Gene Cloning and DNA Analysis: An Introduction, 8th Edition, Wiley-Blackwell.
2. Primrose, S. B. and Twyman, R. M., Principles of Gene Manipulation and Genomics, 8th Edition, Wiley-Blackwell.
3. Watson, J. D., Baker, T. A., Bell, S. P., Gann, A., Levine, M. and Losick, R., Molecular Biology of the Gene, 7th Edition, Pearson.
4. Alberts, B., Johnson, A., Lewis, J., Morgan, D., Raff, M., Roberts, K. and Walter, P., Molecular Biology of the Cell, 7th Edition, Garland Science.
5. Glick, B. R., Pasternak, J. J. and Patten, C. L., Molecular Biotechnology: Principles and Applications of Recombinant DNA, 5th Edition, ASM Press.

Reference Books

1. Clark, D. P. and Pazdernik, N. J., Biotechnology: Applying the Genetic Revolution, 2nd Edition, Academic Press.
2. Smolke, C. D. (Ed.), The Metabolic Pathway Engineering Handbook, CRC Press.
3. Nielsen, J. and Keasling, J. D., Engineering Biology, Academic Press.
4. Old, R. W. and Primrose, S. B., Principles of Gene Manipulation, Blackwell Scientific Publications.
5. Sambrook, J. and Russell, D. W., Molecular Cloning: A Laboratory Manual, 4th Edition, Cold Spring Harbor Laboratory Press.
6. Green, M. R. and Sambrook, J., Molecular Cloning: A Laboratory Manual, 4th Edition, Cold Spring Harbor Laboratory Press.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for a pass in the course.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

**Continuous Internal Evaluation:**

**(i)Theory component**

The CIE marks of 25 shall be earmarked for two tests.

The first test shall be conducted after completing two modules of the syllabus and the second one after completing the rest three modules.

Each test shall be conducted for 25 marks. The average of the two tests scaled down to 25 marks shall constitute the test marks for a maximum of 25 marks.

**(ii) Laboratory component**

Out of 25 marks, 15 marks shall be assigned for assessment of regular laboratory classwork as per the rubrics listed in Table - ICs/IPCCs1.

The remaining 10 marks shall be based on the practical test conducted by two Internal examiners appointed by the HoD. The allotment of marks shall be as per the rubrics defined for the practical test as indicated in the Table – ICs/IPCCs 1.

To qualify and become eligible to appear for the SEE of the IC/IPCC, a student shall secure at least 13 marks out of 25 in the CIE theory component, and at least 12marks in the CIE Practical component.

**Table – ICs/IPCCs 1Distribution of marks corresponding to laboratory component**

| Component | Description | Marks |
|---|---|---|
| **Allotment of marks for regular classwork** | | |
| Ability in Conducting Experiments | Initiative, skill, safety practices, teamwork, and independent handling of equipment during regular lab sessions. | 5 marks |
| Laboratory Record / Journal | Regular and neat maintenance of lab record, accuracy of results, and timely submission. | 10 marks |
| | **Subtotal** | **15** |
| **Allotment of marks for CIE practical test** | | |
| Laboratory Test / Experiment Performance | Ability to set up apparatus, follow procedure, take observations, and obtain correct results in the test experiment. | 5 marks |
| Viva-Voce | Understanding of theory, concepts, and experimental procedure; ability to explain results and answer related questions. | 5 marks |
| | **Subtotal** | **10** |
| | **Total** | **25** |

| Bioinformatics and Omics Technologies | | | |
|---|---|---|---|
| Course Code | **1MBBC202** | Scheme | 2026 |
| Type of Course | **PCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:

**CO1 (L2 – Understand):** Explain the organization, retrieval, management, and quality assessment of biological databases, bioinformatics resources, and biological data formats for genomics and molecular biology applications.

**CO2 (L3 – Apply):** Apply bioinformatics algorithms, computational tools, and statistical approaches for sequence analysis, genome annotation, phylogenetic analysis, genomic variation analysis, and omics data processing.

**CO3 (L4 – Analyze):** Analyze genomics, transcriptomics, proteomics, metabolomics, metagenomics, and single-cell omics datasets using advanced sequencing technologies and computational workflows.

**CO4 (L4 – Analyze):** Analyze clinical next-generation sequencing (NGS) workflows, library preparation strategies, variant interpretation, and precision medicine applications for disease diagnosis and therapeutic decision-making.

**CO5 (L5 – Evaluate):** Evaluate multi-omics integration, systems biology approaches, artificial intelligence, machine learning, and translational bioinformatics for biomarker discovery, personalized medicine, and biomedical research.

**Module-1**

**Biological Databases:** Introduction to biological databases; Primary, Secondary and Composite databases; Nucleic acid databases (GenBank, DDBJ, EMBL and NDB); Protein databases (PIR, SWISS-PROT, TrEMBL, PDB); Metabolic pathway database (KEGG, Reactome, EcoCyc, and MetaCyc); Small molecule databases (PubChem, Drug Bank, ZINC, CSD). Sequence databases, gene expression databases, sequence read archives, peptide databases, metabolite libraries, Phenomic databases, data file formats, conversion between formats, considerations for data submission to databases, considerations for using data retrieved from databases, data quality control.

Number of Hours: 08

**Module-2**

OMICS Data Science

introduction to bioinformatics, data-driven discovery in healthcare, and biological databases, including sequence, gene expression, sequence read archives, peptide, metabolite, and phenomic databases. Data file formats, format conversion, data submission, retrieval, and quality control. Genomic variations and mutations, data repositories, preprocessing, sequence alignment, variant calling, multiple sequence alignment, phylogenetic analysis, and introduction to metagenomics, transcriptomics, and metagenomic workflows. Fundamentals of Machine Learning for bioinformatics, including supervised and unsupervised learning, dimensionality reduction, clustering, classification, feature selection, and GUI-based analysis tools.

Number of Hours: 08

**Module-3**

**OMICS TECHNOLOGIES**

Introduction to NGS technology, NGS run setup, NGS run monitoring, microarray and SNP typing technology, sample QC and call rate identification, introduction to single cell technologies and spatial transcriptomics, sample preparation, for single cell gene expression, single cell immune profiling, fixed RNA profiling, Single Cell Assay for transposase-accessible chromatin using sequencing (ATAC -seq), single cell multiome ATAC + Gene Expression, spatial gene expression for FFPE, spatial gene expression for as well as fresh and frozen, introduction to proteomics, Mass spectrometry, 2D gel electrophoresis, DNA-Protein interaction studies, proteomics and drug designing platforms, Single-OMICS Data Analysis mutability analysis and interpretation, differential mutation analysis, copy number variation (CNV) analysis, genome-wide association studies (GWAS), hypervariable 14 regions of ribosomal RNA, microbiome variability and composition analysis, functional metagenomics, single-cell RNA-seq analysis, case-studies

Number of Hours: 08

**Module-4**

OMICS Data Analysis and Multi-Omics Integration (8 Hours): Genomic, metagenomic, transcriptomic, proteomic, and metabolomic data analysis. Read quality assessment, sequence alignment, variant calling (SNVs, CNVs, SVs), functional annotation, comparative genomics, genome visualization, and taxonomic profiling. Gene expression, differential expression, pathway and functional enrichment analysis. Mass spectrometry and NMR-based proteomic and metabolomic data analysis, peptide mass fingerprinting, and post-translational modifications. Multi-omics data integration, including normalization, batch effect correction, horizontal and vertical integration, meta-analysis, and applications in systems biology and precision medicine.

Number of Hours: 09

**Module-5**

Clinical Next-Generation Sequencing (NGS) Applications and Library Preparation (8 Hours): Clinical applications of NGS in diagnostic genomics, rare diseases, precision oncology, pharmacogenomics, non-invasive prenatal testing (NIPT), infectious disease genomics, and inherited genetic disorders. Clinical library preparation workflows for hereditary disease testing, HLA typing, targeted panels, tumor profiling, exome sequencing, mRNA profiling, preimplantation genetic testing, gene fusion detection, and germline variant analysis. Overview of NGS laboratory workflows, including DNA isolation, quality control, library preparation, target enrichment, fragmentation, adapter ligation, indexing, library QC, sequencing run setup, and onboard data analysis.

Number of Hours: 09

Textbooks

1. Pevsner, J., **Bioinformatics and Functional Genomics**, 4th Edition, Wiley-Blackwell.
2. Lesk, A.M., **Introduction to Bioinformatics**, 6th Edition, Oxford University Press.
3. Xiong, J., **Essential Bioinformatics**, Cambridge University Press.

Reference Books / Manuals

1. Mount, D.W., **Bioinformatics: Sequence and Genome Analysis**, 2nd Edition, Cold Spring Harbor Laboratory Press.
2. Brown, T.A., **Genomes**, 5th Edition, Garland Science.
3. Campbell, A.M. and Heyer, L.J., **Discovering Genomics, Proteomics and Bioinformatics**, 3rd Edition, Pearson.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be **50% each**. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of **40%** of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than **50% of the aggregate marks** obtained in CIE and SEE taken together.

**Continuous Internal Evaluation:**

**Continuous Comprehensive Assessments (CCA)+ Internal Assessment Test (IA) = Continuous Internal Evaluation CIE [25+25=50 marks]**

A minimum of **two Internal Assessment Tests (IA)** shall be conducted. Each test shall be conducted for a maximum of **25 marks**. The average of the two test marks shall be the marks secured by a student in IA.

In addition, **Continuous Comprehensive Assessment (CCA)** shall be conducted for a total of **25 marks**.

| DIGITAL BIOPROCESS ENGINEERING | | | |
|---|---|---|---|
| Course Code | **1MBBC203** | Scheme | 2026 |
| Type of Course | **PCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

CO1 (L2 – Understand): Explain the engineering principles governing the design, operation, and performance of microbial, mammalian, plant, enzyme, and advanced bioreactor systems.
CO2 (L3 – Apply): Apply reaction engineering, transport phenomena, kinetics, and thermodynamics to design and optimize industrial bioreactors.
CO3 (L4 – Analyze): Analyze mixing, aeration, oxygen transfer, scale-up, process control, and reactor performance using mathematical models, simulation tools, and computational techniques.
CO4 (L4 – Analyze): Analyze digital bioprocess technologies including PAT, automation, AI-assisted monitoring, digital twins, and Industry 4.0 concepts for intelligent biomanufacturing.
CO5 (L5 – Evaluate): Evaluate industrial bioreactor systems considering GMP, regulatory compliance, sustainability, techno-economic feasibility, and commercialization strategies.

**Module-1**

Fundamentals of Bioprocess Systems and Process Dynamics
Introduction to bioprocess engineering and industrial biomanufacturing; bioprocess development workflow from laboratory to commercial production; classification of bioprocesses; microbial growth kinetics (Monod, Logistic, Contois and Andrews models); batch, fed-batch, continuous, perfusion, chemostat and turbidostat operations; material and energy balances; reaction engineering fundamentals; transport phenomena; process dynamics; steady-state and transient behavior; process flow diagrams (PFD), Piping and Instrumentation Diagrams (P&ID); introduction to process modeling and simulation; industrial case studies in fermentation and biopharmaceutical manufacturing.

Number of Hours: 08

**Module-2**

Bioprocess Monitoring, Instrumentation and Process Control
Principles of process monitoring and control; process variables; measurement systems; sensors and transducers for temperature, pressure, pH, dissolved oxygen, biomass, glucose and metabolites; signal conditioning and data acquisition; process instrumentation; calibration and validation; Process Analytical Technology (PAT); feedback, feedforward and cascade control strategies; PID controllers; control valve characteristics; process dynamics and controller tuning; soft sensors; statistical process control (SPC); alarm management; fault detection and diagnosis; industrial examples of automated fermentation control.

Number of Hours: 08

**Module-3**

Automation, Digital Bioprocessing and Intelligent Manufacturing
Industrial automation architecture; Programmable Logic Controllers (PLC); Supervisory Control and Data Acquisition (SCADA); Distributed Control Systems (DCS); Human–Machine Interface (HMI); Industrial Internet of Things (IIoT); cloud-based biomanufacturing; digital twins; advanced process control; Model Predictive Control (MPC); artificial intelligence and machine learning for process optimization; digital batch records; Quality by Design (QbD); Design of Experiments (DoE); predictive maintenance; cybersecurity in industrial bioprocessing; digital validation; applications of automation in recombinant protein production, monoclonal antibodies, vaccines, precision fermentation, cultured meat, and cell and gene therapy manufacturing.

Number of Hours: 08

**Module-4**

Smart Bioprocess Monitoring, Automation and Digital Manufacturing
Bioprocess instrumentation; online and inline sensors; pH, dissolved oxygen, biomass, glucose, lactate, ammonia and metabolite sensors; Process Analytical Technology (PAT); Supervisory Control and Data Acquisition (SCADA); Distributed Control Systems (DCS); Programmable Logic Controllers (PLC); Industrial Internet of Things (IIoT); digital twins; soft sensors; advanced process control; model predictive control; Quality by Design (QbD); Design of Experiments (DoE); multivariate statistical process control; data acquisition;

process visualization; AI and machine learning applications; predictive maintenance; cloud-based manufacturing; cyber security in biomanufacturing; industrial software including SuperPro Designer, Aspen Plus, MATLAB, Python and BioPAT platforms.

Number of Hours: 09

**Module-5**

Industrial Biomanufacturing, Sustainability and Emerging Technologies

Industrial bioreactor design methodology; pilot-scale development; technology transfer; process validation; GMP; cGMP; regulatory requirements (USFDA, EMA, CDSCO, WHO); process qualification; continuous biomanufacturing; process intensification; sustainability in bioprocess engineering; carbon footprint; life-cycle assessment; techno-economic analysis; circular bioeconomy; precision fermentation; synthetic biology; modular manufacturing; decentralized biomanufacturing; AI-assisted process optimization; digital supply chains; bioreactors for gene therapy and cell therapy; future trends in autonomous manufacturing and Industry 5.0.

Number of Hours: 09

**Textbooks**

1. Shuler, M. L., & Kargi, F. Bioprocess Engineering: Basic Concepts, 3rd Edition, Pearson Education.
2. Doran, P. M. Bioprocess Engineering Principles, 2nd Edition, Academic Press.
3. Stanbury, P. F., Whitaker, A., & Hall, S. J. Principles of Fermentation Technology, 3rd Edition, Butterworth-Heinemann.
4. Seborg, D. E., Edgar, T. F., Mellichamp, D. A., & Doyle, F. J. III. Process Dynamics and Control, 4th Edition, Wiley.
5. Luyben, W. L. Process Modeling, Simulation and Control for Chemical Engineers, 2nd Edition, McGraw-Hill.

**Reference Books**

1. Nielsen, J., Villadsen, J., & Lidén, G. Bioreaction Engineering Principles, 3rd Edition, Springer.
2. Bailey, J. E., & Ollis, D. F. Biochemical Engineering Fundamentals, 2nd Edition, McGraw-Hill.
3. Lydersen, B. K., D'Elia, N. A., & Nelson, K. L. Bioprocess Engineering Systems, Equipment and Facilities, Wiley.
4. Garcia-Ochoa, F., & Gomez, E. Bioreactor Scale-Up and Oxygen Transfer, Springer.
5. Rathore, A. S., & Sofer, G. Process Validation in Manufacturing of Biopharmaceuticals, CRC Press.
6. Craven, S. Single-Use Technology in Biopharmaceutical Manufacture, Wiley.
7. Béla G. Lipták (Ed.). Instrument Engineers' Handbook: Process Control and Optimization, 5th Edition, CRC Press.
8. Richard C. Dorf & Robert H. Bishop. Modern Control Systems, 14th Edition, Pearson.
9. Smith, C. A., & Corripio, A. B. Principles and Practice of Automatic Process Control, 4th Edition, Wiley.
10. Marlin, T. E. Process Control: Designing Processes and Control Systems for Dynamic Performance, 2nd Edition, McGraw-Hill.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to the course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

**Continuous Internal Evaluation**

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = Continuous Internal Evaluation (CIE) [25 + 25 = 50 Marks]

A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.

**Continuous Comprehensive Assessment (CCA)**

Continuous Comprehensive Assessment (CCA) shall be conducted for 25 marks through bioreactor design assignments, process modeling and simulation exercises, computational analysis using MATLAB/Python/SuperPro Designer, process control and automation case studies, instrumentation and sensor selection exercises, Process Analytical Technology (PAT) and Quality by Design (QbD) applications, digital bioprocessing and Industry 4.0 case analyses, scale-up and techno-economic evaluation reports, industrial case studies, literature reviews, seminars, quizzes, presentations, and mini-projects involving AI-assisted bioprocess optimization, digital twins, and smart biomanufacturing.

| ADVANCED TRANSPORT PHENOMENA IN BIOPROCESS ENGINEERING | | | |
|---|---|---|---|
| Course Code | **1MBBC204** | Scheme | 2026 |
| Type of Course | **PCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:

CO1 (L2 – Understand):Explain the fundamental principles of momentum, heat, and mass transfer in biological and bioprocess systems.
CO2 (L3 – Apply):Apply transport phenomena principles to analyze fluid flow, heat transfer, and mass transfer operations in bioprocess equipment.
CO3 (L4 – Analyze):Analyze transport processes in bioreactors, bioseparations, membrane systems, and downstream processing using mathematical models and computational tools.
CO4 (L4 – Analyze):Analyze multiphase transport, non-Newtonian flow, computational fluid dynamics (CFD), and process intensification strategies in bioprocess engineering.
CO5 (L5 – Evaluate):Evaluate industrial transport systems considering energy efficiency, process optimization, sustainability, scale-up, and emerging digital engineering tools.

**Module-1**

Fundamentals of Transport Phenomena in Bioprocess Engineering
Review of transport processes; continuum concept; molecular and convective transport; transport properties of biological fluids; dimensional analysis; Buckingham π theorem; conservation equations for mass, momentum, and energy; differential and integral balances; transport in biological systems; introduction to non-Newtonian fluids; process flow diagrams; engineering applications in fermentation and biopharmaceutical industries.

Number of Hours: 08

**Module-2**

Momentum Transfer and Fluid Flow in Bioprocesses
Fluid statics and dynamics; laminar and turbulent flow; Reynolds number; Navier–Stokes equations (concepts); boundary layer theory; flow through pipes and fittings; flow measurement devices; pumps and pumping systems; mixing and agitation; power consumption; rheology of fermentation broths; non-Newtonian models (Bingham, Power-law, Herschel–Bulkley); flow in porous media; CFD concepts.

Number of Hours: 08

**Module-3**

Heat and Mass Transfer in Bioprocess Systems
Steady and unsteady heat conduction; convection; radiation; heat exchangers used in biotechnology; sterilization heat transfer; diffusion mechanisms; Fick's laws; convective mass transfer; interphase mass transfer; gas-liquid mass transfer; oxygen transfer coefficient (kLa); oxygen uptake rate (OUR); oxygen transfer rate (OTR); membrane transport; dialysis; ultrafiltration; transport limitations in immobilized cell systems.

Number of Hours: 08

**Module-4**

Multiphase Transport and Computational Bioprocess Engineering
Multiphase flow in bioreactors; bubble dynamics; gas holdup; liquid circulation; mixing time; residence time distribution (RTD); Computational Fluid Dynamics (CFD); turbulence models; numerical methods; process simulation; transport in packed-bed and fluidized-bed reactors; membrane bioreactors; microfluidics; transport in tissue engineering and bioprinting systems.

Number of Hours: 09

**Module-5**

Advanced Applications and Emerging Technologies

Transport phenomena in continuous bioprocessing; process intensification; microreactors; organ-on-chip systems; digital process modeling; AI-assisted transport modeling; machine learning for process optimization; sustainability; energy-efficient bioprocess design; carbon footprint reduction; techno-economic analysis; scale-up strategies; Industry 4.0; digital twins; future trends in smart bioprocess engineering.

Number of Hours: 09

**Textbooks**

1. Bird, R. B., Stewart, W. E., & Lightfoot, E. N., Transport Phenomena, 2nd Edition, John Wiley & Sons.
2. Welty, J. R., Wicks, C. E., Wilson, R. E., & Rorrer, G. L., Fundamentals of Momentum, Heat and Mass Transfer, 6th Edition, John Wiley & Sons.
3. Doran, P. M., Bioprocess Engineering Principles, 2nd Edition, Academic Press.

**Reference Books**

1. Shuler, M. L., & Kargi, F., Bioprocess Engineering: Basic Concepts, 3rd Edition, Pearson.
2. Geankoplis, C. J., Transport Processes and Separation Process Principles, 5th Edition, Pearson.
3. Bennett, C. O., & Myers, J. E., Momentum, Heat and Mass Transfer, McGraw-Hill.
4. Levenspiel, O., Chemical Reaction Engineering, 3rd Edition, Wiley.
5. Nielsen, J., Villadsen, J., & Lidén, G., Bioreaction Engineering Principles, Springer.
6. Incropera, F. P., Bergman, T. L., Lavine, A. S., & DeWitt, D. P., Fundamentals of Heat and Mass Transfer, Wiley.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to the course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

**Continuous Internal Evaluation**

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = Continuous Internal Evaluation (CIE) [25 + 25 = 50 Marks]

A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.

**Continuous Comprehensive Assessment (CCA)**

Continuous Comprehensive Assessment (CCA) shall be conducted for 25 marks through transport phenomena problem-solving assignments, computational modeling using MATLAB/Python, CFD-based case studies, heat and mass transfer calculations, process simulation exercises, industrial case analyses, membrane transport design problems, scale-up studies, literature reviews, seminars, quizzes, presentations, and mini-projects involving process optimization, energy-efficient bioprocess design, and digital engineering tools for transport analysis.

| DESIGN AND OPERATION OF BIOREACTOR SYSTEMS | | | |
|---|---|---|---|
| Course Code | **1MBBC205A** | Scheme | 2026 |
| Type of Course | **PEC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:

CO1 (L2 – Understand): Explain the principles governing the design, operation, and performance of microbial, mammalian, plant, and enzyme bioreactor systems.

CO2 (L3 – Apply): Apply engineering principles, transport phenomena, reaction kinetics, and mass transfer concepts for bioreactor design and process optimization.

CO3 (L4 – Analyze): Analyze mixing, oxygen transfer, scale-up, process control, and bioreactor performance using mathematical models and computational tools.

CO4 (L4 – Analyze): Analyze advanced bioreactor configurations, automation systems, digital bioprocessing, and Process Analytical Technology (PAT) for industrial biomanufacturing.

CO5 (L5 – Evaluate): Evaluate industrial bioreactor systems considering GMP, sustainability, continuous bioprocessing, techno-economic analysis, and emerging applications in biopharmaceutical and bio-based industries

**Module-1**

Fundamentals of Bioreactor Engineering

Introduction to bioreactor systems; classification and applications of bioreactors in pharmaceutical, food, environmental and industrial biotechnology; bioprocess development workflow; microbial growth kinetics (Monod, Contois and Logistic models); batch, fed-batch, continuous culture, chemostat and turbidostat; material and energy balances; transport phenomena in bioreactors; reactor performance parameters; residence time distribution; process flow diagrams; industrial case studies.

Number of Hours: 08

**Module-2**

Bioreactor Design Principles

Bioreactor design criteria; reactor geometry; agitation and mixing; impeller design and selection; power requirement; gas dispersion; sparger design; oxygen transfer mechanisms; volumetric oxygen transfer coefficient (kLa); gas holdup; heat transfer; foam formation and control; sterilization in bioreactors; CIP and SIP systems; scale-up and scale-down strategies; geometric, kinematic and dynamic similarity; computational fluid dynamics (CFD) concepts.

Number of Hours: 08

**Module-3**

Advanced Bioreactor Systems

Stirred tank reactors; airlift and bubble column reactors; packed-bed, fluidized-bed and membrane bioreactors; immobilized enzyme and immobilized cell reactors; perfusion bioreactors; hollow fiber bioreactors; wave bioreactors; single-use bioreactors; photobioreactors; anaerobic digesters; bioelectrochemical reactors; stem-cell and tissue engineering bioreactors; cultured meat bioreactors; applications in recombinant protein production, monoclonal antibodies, vaccines, enzymes and cell therapy.

Number of Hours: 08

**Module-4**

Bioprocess Monitoring, Automation and Digital Biomanufacturing

Bioreactor instrumentation; sensors for pH, dissolved oxygen, temperature, biomass, glucose and metabolites; Process Analytical Technology (PAT); Supervisory Control and Data Acquisition (SCADA); Programmable Logic Controllers (PLC); Distributed Control Systems (DCS); soft sensors; digital twins; Industrial Internet of Things (IIoT); artificial intelligence and machine learning for fermentation optimization; statistical process control; Design of Experiments (DoE); Quality by Design (QbD); data acquisition and bioprocess analytics; industrial software (SuperPro Designer, Aspen Plus, MATLAB, Python applications).

Number of Hours: 08

**Module-5**

Industrial Bioreactor Design and Emerging Applications

Industrial scale-up and commercialization; GMP and regulatory requirements for biopharmaceutical manufacturing; validation and process qualification; continuous biomanufacturing; process intensification; sustainability and green bioprocess engineering; techno-economic analysis; life-cycle assessment; carbon footprint analysis; circular bioeconomy; precision fermentation; synthetic biology; bioreactors for gene and cell therapy; AI-assisted bioprocess optimization; future trends in smart biomanufacturing and Industry 4.0.

Number of Hours: 09

Textbooks

- Shuler, M. L. and Kargi, F., Bioprocess Engineering: Basic Concepts, 3rd Edition, Pearson Education.
- Doran, P. M., Bioprocess Engineering Principles, 2nd Edition, Academic Press.
- Stanbury, P. F., Whitaker, A., and Hall, S. J., Principles of Fermentation Technology, 3rd Edition, Butterworth-Heinemann.

Reference Books / Manuals

- Nielsen, J., Villadsen, J., and Lidén, G., Bioreaction Engineering Principles, 3rd Edition, Springer.
- Bailey, J. E. and Ollis, D. F., Biochemical Engineering Fundamentals, 2nd Edition, McGraw-Hill.
- Lydersen, B. K., D'Elia, N. A., and Nelson, K. L., Bioprocess Engineering Systems, Equipment and Facilities, Wiley.
- Garcia-Ochoa, F. and Gomez, E., Bioreactor Scale-Up and Oxygen Transfer, Springer.
- Craven, S., Single-Use Technology in Biopharmaceutical Manufacture, Wiley.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

Continuous Internal Evaluation

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = Continuous Internal Evaluation (CIE) [25 + 25 = 50 Marks]

A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.
Continuous Comprehensive Assessment (CCA) shall be conducted for 25 marks through assignments, seminars, case studies, computational exercises, literature reviews, industrial case analyses, quizzes, presentations, and mini-projects on bioreactor design and digital bioprocessing.

| ADVANCED BIOPROCESS DATA ANALYSIS AND MODELING | | | |
|---|---|---|---|
| Course Code | **1MBBC205B** | Scheme | 2026 |
| Type of Course | **PEC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:

CO1 (L2 – Understand): Explain the principles of bioprocess data acquisition, statistical analysis, and mathematical modeling used in modern bioprocess industries.
CO2 (L3 – Apply): Apply statistical methods, data visualization techniques, and computational tools to analyze bioprocess data.
CO3 (L4 – Analyze): Analyze microbial growth kinetics, substrate utilization, product formation, and bioreactor performance using mathematical and mechanistic models.
CO4 (L5 – Evaluate): Evaluate machine learning, multivariate analysis, Process Analytical Technology (PAT), and digital bioprocess monitoring for process optimization.
CO5 (L5 – Evaluate): Evaluate predictive models, digital twins, techno-economic analysis, and data-driven decision-making for industrial bioprocess development.

**Module-1**

Fundamentals of Bioprocess Data Analysis
Introduction to bioprocess data science; types and sources of bioprocess data; experimental design; data acquisition systems; data quality assessment; preprocessing of biological data; data cleaning, normalization and scaling; exploratory data analysis; statistical distributions; descriptive statistics; hypothesis testing; confidence intervals; regression analysis; correlation analysis; data visualization techniques; industrial applications in fermentation and biopharmaceutical manufacturing.

Number of Hours: 08

**Module-2**

Mathematical Modeling of Bioprocesses
Modeling concepts; deterministic and stochastic models; structured and unstructured models; segregated and unsegregated models; microbial growth kinetics (Monod, Andrews, Contois, Logistic and Luedeking–Piret models); substrate utilization and product formation kinetics; enzyme kinetics; oxygen transfer modeling; mass and energy balances; dynamic models of batch, fed-batch and continuous bioreactors; parameter estimation; model validation and sensitivity analysis.

Number of Hours: 08

**Module-3**

Statistical Modeling and Multivariate Data Analysis
Design of Experiments (DoE); factorial and fractional factorial designs; Response Surface Methodology (RSM); Analysis of Variance (ANOVA); Principal Component Analysis (PCA); Partial Least Squares (PLS); cluster analysis; multivariate statistical process control (MSPC); chemometrics; process capability analysis; statistical quality control; process optimization; industrial case studies in fermentation, downstream processing, and pharmaceutical manufacturing.

Number of Hours: 08

**Module-4**

Machine Learning and Artificial Intelligence in Bioprocess Engineering
Introduction to machine learning; supervised and unsupervised learning; regression models; decision trees; random forests; support vector machines; artificial neural networks; deep learning overview; predictive analytics; soft sensors; real-time process monitoring; anomaly detection; digital twins; Industrial Internet of Things (IIoT); cloud-based bioprocess analytics; applications of Python, R, MATLAB, and JMP in bioprocess modeling.

Number of Hours: 09

**Module-5**

Industrial Applications and Emerging Trends
Digital biomanufacturing; Quality by Design (QbD); Quality by Control (QbC); process optimization using AI; model predictive control (MPC); process simulation; techno-economic analysis; life cycle assessment (LCA);

sustainability metrics; continuous bioprocessing; precision fermentation; synthetic biology data analytics; omics data integration; systems biology; regulatory considerations for data integrity (FDA 21 CFR Part 11); FAIR data principles; future trends in Industry 4.0 and Bioprocess 4.0.

Number of Hours: 09

**Textbooks**

1. Shuler, M. L., Kargi, F., and DeLisa, M. P., Bioprocess Engineering: Basic Concepts, 3rd Edition, Pearson.
2. Doran, P. M., Bioprocess Engineering Principles, 2nd Edition, Academic Press.
3. Dunn, W. B., Ellis, D. I., and Goodacre, R., Metabolomics, Data Analysis and Bioinformatics, Springer.

**Reference Books / Manuals**

1. Montgomery, D. C., Design and Analysis of Experiments, 10th Edition, Wiley.
2. Box, G. E. P., Hunter, J. S., and Hunter, W. G., Statistics for Experimenters, 2nd Edition, Wiley.
3. James, G., Witten, D., Hastie, T., and Tibshirani, R., An Introduction to Statistical Learning, 2nd Edition, Springer.
4. Hastie, T., Tibshirani, R., and Friedman, J., The Elements of Statistical Learning, 2nd Edition, Springer.
5. Nielsen, J., Villadsen, J., and Lidén, G., Bioreaction Engineering Principles, 3rd Edition, Springer.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

Continuous Internal Evaluation

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = Continuous Internal Evaluation (CIE) [25 + 25 = 50 Marks]

A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.

Continuous Comprehensive Assessment (CCA) shall be conducted for 25 marks through assignments, case studies, Python/R-based data analysis exercises, statistical modeling, process simulation, journal article reviews, seminars, industrial datasets, and mini-projects involving bioprocess optimization.

| TECHNOLOGY TRANSFER AND COMMERCIALIZATION OF BIOPRODUCTS | | | |
|---|---|---|---|
| Course Code | **1MBBC205C** | Scheme | 2026 |
| Type of Course | **PEC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

1. At the end of the course, the student will be able to:
2. CO1 (L2 – Understand): Explain the principles of bioprocess data acquisition, statistical analysis, and mathematical modeling used in modern bioprocess industries.
3. CO2 (L3 – Apply): Apply statistical methods, data visualization techniques, and computational tools to analyze bioprocess data.
4. CO3 (L4 – Analyze): Analyze microbial growth kinetics, substrate utilization, product formation, and bioreactor performance using mathematical and mechanistic models.
5. CO4 (L5 – Evaluate): Evaluate machine learning, multivariate analysis, Process Analytical Technology (PAT), and digital bioprocess monitoring for process optimization.
6. CO5 (L5 – Evaluate): Evaluate predictive models, digital twins, techno-economic analysis, and data-driven decision-making for industrial bioprocess development.

**Module-1**

Innovation Ecosystem and Technology Transfer

Innovation in biotechnology; research translation; Technology Readiness Levels (TRLs); innovation lifecycle; laboratory-to-market pathway; innovation ecosystems; university-industry collaboration; technology transfer offices (TTOs); invention disclosure; technology scouting; innovation management; entrepreneurship in biotechnology; incubation centres; accelerators; technology parks; startup ecosystem; National Innovation Foundation (NIF); Biotechnology Industry Research Assistance Council (BIRAC); Atal Innovation Mission (AIM); case studies of successful biotechnology commercialization.

Number of Hours: 08

**Module-2**

Intellectual Property Rights and Regulatory Framework

Intellectual property in biotechnology; patents, copyrights, trademarks, industrial designs, geographical indications, trade secrets, plant breeders' rights; patentability criteria; patent drafting and filing; patent landscape analysis; freedom-to-operate (FTO); patent infringement; licensing agreements; material transfer agreements (MTA); confidentiality agreements (NDA); international treaties (TRIPS, PCT, Budapest Treaty); regulatory framework for biopharmaceuticals, biosimilars, medical devices, diagnostics, food biotechnology and industrial biotechnology; biosafety, bioethics, Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Clinical Practices (GCP).

Number of Hours: 08

**Module-3**

Commercialization Strategies and Business Development

Technology valuation; market assessment; customer discovery; value proposition design; business model development using Business Model Canvas (BMC); Lean Startup methodology; product-market fit; market access strategies; competitive analysis; pricing strategies; reimbursement concepts; licensing, franchising, joint ventures, contract research and manufacturing; project management; supply chain management; manufacturing scale-up; commercialization roadmap; industrial case studies.

Number of Hours: 08

**Module-4**

Bioentrepreneurship, Funding and Financial Management

Entrepreneurship fundamentals; startup formation; company registration; business plan preparation; financial statements; budgeting; cost estimation; techno-economic analysis; venture capital; angel investors; crowdfunding; seed funding; government funding schemes (BIRAC, DBT, DST, Startup India, MSME); investment readiness; valuation of biotechnology startups; mergers and acquisitions; risk assessment; ESG principles; sustainability and circular bioeconomy; AI-enabled market intelligence.

Number of Hours: 09

**Module-5**

Commercialization of Bioproducts and Emerging Technologies

Commercialization pathways for vaccines, biosimilars, monoclonal antibodies, recombinant proteins, industrial enzymes, probiotics, nutraceuticals, precision fermentation products, cultured meat, cell and gene therapies, biomaterials, biofertilizers, biofuels and medical devices; regulatory submissions (IND, NDA, BLA, CDSCO); quality assurance; technology transfer documentation; validation protocols; digital manufacturing; Industry 4.0; technology due diligence; product launch strategy; global commercialization; case studies of successful biotechnology startups and technology transfer.

Number of Hours: 09

Textbooks

- Wheelwright, S. C. and Clark, K. B., Revolutionizing Product Development, Free Press.
- Schilling, M. A., Strategic Management of Technological Innovation, 7th Edition, McGraw-Hill.
- Hisrich, R. D., Peters, M. P., and Shepherd, D. A., Entrepreneurship, 12th Edition, McGraw-Hill.

Reference Books / Manuals

- Pressman, L., Patent It Yourself, Nolo Press.
- Barringer, B. R. and Ireland, R. D., Entrepreneurship: Successfully Launching New Ventures, Pearson.
- Cooper, R. G., Winning at New Products, Basic Books.
- OECD, Commercialising Public Research: New Trends and Strategies, OECD Publications.
- World Intellectual Property Organization (WIPO), WIPO Intellectual Property Handbook.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

Continuous Internal Evaluation

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = Continuous Internal Evaluation (CIE) [25 + 25 = 50 Marks]

A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.

Continuous Comprehensive Assessment (CCA) shall be conducted for 25 marks through patent landscape analysis, technology transfer case studies, startup business plan preparation, commercialization strategy reports, market analysis, investment pitch presentations, regulatory documentation exercises, and seminars.

| REGULATORY AFFAIRS AND QUALITY COMPLIANCE | | | |
|---|---|---|---|
| Course Code | **1MBBC205D** | Scheme | 2026 |
| Type of Course | **PEC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:

1. CO1 (L2 – Understand): Explain the principles of global regulatory affairs, quality management systems, and compliance requirements governing biotechnology, biopharmaceutical, medical device, and cell and gene therapy products.
2. CO2 (L3 – Apply): Apply Good Regulatory Practices (GxP), quality systems, documentation, validation, and risk management principles to ensure compliance throughout the product lifecycle.
3. CO3 (L4 – Analyze): Analyze regulatory pathways, product registration requirements, quality assurance systems, audits, inspections, and regulatory submissions for biologics and advanced therapies.
4. CO4 (L5 – Evaluate): Evaluate international regulatory frameworks, digital quality systems, regulatory intelligence, and quality risk management strategies for global commercialization.
5. CO5 (L6 – Create): Develop regulatory strategies, quality documentation, validation protocols, audit plans, and compliance programs for biotechnology industries.

**Module-1**

Fundamentals of Regulatory Affairs and Global Regulatory Frameworks

Introduction to regulatory affairs; regulatory science; product lifecycle management; regulatory strategy; global regulatory environment; regulatory agencies and their roles (CDSCO, US FDA, EMA, MHRA, PMDA, WHO, ICH, PIC/S); pharmaceutical, biotechnology and medical device regulations; biologics, biosimilars, vaccines, gene therapy and cell therapy regulations; Quality Management Systems (QMS); Quality Assurance (QA), Quality Control (QC), Quality by Design (QbD); Pharmaceutical Quality System (ICH Q10); Good Documentation Practices (GDP); ALCOA+ principles; regulatory compliance throughout product development.

Number of Hours: 08

**Module-2**

Good Regulatory Practices and Validation

Good Manufacturing Practices (cGMP); Good Laboratory Practices (GLP); Good Clinical Practices (GCP); Good Distribution Practices (GDP); Good Pharmacovigilance Practices (GVP); Good Automated Manufacturing Practices (GAMP 5); Standard Operating Procedures (SOPs); documentation practices; deviation management; Corrective and Preventive Actions (CAPA); change control; qualification and validation (DQ, IQ, OQ, PQ); process validation; cleaning validation; analytical method validation; equipment qualification; computerized system validation; electronic records and electronic signatures (21 CFR Part 11); Annex 11; quality metrics; contamination control strategy (CCS).

Number of Hours: 08

**Module-3**

Regulatory Submission and Product Approval

Drug discovery and development; preclinical studies; clinical trials; Investigational New Drug (IND); Clinical Trial Application (CTA); New Drug Application (NDA); Biologics License Application (BLA); Abbreviated New Drug Application (ANDA); biosimilar approval pathway; Chemistry, Manufacturing and Controls (CMC); Common Technical Document (CTD); electronic CTD (eCTD); pharmacovigilance; post-marketing surveillance; product recalls; labeling requirements; regulatory inspections; lifecycle management; regulatory intelligence; international harmonization (ICH, WHO, ISO).

Number of Hours: 08

**Module-4**

Quality Compliance, Audits and Risk Management

Quality audits (internal, supplier and regulatory); inspection readiness; FDA and WHO inspections; ISO 9001 and ISO 13485 Quality Management Systems; Quality Risk Management (ICH Q9); Failure Mode and Effects Analysis (FMEA); Hazard Analysis and Critical Control Points (HACCP); Statistical Process Control (SPC); Six

Sigma and Lean Quality; root cause analysis; complaint handling; product recalls; environmental monitoring; contamination control; supplier qualification; continuous improvement; digital Quality Management Systems (eQMS); AI-assisted quality monitoring and compliance analytics.

Number of Hours: 09

**Module-5**

Emerging Trends in Regulatory Affairs and Quality Compliance
Regulatory requirements for ATMPs (Advanced Therapy Medicinal Products); CAR-T cell therapy; stem cell products; mRNA therapeutics; regenerative medicine; tissue-engineered products; nanomedicines; companion diagnostics; Software as a Medical Device (SaMD); Artificial Intelligence in healthcare regulation; cybersecurity for regulated industries; Regulatory Affairs 4.0; digital quality management systems (eQMS); blockchain in pharmaceutical supply chains; Real-World Evidence (RWE); Real-World Data (RWD); sustainability and ESG compliance; regulatory intelligence platforms; global harmonization; future trends in biotechnology regulation.

Number of Hours: 09

Textbooks

1. Douglas J. Pisano and David S. Mantus, Textbook of FDA Regulatory Affairs, 3rd Edition, Informa Healthcare.
2. Sandy Weinberg, Good Manufacturing Practices for Pharmaceuticals, 7th Edition, CRC Press.
3. Richard M. Pai and H. Joanne Lee, Biotechnology Regulatory Affairs, CRC Press.

Reference Books / Manuals

1. ICH Guidelines (Q8, Q9, Q10, E6, M4 – Latest Versions).
2. US FDA Guidance for Industry (Current Editions).
3. WHO Good Manufacturing Practices for Pharmaceutical Products.
4. ISO 13485: Medical Devices – Quality Management Systems.
5. EudraLex – The Rules Governing Medicinal Products in the European Union.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

**Continuous Internal Evaluation**

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = Continuous Internal Evaluation (CIE) [25 + 25 = 50 Marks]

A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.

Continuous Comprehensive Assessment (CCA) shall include regulatory dossier preparation, SOP development, validation protocol design, audit simulation, CAPA reports, quality risk assessment, regulatory case studies, seminars, literature reviews, and a mini-project on regulatory strategy or quality compliance.

| Biotherapeutics and Biosimilars | | | |
|---|---|---|---|
| Course Code | 1MBBC206A | Scheme | 2026 |
| Type of Course | **PCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:

CO1 (L2 – Understand): Explain the principles of biotherapeutics, biosimilars, their classification, mechanisms of action, and clinical applications.

CO2 (L3 – Apply): Apply molecular biology, recombinant DNA technology, cell culture, and bioprocess engineering principles for the development and production of biotherapeutic products.

CO3 (L3 – Apply): Demonstrate knowledge of analytical characterization, quality assessment, formulation, and manufacturing strategies for biotherapeutics and biosimilars.

CO4 (L4 – Analyze): Analyze regulatory requirements, comparability studies, immunogenicity, pharmacokinetics, pharmacovigilance, and quality-by-design approaches for biosimilar development.

CO5 (L5 – Evaluate): Evaluate emerging trends in next-generation biotherapeutics, cell and gene therapies, personalized medicine, and global regulatory frameworks.

**Module-1**

Introduction to Biotherapeutics

Overview of biopharmaceuticals and biotherapeutics; evolution of biologics; classification of biotherapeutics; recombinant proteins; monoclonal antibodies; antibody fragments; fusion proteins; peptide therapeutics; hormones; cytokines; growth factors; enzymes; vaccines; nucleic acid therapeutics; mechanism of action; therapeutic targets; comparison of biologics with conventional pharmaceuticals

Number of Hours: 08

**Module-2**

Development and Manufacturing of Biotherapeutics

Selection of therapeutic targets; recombinant DNA technology; host expression systems (bacterial, yeast, mammalian, insect and plant cells); vector design; upstream bioprocessing; cell culture technologies; fermentation; downstream processing; purification strategies; chromatography; viral clearance; formulation development; stability studies; Good Manufacturing Practices (GMP); Quality by Design (QbD); Process Analytical Technology (PAT).

Number of Hours: 08

**Module-3**

Biosimilars: Development and Analytical Characterization

Concept of biosimilars; reference biologics; comparability exercises; physicochemical characterization; structural characterization; biological activity assays; bioanalytical techniques; glycosylation analysis; protein aggregation; impurity profiling; stability assessment; bioequivalence; pharmacokinetics and pharmacodynamics; immunogenicity evaluation; analytical similarity assessment.

Number of Hours: 08

**Module-4**

Regulatory Affairs and Clinical Development of Biosimilars

Global regulatory guidelines for biosimilars; WHO, USFDA, EMA, CDSCO and ICH guidelines; preclinical evaluation; clinical trial design; biosimilar approval pathway; pharmacovigilance; risk management; intellectual property rights; patent landscape; naming conventions; interchangeability; substitution policies; quality assurance; regulatory documentation; commercialization strategies.

Number of Hours: 09

**Module-5**

Emerging Biotherapeutics and Future Perspectives

Next-generation monoclonal antibodies; antibody-drug conjugates; bispecific antibodies; nanobody therapeutics; RNA therapeutics; CRISPR-based therapeutics; gene therapy; CAR-T cell therapy; stem cell

therapeutics; regenerative medicine; microbiome therapeutics; precision medicine; AI in biologics discovery and development; continuous biomanufacturing; future trends in biotherapeutics and biosimilars.

**Number of Hours: 09**

Textbooks

1. Walsh, G., Biopharmaceuticals: Biochemistry and Biotechnology, 3rd Edition, Wiley.
2. Crommelin, D. J. A., Sindelar, R. D. and Meibohm, B. (Eds.), Pharmaceutical Biotechnology: Fundamentals and Applications, 5th Edition, Springer.
3. Shukla, A. A., Etzel, M. R. and Gadam, S., Process Scale Purification of Antibodies, Wiley.
4. Jiskoot, W., Crommelin, D. J. A. and Storm, G. (Eds.), Methods for Structural Analysis of Protein Pharmaceuticals, AAPS Press.

Reference Books / Manuals

1. Rosenberg, A. S. and Demeule, B. (Eds.), Biobetters: Protein Engineering to Approach the Curative, Springer.
2. Rader, R. A., Biosimilars and Interchangeable Biologics: Strategic Elements, BioPlan Associates.
3. Wang, W. and Roberts, C. J., Aggregation of Therapeutic Proteins, Wiley.
4. Sharma, B. (Ed.), Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development, Springer.
5. Jha, A., Biopharmaceuticals and Biosimilars: Regulatory and Quality Perspectives, CRC Press.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be **50% each**. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of **40%** of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than **50% of the aggregate marks** obtained in CIE and SEE taken together.

**Continuous Internal Evaluation:**

**Continuous Comprehensive Assessments (CCA)+ Internal Assessment Test (IA) = Continuous Internal Evaluation CIE [25+25=50 marks]**

A minimum of **two Internal Assessment Tests (IA)** shall be conducted. Each test shall be conducted for a maximum of **25 marks**. The average of the two test marks shall be the marks secured by a student in IA.

In addition, **Continuous Comprehensive Assessment (CCA)** shall be conducted for a total of **25 marks**.

| Metabolic Engineering and Synthetic Biology | | | |
|---|---|---|---|
| Course Code | 1MBBC206B | Scheme | 2026 |
| Type of Course | **PCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:
CO1 (L2 – Understand): Explain the principles of cellular metabolism, metabolic networks, metabolic fluxes, and synthetic biology for engineering biological systems.
CO2 (L3 – Apply): Apply metabolic engineering strategies, recombinant DNA technology, and synthetic biology tools to redesign metabolic pathways for enhanced production of biomolecules.
CO3 (L3 – Apply): Utilize systems biology, genome engineering, metabolic flux analysis, and computational tools for pathway optimization and strain development.
CO4 (L4 – Analyze): Analyze engineered metabolic pathways using omics data, metabolic models, flux balance analysis, and systems-level approaches.
CO5 (L5 – Evaluate): Evaluate synthetic biology platforms and metabolic engineering strategies for industrial biotechnology, sustainable biomanufacturing, and precision medicine.

**Module-1**

Fundamentals of Metabolic Engineering
Introduction to metabolic engineering; review of cellular metabolism; central carbon metabolism; glycolysis; pentose phosphate pathway; TCA cycle; amino acid, lipid and nucleotide metabolism; metabolic regulation; metabolic networks; stoichiometry; metabolic control analysis; principles of pathway engineering; design-build-test-learn (DBTL) cycle; overview of synthetic biology.

Number of Hours: 08

**Module-2**

Metabolic Pathway Engineering
Metabolic flux analysis; flux balance analysis (FBA); isotope labeling; elementary mode analysis; pathway optimization; precursor engineering; cofactor engineering; elimination of competing pathways; transporter engineering; genome-scale metabolic models; engineering microbial cell factories; industrial microorganisms; pathway optimization for production of amino acids, organic acids, biofuels, enzymes and pharmaceuticals.

Number of Hours: 08

**Module-3**

Synthetic Biology and Genome Engineering
Synthetic biology principles; biological parts, devices and systems; BioBricks; synthetic promoters; ribosome binding sites; gene circuits; genetic toggle switches; oscillators; CRISPR-Cas systems; genome editing; multiplex genome engineering; directed evolution; protein engineering; pathway refactoring; chassis organisms; biosensors; orthogonal biological systems.

Number of Hours: 08

**Module-4**

Systems Biology and Computational Metabolic Engineering
Genome-scale metabolic reconstruction; systems biology approaches; transcriptomics; proteomics; metabolomics; fluxomics; metabolic network analysis; constraint-based modeling; machine learning in metabolic engineering; AI-assisted pathway design; kinetic modeling; metabolic databases (KEGG, BioCyc, MetaCyc); pathway prediction; computational tools for synthetic biology.

Number of Hours: 09

**Module-5**

Industrial Applications and Emerging Trends

Engineering microorganisms for biopharmaceuticals, recombinant proteins, vaccines, biofuels, bioplastics, specialty chemicals and nutraceuticals; microbial consortia; cell-free synthetic biology; precision fermentation; sustainable biomanufacturing; automation in synthetic biology; laboratory automation; biofoundries;

biosafety; biosecurity; ethical and regulatory aspects; future trends in metabolic engineering and synthetic biology.

Number of Hours: 09

Textbooks

1. Stephanopoulos, G., Aristidou, A. A. and Nielsen, J., Metabolic Engineering: Principles and Methodologies, Academic Press.
2. Nielsen, J. and Keasling, J. D., Engineering Biology, Academic Press.
3. Smolke, C. D. (Ed.), The Metabolic Pathway Engineering Handbook, CRC Press.
4. Voigt, C. A. (Ed.), Synthetic Biology: Methods for Engineering Biological Systems, Academic Press.

Reference Books

1. Lee, S. Y., Systems Metabolic Engineering, Springer.
2. Alper, H. S., Systems Metabolic Engineering, Humana Press.
3. Keasling, J. D. and Nielsen, J., Synthetic Biology and Metabolic Engineering, Wiley.
4. Clark, D. P. and Pazdernik, N. J., Biotechnology: Applying the Genetic Revolution, Academic Press.
5. Nielsen, J., Villadsen, J. and Lidén, G., Bioreaction Engineering Principles, Springer.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be **50% each**. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of **40%** of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than **50% of the aggregate marks** obtained in CIE and SEE taken together.

**Continuous Internal Evaluation:**

**Continuous Comprehensive Assessments (CCA)+ Internal Assessment Test (IA) = Continuous Internal Evaluation CIE [25+25=50 marks]**

A minimum of **two Internal Assessment Tests (IA)** shall be conducted. Each test shall be conducted for a maximum of **25 marks**. The average of the two test marks shall be the marks secured by a student in IA.

In addition, **Continuous Comprehensive Assessment (CCA)** shall be conducted for a total of **25 marks**.

| Clinical Research and Data Management | | | |
|---|---|---|---|
| Course Code | 1MBBC206C | Scheme | 2026 |
| Type of Course | **PCC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

**Course Objectives**

At the end of the course, the student will be able to:
CO1 (L2 – Understand): Explain the principles of clinical research, drug development, clinical trial phases, ethical guidelines, and regulatory requirements.
CO2 (L3 – Apply): Apply Good Clinical Practice (ICH-GCP), clinical trial protocols, and data management principles in the planning and execution of clinical studies.
CO3 (L3 – Apply): Utilize clinical data management systems, electronic data capture tools, data standards, and quality assurance practices for efficient clinical data handling.
CO4 (L4 – Analyze): Analyze clinical trial data, safety reporting, biostatistical methods, and regulatory documentation to ensure data integrity and compliance.
CO5 (L5 – Evaluate): Evaluate emerging technologies including AI, real-world evidence, decentralized clinical trials, and digital health in clinical research and data management.

**Module-1**

Introduction to Clinical Research
Overview of clinical research; drug discovery and development process; preclinical studies; clinical trial phases (Phase I–IV); study designs; randomized controlled trials; observational studies; clinical pharmacology; bioavailability and bioequivalence; clinical trial stakeholders; Contract Research Organizations (CROs); investigator responsibilities; informed consent; clinical trial documentation.

Number of Hours: 08

**Module-2**

Clinical Trial Regulations and Good Clinical Practice
History of clinical research ethics; Nuremberg Code; Declaration of Helsinki; Belmont Report; ICH-GCP guidelines; ICMR ethical guidelines; CDSCO regulations; USFDA and EMA regulations; protocol development; Institutional Ethics Committees (IEC/IRB); regulatory submissions; safety reporting; adverse events (AE) and serious adverse events (SAE); pharmacovigilance; quality assurance and audits.

Number of Hours: 08

**Module-3**

Clinical Data Management
Clinical Data Management (CDM) lifecycle; Data Management Plan (DMP); Case Report Forms (CRFs); electronic Case Report Forms (eCRFs); Electronic Data Capture (EDC) systems; database design and validation; data entry; edit checks; query management; audit trails; medical coding (MedDRA, WHO Drug Dictionary); CDISC standards; SDTM; data cleaning; database lock; quality management; Good Clinical Data Management Practices (GCDMP).

Number of Hours: 08

**Module-4**

Clinical Data Analysis and Quality Management
Clinical trial databases; descriptive and inferential statistics; data visualization; interim analysis; missing data handling; statistical analysis plans; data monitoring committees; risk-based monitoring; source data verification; validation and reconciliation; clinical study reports; electronic Trial Master File (eTMF); data privacy; HIPAA; GDPR; cybersecurity; quality management systems; inspection readiness.

Number of Hours: 09

**Module-5**

Emerging Trends in Clinical Research

Decentralized clinical trials (DCTs); digital health technologies; wearable devices; telemedicine; real-world data (RWD); real-world evidence (RWE); artificial intelligence and machine learning in clinical research;

predictive analytics; blockchain in clinical trials; cloud-based clinical data management; precision medicine; adaptive clinical trial designs; regulatory innovations; future trends in clinical research and data management.

Number of Hours: 09

Textbooks

1. Rondel, R. K. and Varley, S. A., Clinical Data Management, 2nd Edition, Wiley.
2. Friedman, L. M., Furberg, C. D., DeMets, D. L., Reboussin, D. M. and Granger, C. B., Fundamentals of Clinical Trials, 5th Edition, Springer.
3. Gallin, J. I., Ognibene, F. P. and Johnson, L. L., Principles and Practice of Clinical Research, 4th Edition, Academic Press.
4. Chin, R. and Lee, B. Y., Principles and Practice of Clinical Trial Medicine, Academic Press.

Reference Books / Manuals

1. Piantadosi, S., Clinical Trials: A Methodologic Perspective, 3rd Edition, Wiley.
2. Spilker, B., Guide to Clinical Trials, Lippincott Williams & Wilkins.
3. Prokscha, S., Practical Guide to Clinical Data Management, 4th Edition, CRC Press.
4. Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP).
5. ICH, Integrated Addendum to ICH E6(R2): Guideline for Good Clinical Practice.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be **50% each**. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of **40%** of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than **50% of the aggregate marks** obtained in CIE and SEE taken together.

**Continuous Internal Evaluation:**

**Continuous Comprehensive Assessments (CCA)+ Internal Assessment Test (IA) = Continuous Internal Evaluation CIE [25+25=50 marks]**

A minimum of **two Internal Assessment Tests (IA)** shall be conducted. Each test shall be conducted for a maximum of **25 marks**. The average of the two test marks shall be the marks secured by a student in IA.

In addition, **Continuous Comprehensive Assessment (CCA)** shall be conducted for a total of **25 marks**.

| BIOMEDICAL IMAGING AND IMAGE ANALYSIS | | | |
|---|---|---|---|
| Course Code | **1MBBC206D** | Scheme | 2026 |
| Type of Course | **PEC** | Semester | 2 |
| Teaching Hours/Week (L:T:P) | 3: 0 :0 | CIE Marks | 50 |
| Total Hours of Pedagogy L /T/P/SL&TW: | 42:0:0:48 | SEE Marks | 50 |
| Credits | **03** | Total Marks | 100 |
| Examination type (SEE) | Theory | Exam Hours | 03 |

Course Objectives

CO1 (L2 – Understand): Explain the fundamental principles of biomedical imaging modalities, image formation mechanisms, image quality parameters, and their applications in clinical diagnosis and biomedical research.

CO2 (L3 – Apply): Apply digital image processing techniques, including image enhancement, filtering, segmentation, feature extraction, and quantitative analysis using biomedical image processing tools and software.

CO3 (L3 – Apply): Utilize machine learning and deep learning approaches for biomedical image classification, segmentation, computer-aided diagnosis, and image-based clinical decision support.

CO4 (L4 – Analyze): Analyze multimodal biomedical images using advanced imaging technologies, image informatics, and standardized medical imaging protocols for diagnosis and research applications.

CO5 (L5 – Evaluate): Evaluate emerging biomedical imaging technologies, AI-driven imaging systems, and precision medicine approaches by considering their clinical utility, ethical implications, regulatory requirements, and future trends in healthcare.

**Module-1**

Fundamentals of Biomedical Imaging

Introduction to biomedical imaging; image formation principles; electromagnetic spectrum; interaction of radiation with biological tissues; image quality parameters (spatial, contrast and temporal resolution, signal-to-noise ratio, artifacts); X-ray imaging, fluoroscopy, mammography, Computed Tomography (CT), ultrasound imaging, Magnetic Resonance Imaging (MRI), functional MRI (fMRI), Diffusion Tensor Imaging (DTI), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Optical Coherence Tomography (OCT), fluorescence imaging, photoacoustic imaging, radiation dosimetry, image safety, and clinical applications.

Number of Hours: 08

**Module-2**

Digital Image Processing

Digital image representation; image acquisition and sampling; image preprocessing; noise models; spatial and frequency domain filtering; histogram processing; contrast enhancement; image restoration; image registration; image fusion; image interpolation; image reconstruction; edge detection; morphological image processing; feature extraction; texture analysis; shape analysis; wavelet transforms; image compression; quantitative image analysis; introduction to MATLAB, Python, OpenCV, ImageJ and FIJI for biomedical image processing.

Number of Hours: 08

**Module-3**

Biomedical Image Analysis and Artificial Intelligence

Image segmentation techniques; thresholding; region growing; watershed segmentation; active contour models; feature engineering; pattern recognition; radiomics; image biomarkers; computer-aided diagnosis (CAD); machine learning algorithms; convolutional neural networks (CNNs); transfer learning; Vision Transformers (ViTs); deep learning for image classification, object detection and segmentation; explainable AI (XAI); digital pathology; multimodal image analysis; validation metrics; clinical decision support systems; AI ethics in medical imaging.

Number of Hours: 08

**Module-4**

Advanced Biomedical Imaging Technologies

Confocal microscopy; fluorescence microscopy; super-resolution microscopy; Cryo-Electron Microscopy (Cryo-EM); hyperspectral and multispectral imaging; molecular imaging; elastography; functional imaging; optical imaging; image-guided surgery; robotic imaging systems; Picture Archiving and Communication Systems

(PACS); Digital Imaging and Communications in Medicine (DICOM); cloud-based medical imaging; medical image databases; telemedicine; biomedical image informatics; cybersecurity in healthcare imaging.

Number of Hours: 09

**Module-5**

Emerging Trends in Biomedical Imaging
Radiogenomics and imaging genomics; computational pathology; whole-slide imaging; digital twins in healthcare; quantitative imaging biomarkers; foundation models and multimodal AI for biomedical imaging; federated learning; self-supervised learning; wearable and smartphone-based imaging systems; augmented reality (AR) and virtual reality (VR) in image-guided interventions; precision medicine; regulatory and ethical considerations in AI-based medical imaging; future trends in Biomedical Imaging 4.0.

Number of Hours: 09

Textbooks

1. Bushberg, J. T., Seibert, J. A., Leidholdt, E. M., and Boone, J. M., The Essential Physics of Medical Imaging, 4th Edition, Wolters Kluwer.
2. Gonzalez, R. C. and Woods, R. E., Digital Image Processing, 4th Edition, Pearson.
3. Rangayyan, R. M., Biomedical Image Analysis, CRC Press.
4. Webb, A., Introduction to Biomedical Imaging, Wiley.

Reference Books / Manuals

1. Prince, J. L. and Links, J. M., Medical Imaging Signals and Systems, 3rd Edition, Pearson.
2. Sinha, G. R. and Patel, B. C., Medical Image Processing: Concepts and Applications, PHI Learning.
3. Sonka, M., Hlavac, V., and Boyle, R., Image Processing, Analysis and Machine Vision, Cengage.
4. Goodfellow, I., Bengio, Y., and Courville, A., Deep Learning, MIT Press.
5. Zhou, S. K., Greenspan, H., Duncan, J. S., et al., Deep Learning for Medical Image Analysis, Academic Press.

**Assessment Structure (both CIE and SEE)**

The weightage assigned to Continuous Internal Evaluation (CIE) and Semester End Examination (SEE) shall be 50% each. A student shall secure a minimum of 50% of the maximum marks prescribed for CIE and a minimum of 40% of the maximum marks prescribed for SEE to be eligible for passing.

A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to a subject/course only if he/she secures not less than 50% of the aggregate marks obtained in CIE and SEE taken together.

**Continuous Internal Evaluation**

Continuous Comprehensive Assessment (CCA) + Internal Assessment Test (IA) = CIE [25 + 25 = 50 Marks]
A minimum of two Internal Assessment Tests (IA) shall be conducted, each carrying 25 marks. The average of the two tests shall constitute the IA marks.
Continuous Comprehensive Assessment (CCA) shall include assignments, image processing exercises, AI model implementation, image annotation, case studies, seminars, literature review, and mini-projects.

| Artificial Intelligence in Computational Biology Laboratory | | | |
|---|---|---|---|
| Course Code | **MBBCL207** | Scheme | 2026 |
| Type of Course | Ability Enhancement Course Lab | Semester | 2 |
| Teaching Hours/Week (L :T : P) | 0: 2 : 0 | CIE Marks | 50 |
| Total Hours of Pedagogy L :T:P:SL:TW | 0:0:28:2 | SEE Marks | 50 |
| Credits | 1 | Total Marks | 100 |
| Type of Examination | Practical | Exam Hours | 3 |

**Course outcome (Course Skill Set)**

At the end of the course, the student will be able to:
CO1 (L3 – Apply): Apply artificial intelligence, machine learning, and bioinformatics tools for the analysis of genomic, transcriptomic, proteomic, and clinical datasets.
CO2 (L3 – Apply): Utilize computational platforms and AI-based software for genomic variant annotation, protein structure prediction, protein function analysis, and biomedical data interpretation.
CO3 (L4 – Analyze): Analyze biological and clinical datasets using supervised and unsupervised machine learning, dimensionality reduction techniques, and deep learning models for disease prediction and biomarker discovery.
CO4 (L5 – Evaluate): Evaluate AI-driven approaches for medical image analysis, clinical data analytics, pharmaceutical data modeling, and biological sequence classification to support precision medicine and healthcare research.
CO5 (L6 – Create): Develop AI-enabled computational workflows integrating machine learning, deep learning, bioinformatics, and large language models (LLMs) for solving complex problems in computational biology, biomedical research, and drug discovery.

**List of experiments**

1. AI-Assisted Genomic Variant Annotation using DeepVariant and Ensembl VEP
2. Machine Learning-Based Gene Expression Data Analysis using GEO Datasets
3. Proteomics Data Analysis using MaxQuant/Proteome Discoverer (Demo Dataset)
4. Disease Prediction using Clinical and Genomic Datasets with Scikit-learn
5. Biomarker Discovery using Supervised and Unsupervised Machine Learning
6. Dimensionality Reduction of Omics Data using PCA, t-SNE and UMAP
7. Machine Learning Model Development for Pharmaceutical Datasets using Open-Source Platforms (Kaggle, Iris, MNIST, etc.)
8. Protein Structure Prediction using AlphaFold Protein Structure Database
9. QSAR Modeling using Machine Learning
10. Protein Function Prediction using AI-Based Bioinformatics Tools
11. Clinical Data Analytics for Rare Disease Identification, Physician Trend Analysis, Risk-Based Monitoring and Market Research
12. Deep Learning for Medical Image Analysis using Keras
13. Gene Expression Prediction using Artificial Neural Networks (ANNs)

Additional/Open-ended Experiments

1. Exploring Medical Image Analysis
2. Building a Deep Learning-Based Medical Imaging Dataset
3. Biological Sequence Classification using Convolutional Neural Networks (CNNs)
4. Large Language Models (LLMs) for Literature Mining and Biological Knowledge Extraction

**Suggested Learning Resources: (Text Book/ Reference Book/ Manuals):**

Textbooks


1. Lesk, A. M., *Introduction to Bioinformatics*, 6th Edition, Oxford University Press.
2. Baldi, P. and Brunak, S., *Bioinformatics: The Machine Learning Approach*, 3rd Edition, MIT Press.
3. Alpaydin, E., *Introduction to Machine Learning*, 4th Edition, MIT Press.
4. Goodfellow, I., Bengio, Y. and Courville, A., *Deep Learning*, MIT Press.
5. Bishop, C. M., *Pattern Recognition and Machine Learning*, Springer.
6. Rashidi, H. H. and Buehler, L. K. (Eds.), *Bioinformatics Basics: Applications in Biological Science and Medicine*, 3rd Edition, CRC Press.


Reference Books / Manuals


1. Jones, N. C. and Pevzner, P. A., *An Introduction to Bioinformatics Algorithms*, MIT Press.
2. Mount, D. W., *Bioinformatics: Sequence and Genome Analysis*, 2nd Edition, Cold Spring Harbor Laboratory Press.
3. Hastie, T., Tibshirani, R. and Friedman, J., *The Elements of Statistical Learning*, 2nd Edition, Springer.
4. Géron, A., *Hands-On Machine Learning with Scikit-Learn, Keras and TensorFlow*, 3rd Edition, O'Reilly Media.
5. Brown, T. A., *Genomes*, 5th Edition, Garland Science.


**Web links and Video Lectures (e-Resources):**

**Web Resources / e-Resources**

1. Google Colab – https://colab.research.google.com/
2. Jupyter Notebook – https://jupyter.org/
3. Biopython Documentation – https://biopython.org/
4. Scikit-learn – https://scikit-learn.org/
5. TensorFlow – https://www.tensorflow.org/
6. Keras – https://keras.io/
7. AlphaFold Protein Structure Database – https://alphafold.ebi.ac.uk/
8. Ensembl Variant Effect Predictor (VEP) – https://www.ensembl.org/info/docs/tools/vep/
9. NCBI Gene Expression Omnibus (GEO) – https://www.ncbi.nlm.nih.gov/geo/
10. UniProt – https://www.uniprot.org/
11. Kaggle Datasets – https://www.kaggle.com/datasets
12. EMBL-EBI Training – https://www.ebi.ac.uk/training/
13. NPTEL – https://nptel.ac.in/
14. MIT OpenCourseWare – https://ocw.mit.edu/
15. Coursera – https://www.coursera.org/

**Evaluation of Ability Enhancement Laboratory Courses**

Evaluation of Ability Enhancement Laboratory Courses shall be evaluated with the following marks distribution:

CIE marks: 50, SEE Maximum evaluation marks:100.

**(a)Continuous Internal Evaluation (CIE)**

Out of 50 marks, 30 marks shall be to assess the regular classwork and the remaining 20 marks shall be for the Test.

The allotment of marks for regular class assessment and test shall be as per the rubrics indicated in Table -1.

A student shall obtain a minimum of 50 % of CIE marks or 25 out of 50 marks allotted to CIE to become eligible to appear for the SEE.

| Table-1 Distribution of CIE marks | | |
|---|---|---|
| **Component** | **Description** | **Marks** |

| | | |
|---|---|---|
| Attendance, punctuality, Ability in Conducting Experiments | Initiative, skill, safety practices, and independent handling of equipment or following the appropriate procedures during regular lab sessions. | 10 marks |
| Laboratory Record / Journal | Regular and neat maintenance of lab record, accuracy of results, and timely submission, units, graphical work, etc. Each experiment shall be evaluated for 30 marks. Total marks for the all experiment report shall be scaled down to 10 marks. | 20 marks |
| Laboratory Test / Experiment performance The 03-hour laboratory test shall be conducted at the end of the last week of the semester /after completion of all the experiments (whichever is early). The test shall be conducted for 50 marks and Marks scored shall be scaled down to 20 marks. | Ability to set up apparatus, follow procedure, take observations, and obtain correct results in the test experiment. | 15 marks |
| Viva-Voce | Understanding of theory, concepts, and experimental procedure; ability to explain results and answer related questions. | 05 marks |
| | **Total** | **50** |

### (b) Passing requirement in SEE

For a pass in the Semester End Examination (SEE), a student shall secure a minimum of 40 marks out of 100. For the declaration of a pass grade, the sum of the Continuous Internal Evaluation (CIE) marks (out of 50) and the SEE marks scaled down to 50 shall be greater than or equal to 50 marks.

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