MANIPAL
ACADEMY of HIGHER EDUCATION
(Deemed to be University under Section 3 of the UGC Act, 1956)

Manipal Centre for Biotherapeutics Research

Manipal Academy of Higher Education, Manipal

Outcomes Based Education (OBE) Framework

Two Year Full-Time Graduate Program

MSc (by Research) in Biotherapeutics

(w.e.f 2023- 2024)

MANIPAL
ACADEMY of HIGHER EDUCATION
(Deemed to be University under Section 3 of the UGC Act, 1956)

Table of content

NATURE AND EXTENT OF THE PROGRAM

M.Sc. (by Research) in Biotherapeutics Degree Programme:

M.Sc. (by Research) in Biotherapeutics is a graduate program covering the broad aspects of various areas of Research in Biotherapeutics to help choose a career in basic and advanced research in Biotherapeutics. The focus of the program is to gain basic and advanced knowledge in all aspectsof Biotherapeutics research including technical skills, knowledge at a high level of interpretation, and problem-solving abilities through lectures and hands-on training, culminating in a researchproject work.

Duration of the Programme:

The duration of the study of the M.Sc. degree shall extend over a total period of two academic years divided into four semesters of about 6 months (2 odd semesters and 2 even semesters) each from the date of commencement of study for courses comprising the curriculum. The student will learn theoretical knowledge of multifarious aspects of research in the first semester of the curriculum and he/she has to carry out project work in the subsequent semesters (from the secondSemester onwards; for 18 months).

Medium: The medium of instruction and examination of the programme shall be in English.

Eligibility:

Qualification: Candidates who have completed their Bachelor's degree in any branch of biology (B.Sc. in Zoology/Biotechnology/Microbiology/Biochemistry/Life Sciences/Medical Lab Technology/Food Science/Nutrition) from a recognized university with a minimum of 60% aggregate marks or an equivalent CGPA;
Bachelor's degree Medical Sciences (M.B.B.S./B.A.M.S.)/Veterinary Sciences (B.V.Sc.)/Pharmacy (B. Pharm.)/B.E/ B.Tech in Biomedical Engineering/ Biotechnology with a minimum of 55% aggregate marks or an equivalent CGPA;
Bachelor's degree with 55% or equivalent for Biotechnology Industry sponsored candidates (Industry sponsored candidates should be employers of sponsoring industry with minimum 2 years experience are eligible to apply for this program.
Those in the final year of their qualifying examination and awaiting results are also eligible to apply. However, they should have completed all the requirements for the award of the qualifying degree, including all examinations, dissertation projects, viva-voce, etc. by the time of joining and commencement of the program (as announced by the university).

Courses covered include different aspects of Biotherapeutics including knowledge in the field of cellular and molecular biology, research methodology, biostatistics, and bioinformatics, biotherapeutic product and process development with a broad remit covering the areas of cell and gene therapy, protein therapy, nanotechnology, regenerative medicine and biomaterials, quality assurance, and accreditation. Hands-on training of the basic to advanced instruments, analysis, and interpretation of the data and fundamental to contemporary advanced techniques in the fieldof biotherapeutics will be provided with state-of-the-art facilities. The

program essentially includes a research project in-house or in an industry that will boost the technical and research-oriented skills of the students.

Meritorious graduates with a penchant for research gain admissions for doctoral programs in various fields in life sciences, health sciences, and such, in India and abroad, while those looking for job opportunities can gain employment in biotechnology and pharmaceutical industries, contract research organizations, teaching institutions, and start-up entrepreneurship.

1. PROGRAM EDUCATION OBJECTIVE (PEO)

The overall objectives of the Learning Outcomes-based Curriculum Framework (LOCF) for **M.Sc. (by Research) in Biotherapeutics** are as follows.

PEO No	Education Objective
PEO 1	Students will be able to use the fundamental concepts and technical competence in research as and when required to achieve professional excellence.
PEO 2	Students will demonstrate strong and well-defined practical knowledge in different areas of basic and advanced research including, biotherapeutic product and process development, bioinformatics, and research methods/techniques in biotherapeutic applications.
PEO 3	Students will be able to practice the profession with a highly professional and ethical attitude, strong communication skills, and effective professional skills to work in a team with multidisciplinary approval.
PEO 4	Students will be able to use interpersonal and collaborative skills to identify, assess, and formulate problems and execute the solution in closely related issues in the life sciences research domain.
PEO 5	Students will be able to imbibe the culture of research, ethical practices, innovation, entrepreneurship, and incubation.
PEO 6	Students will be able to participate in a lifelong learning process for a highly productive career and will be able to relate the concepts of research in life sciences to serving the cause of society.

2. GRADUATE ATTRIBUTES:

S No.	Attribute	Description
1	**Disciplinary Knowledge**	Knowledge of fundamental and advanced life sciences, cellular, andmolecular theories/principles in the field of Biotherapeutics research. Acquiring knowledge of different dimensions of the research, learning various basic and advanced techniques employed in Biotherapeutics and otherrelated areas of studies such as molecular biology, drug discovery, use of experimental models, research, and statistical tools.
2	**Understanding different subsets of Research in Biotherapeutics**	Different areas of research in Biotherapeutics include molecular biology, cell biology, immunology, bioinformatics, biostatistics, molecular cloning, recombinant DNA technology, quality assurance and accreditation, use of experimental models, research ethics, and fundamental biological aspects.
3	**Measurable Skills and Industry-ready Professionals**	Strengthening the abilities of a learner by skills, gaining knowledgeof the present scenario of research in life sciences, and developmentin industry and training.
4	**Effective and Influencing communication**	Effective and influencing communicability to share thoughts, ideas,and applied skills of communication in its various forms like writtencommunication, oral communication, etc.
5	**Leadership readiness/ Qualities**	To make learners fluent in multiple facets of leadership. Creating the ability & enhancing the qualities to be an efficient leader. Cultivating key characteristics in learners, to be visionary leaderswho can inspire the team to greatness.
6	**Critical/ Reflective thinking & language Efficiency**	Students will be able to possess critical and reflective thinking ability to create a sense of awareness of themselves and society.
7	**Technologically Efficient Professional**	Capability to employ various basic and advanced biological research techniques and tools.
8	**Ethical Awareness**	As a researcher in the field of life sciences, one has to understand the importance of ethical values and its application in professional life.
9	**Lifelong Learning**	Every graduate to be converted into a lifelong learner and consistently update himself or herself with current knowledge, skills, and technologies in the field of biological research. Acquiring knowledge and creating the understanding in learners that learningwill continue throughout life.
10	**Research-related Skills**	A sense of inquiry and investigation for raising relevant and contemporary questions, synthesizing and articulating.
11	**Cooperation/ Teamwork**	Building a team, motivating, and inspiring the team members towork up with cooperation to their utmost efficiency.

3. QUALIFICATIONS DESCRIPTORS

Demonstrate

(i) A systematic, extensive, and coherent knowledge and understanding of the research domain as a whole and its applications, and links to related disciplinary areas/subjects of study; including a critical understanding of the established theories, principles, and concepts, and a number of advanced and emerging issues in the field of life sciences.

(ii) Procedural knowledge that creates different types of professionals related to the life sciences, biotechnology, and pharma industry, including research and development, research in government and public service.

(iii) Professional and communication skills in the domain of life sciences research.

2. Demonstrate comprehensive knowledge about materials, including current research, scholarly, and/or professional literature, relating to essential and advanced learning areas of Biotherapeutics, cellular and molecular techniques, and skills required for identifying problems and related issues.

3. Demonstrate skills in identifying information needs, collection of relevant quantitative and/or qualitative data drawing on a wide range of sources, analysis and interpretation of data using methodologies as appropriate to the subject(s) for formulating evidence-based solutions and arguments.

4. Use knowledge, understanding, and skills for the critical assessment of a wide range of ideas and complex problems and issues relating to the chosen field of study.

5. Communicate the results of studies undertaken in the research field accurately in a rangeof different contexts using the research concepts and techniques in the field of life science studies.

6. Address one's own learning needs relating to current and emerging areas of study, making use of research, development, and professional materials as appropriate, including those related to new frontiers of knowledge.

7. Apply one's disciplinary knowledge and transferable skills to new/unfamiliar contexts and identify and analyze problems and issues and seek solutions to real-life problems.

4. **<u>PROGRAM OUTCOMES</u>: After successful completion of the M.Sc. by Research in Biotherapeutics program, Students will be able to:**

PO No	Attribute	Competency
PO 1	**Disciplinary knowledge**	Demonstrate knowledge for in-depth analytical and critical thinking to identify, formulate and solve the issues related to Biotherapeutics and Bioprocess engineering, Industry, & Academia.
PO 2	**Communication Skills**	Demonstrate communication skills, scientific writing and data recording abilities in all the fields of Biotherapeutics.
PO 3	**Critical thinking**	Apply analytic thought to a body of knowledge; analyze and evaluate evidence, arguments, claims, and beliefs based on empirical evidence; identify relevant assumptions or implications; formulate coherent arguments; critically evaluate practices, policies, and theories by following a scientific approach to knowledge development.
PO 4	**Problem-solving**	Extrapolate from what one has learned and apply their competencies to solve different kinds of non-familiar problems, rather than replicate curriculum content knowledge; and apply one's learning to real-life situations.
PO 5	**Research-related skills**	Demonstrate the ability to sense the scientific and technological trends in different academic and industry settings, identify the pertinent questions to be addressed, build hypotheses, and design experimental strategies to solve the scientific problems.
PO 6	**Cooperation/ Teamwork**	Demonstrate the ability to work on research projects and assignments in teams of students coming from different academic disciplines, diverse cultures and ethnicities.
PO 7	**Self-directed learning**	Work independently, identify appropriate resources required for a project, and manage a project through to completion.
PO 8	**Moral and ethical awareness/ Reasoning**	Demonstrate the ability to identify ethical issues related to recombinant DNA technology, genetic engineering, animals handling, intellectual property rights, biosafety and handling of sensitive experiments; awareness about the difference between data beautification and data manipulation/scientific misconduct.
PO 9	**Leadership readiness/ Qualities**	Demonstrate the ability to take initiative, set direction, design strategy, and build social cohesion not only in research labs but also in social contexts.
PO 10	**Lifelong learning**	Acquire knowledge and skills, including "learning how to learn", that is necessary for participating in learning activities throughout life, through self-paced and self-directed learning aimed at personal development, meeting economic, social, and cultural objectives, and adapting to changing trades anddemands of the workplace through knowledge/skill development/reskilling.

5. Course distribution and Evaluation table

First Year: First Semester								
		No. of hours per week				Evaluation Scheme		
Subject Code	**Subject Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Credit (C)**	**Internal Assessment**	**University Exam**	**Total**
MBT-501	Biotherapeutic Discovery & Development	6	-	-	6	30	70	100
MBT-503	Bioprocess engineering	3	-	-	3	30	70	100
MBT-505	Biostatistics and Research Methodology	3	-	-	3	30	70	100
MBT-521 MBT-523	*Electives*:* 1)Pharmaceutical quality control, quality assurance, and regulatory affairs 2) 3D Bioprinting (*Select any 1)	3	-	-	3	30	70	100
MBT-531	Journal club presentation/ assignments	-	2	-	2	50	-	50
MBT-507	Biotherapeutic Discovery and Development	-	-	6	3	30	70	100
	Total	15	2	6	20	200	350	550

*Minimum of 5 students are mandatorily required for running an elective course

First Year: Second Semester								
		No. of hours per week				Evaluation Scheme		
Subject Code	**Subject Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Credit (C)**	**Internal Assessment**	**University Exam**	**Total**
MBT-630	Soft Skills – I (Tutorials/ Seminars/Journal Club/special lectures)	-	4	-	4	50	-	50
MBT - 699	Research Project work/ presentation#	-	-	32	16	100*	-	100*
	Total	**-**	**4**	**32**	**20**	**150**	**-**	**150**

Second Year: Third Semester								
		No. of hours per week				Evaluation Scheme		
Subject Code	**Subject Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Credit (C)**	**Internal Assessment**	**University Exam**	**Total**
MBT-631	Soft Skills – II (Tutorials/ Seminars/ Journal Club/ special lectures)	-	4	-	4	50	-	50
MBT-699	Research Project work/ presentation#	-	-	32	16	100*	-	100*
	Total	**-**	**4**	**32**	**20**	**150**	**-**	**150**

Second Year: Fourth Semester								
		No. of hours per week				Evaluation Scheme		
Subject Code	**Subject Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Credit (C)**	**Internal Assessment**	**University Exam**	**Total**
MBT-632	Soft Skills – III (Tutorials/ Seminars/ Journal Club/ special lectures)	-	4	-	4	50	-	50
MBT-699	Research Project work /Submission of manuscript#	-	-	32	16 (+32*)	100 (+200*)	300	**400 (+200*)**

	Total	**-**	**4**	**32**	**20 (+32*)**	**150 (+200*)**	**300**	**650***

Continuous activity for semesters 2nd, 3rd, and 4th. The final assessment is to be done at the end of the 4th semester.

*The Internal Assessment Marks from semester 2 and semester 3 to be included in total marks in semester 4

Semester I
Course Code : MBT 501

Course : Biotherapeutic Discovery & Development – Theory

Name of the Program:	**M.Sc. (By Research) in Biotherapeutics**
Course Title:	**Biotherapeutic Discovery & Development (Theory)**
Course Code: MBT-501	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 6	**Prerequisites: Admission to M.Sc. (BT) program**
Synopsis:	1. Introduction to different approaches of Biotherapeutic discovery and development that includes cell and gene therapy products and engineered protein and biomaterials for therapy. 2. Studies on the effect of various aspects of cell therapy covering stem cell therapy and immune therapy. 3. Studies of gene and gene editing products, vectors, and transgenic products for therapy. 4. Protein structure, stability, and folding along with mutation of protein and methods of biophysical characterization of proteins. 5. Examples of engineered proteins used in industrial, pharmaceutical, and other applications. 6. The basic concept of biomaterial, classification, and properties of materials used in biomedical application. 7. Applications of biomaterials in medicine, including tissue engineering and bioartificial organ manufacturing for therapeutic purposes.
Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Comprehend the basic concepts of biotherapeutics development with reference to Cell and gene therapy, Protein therapy, and Regenerative medicine, including the use of biomaterials used in the healthcare industry (C1, C2).
CO 2:	Understand the various classification of Biotherapeutics used in medicine, their properties, and their wide applications (C1, C2).
CO 3:	Envision the different aspects of cell and gene application in immunotherapy (C1, C3).
CO 4:	Perceive the knowledge of host response to biomaterial, toxic effect, and interactions (C3, C6).
CO 5:	Understand various methods of incorporating mutations in proteins and the pros and cons of each technique (C2, C5).
CO 6:	Review of factors significant for protein folding processes and stability (C2, C6).

CO 7:	Understand advanced biophysical techniques for protein analysis, including the capacity to discuss their relative merits and interpret data from those techniques (C3, C4).
CO 8:	Perceive the knowledge on host response to biomaterial, toxic effect, and interactions (C5, C6).

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO10*
CO 1	×	×			×					×
CO 2	×	×								
CO 3	×	×								
CO 4	×	×		×						
CO 5	×	×								
CO 6	×	×						×	×	
CO 7	×	×		×						
CO 8	×	×								

Course content and outcomes:

Content	*Competencies*	
Development of cell and gene therapy products credits		**2**
Module 1:		**No of hours**
Introduction and overview of Stem cell therapy	Introduction - Stem cell therapy – Types of stem cells used for therapy – Stem cell therapy for Various indications - Manufacturing of Complex Cell-based Therapeutics - Translating Cell Therapies into Viable Commercial Products (C1, C2, C3).	10
Module 2:		
Introduction and overview of gene therapy	Introduction - Gene Editing - Gene Therapy Vectors – the viral and non-viral vectors - successes and problems in gene therapy - Manufacturing of Complex gene-based Therapies - Translating Gene Therapies into Viable Commercial Products (C1, C3).	10
Module 3:		
Immunotherapy	Introduction – Conventional Immunotherapies - Application of Immunotherapy – e.g., immune therapy with details like CRISPR, CAR T cells, etc (C1).	8
Module 4:		
Overview of Safety, regulation and IP	Pre-clinical Safety Testing of Vector-based Gene Therapies and cell therapies - The concept of GMP production - FDA Guidance and ICMR guidelines on Cell & Gene Therapies - Patenting Gene & Cell Therapies (C2, C3, C4).	8
Development of advanced protein therapeutics credits		**2**
Module 1:		**No of hours**

Introduction and scope of Protein Engineering	Different approaches of protein engineering – Protein sequencing - Mutagenesis - Random and rational design - Effect of mutation on protein structure, stability, and folding phi value analysis – Protein-protein interaction studies Protein post-translation modifications and proteomics (C2).	8
Module 2:		
Strategies for Protein identification	Protein structural and biochemical characterization using fluorescence spectroscopy, circular dichroism, x-ray crystallography, NMR, FTIR, mass spectrometry, etc (C1, C3, C4).	10
Module 3:		
Applications of protein engineering	Protein therapeutics with enzymatic or regulatory activity: Replacing a protein that is deficient or abnormal - Augmenting an existing pathway - Providing a novel function or activity (C1, C2, C3).	9
Module 4:		
Protein therapeutics with special targeting activity	Interfering with a molecule or organism - Delivering other compounds or proteins - protein vaccines (C1, C3).	9
Development of advanced functional biomaterials as therapeutics		**2 credits**
Module 1:		**No of hours**
Biomaterials	Introduction and History of biomaterials, General Properties of materials - Classes of materials used in medicine – Metals – Polymers - Hydrogels -bioresorbable and biodegradable materials – Ceramics - Natural materials - Composites thin films – Grafts - Coating medical fabrics and biologically functional materials - Smart materials - Pyrolytic carbon for long term medical implants -Textured and porous materials non-fouling surfaces (C1).	5
Module 2:		
Properties of materials	Properties of materials - Bulk and surface properties and their characterization. Mechanical Properties of Biomaterials. Classes of materials used in medicine - Metals, Polymers, Hydrogels Bioresorbable and Biodegradable Materials (C1, C2).	5
Module 3:		
Metallic and Ceramic biomaterials	Stainless steel, Titanium, Alloys, Cardiovascular Orthopedic, and Dental applications. Corrosion of Bio-metals - Types of Valve Prostheses - Cardiac Stent- Bio-Ceramics - Bio–inert ceramics, Bioactive ceramics, Biodegradable ceramics, Alumina, Zirconia, Hydroxyapatite (C1, C2, C3).	2
Module 4:		
Polymeric Biomaterials	Types of polymers - Sterilization, Structure, Bio-compatibility relationship, Stability, Examples of polymers used in medicine - Hydrogels and drug delivery systems - Sutures, Adhesives, and	2

	Hydrocolloids – Super absorbents - artificial skin and blood (C1, C2).	
Module 5:		
Natural Biomaterials	Introduction - Advantages of natural biomaterials over synthetic – types of natural biomaterials – Chemistry and application of Polysaccharides, Amylose, dextran, Chitin, glycosaminoglycan, polynucleotide, protein, collagen as biomaterials (C1).	2
Module 6:		
Testing of biomaterials	In vitro and In vivo assessment of tissue compatibility - Testing of blood-materials interactions -Degradation of materials in the biological environment - Effects of the Biological environment on metals, polymers, and ceramics (C1, C2).	2
Module 7:		
Biomaterials reactions to host and its testing	Host reactions to biomaterials – Inflammation - Wound healing and foreign body response - Systemic toxicity and hypersensitivity - Blood coagulation and blood-material interactions – Tumorigenesis - Implant associated infection - Testing of biomaterials – in-vitro & in-vivo assessment of tissue compatibility - Testing of blood material interactions - Degradation of materials in the biological environment - Effects of the biological environment on metals - Polymers and ceramics (C1, C2).	2
Module 8:		
Design of artificial organs	Substitutive medicine - Biomaterial concentration - Outlook for organ replacement - Design consideration - Evaluation of artificial organs (C1, C2).	2
Module 9:		
Artificial heart and circulatory assist devices	Design of artificial heart - History of artificial heart - Types of valve prostheses - Thrombus deposition – Durability - Mechanical circulatory assistance - Two main categories - Intra-aortic balloon pump - Percutaneous cardio-pulmonary bypass (C1, C4).	4
Module 10:		
Artificial lungs and blood gas exchange devices	Gas exchange systems - Cardiopulmonary bypass - Comparison of artificial lungs and natural lungs - Oxygen transport - Carbon-dioxide transport - Coupling of oxygen & carbon-dioxide exchange – Shear-induced transport - Augmentation and devices for improved gas transport (C1, C2, C3).	4
Module 11:		

Artificial kidney, artificial pancreas & artificial liver	Artificial kidney - Renal transplantation - Mass transfer in dialysis – Membranes – Hemofiltration - Adequacy of dialysis - Peritoneal dialysis equipment - Artificial pancreas - Insulin therapy - Therapeutic options in diabetes - Insulin administration system - Insulin production system (C1, C2).	4
Module 12:		
Standards for Biomaterials	World standards - Indian Standards - Specifications - General specifications, Classification of Specifications (C1).	2

Total Contact Hours (All modules) 108 Hours

Reference:

1. Nóbrega C, Mendonça L, Matos CA. A Handbook of Gene and Cell Therapy 1st ed. 2020. Springer, Cham.
2. Templeton NS, editor. Gene and cell therapy: therapeutic mechanisms and strategies. 4th ed. 2015.CRC Press.
3. Vertes A, Dowden NJ, Smith D, Qureshi N, editors. Second Generation Cell and Gene-Based Therapies: Biological Advances, Clinical Outcomes and Strategies for Capitalisation. 1st ed. 2020 Academic Press.
4. Scherman D, editor. Advanced textbook on gene transfer, gene therapy and genetic pharmacology: principles, delivery and pharmacological and biomedical applications of nucleotide-based therapies. 2nd ed. 2019. World Scientific publishing, Europe.
5. Quesenberry PJ, Stein GS, Forget BG, Weissman SM, editors. Stem cell biology and gene therapy. 1st ed.1998. John Wiley & Sons.
6. Walsh G. Proteins: biochemistry and biotechnology.2nd ed. 2014. John Wiley & Sons
7. Park SJ, Cochran JR, editors. Protein engineering and design. 1st ed. 2009. CRC press
8. Wittrup KD, Verdine GL. Protein engineering for therapeutics, part B. 1st ed. 2012. Academic Press.
9. Purich DL, Allison RD. The enzyme reference: a comprehensive guidebook to enzyme nomenclature, reactions, and methods. 1st ed. 2003. Elsevier.
10. Park SJ, Cochran JR, editors. Protein engineering and design. 2010. 1st ed. CRC press.

Mode of Evaluation:

First semester: Two written sessional exams (internal evaluation) and the end semester written exam

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies: 29.11.2022

Semester: I

Course Code: MBT-503

Course : BIOPROCESS ENGINEERING - Theory

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title:	**Bioprocess Engineering (Theory)**
Course Code: MBT-503	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 3	**Prerequisites: Admission to M.Sc. (BT) program**
Synopsis:	The objective of the course is to apply the principles of biochemical technologies and engineering in the large-scale cultivation of cells and cellular products for the production of therapeutic and relevant products.
Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	The common practice in the bioprocess technology used in the pharmaceutical and biotechnology industry developments.
CO 2:	The principles and practices of Large-scale production with scale-up techniques, aseptic process technology, manufacturing of products derived from cells, extracellular products, and cellular extracts.
CO 3:	The principles and implementation of bioprocess technology in therapeutic product manufacturing.

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO10*
CO 1	×	×								×
CO 2	×	×			×					
CO 3	×	×								

Course content and outcomes:

Content	*Competencies*	
Bioprocess Engineering credits		**3**
Module 1:		**No of hours**
The basic principle in Bioprocess Technology	Upstream: Introduction to cellular (Animal and microbial) growth, chemostat with immobilized cells, Chemo state with cell recycling, Media formulation and Sterilization, Cell culture techniques, Inoculum development, and aseptic transfers. Bioprocess technology: Different types of bioreactors and their application. Different types of pumps, valves, line materials, piping conventions, etc., are used in the Biochemical Process. Fermentation: Fermentation process design, operation, and characteristics of fermentation processes; batch, fed-batch, and continuous culture systems, instrumentation, and bioprocess control.	18

	substrate utilization and product formation in a bioreactor, Scale-up of Bioreactors. Downstream process: Introduction to various downstream process operations in biopharmaceutical manufacturing such as centrifugation, filtration, tangential flow filtration, cell disintegration, solvent-solvent extraction, supercritical fluid extraction, etc (C1, C2, C3, C5, C6). .	
Module 2:		
Advantage of bioprocess over chemical process	Production of secondary metabolites: Metabolites from animal cell culture, chemical structure, production, harvest and recovery, use by-products of Animal Cell culture (C1, C2, C3).	6
Module 3:		
Industrial enzymes in drug development	Penicillin amidase, lipase, oxidoreductase, nitrilase, protease, etc., use of all these enzymes for enantioselective synthesis of pharmaceutically important drugs/drug intermediates, future directions (C1, C2).	8
Module 4:		
Biotechnology in pharmaceutical industry	Significant areas of biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF, and therapeutic proteins, etc.); commercial aspects, priorities for future biotechnological research (C1, C3).	8
Module 5		
Bioprocessing of gene	Optimizing Viral Vector Process Development - Vector Production for Early Phase Clinical Trials - Optimized, Efficient, and Scalable Transient Transfection for High Titre (e.g., AAV and LV Generation) - methods to enrich full recombinant viral vectors through high throughput screening system (C1, C3, C4).	5
Module 6		
Bioprocessing of Recombinant proteins	Expression Hosts for Recombinant Protein Production in E. Coli, Insect cells and Mammalian cells - Transgenic Animals - enhance recombinant biopharmaceutical production through transgenic plants – Extraction procedure for recombinant protein (C1, C2).	5
Module 7		
Bioprocessing for Tissue Engineering	Design of bioreactors to control the culture conditions of cells/tissues including temperature, pH, fluid mixing, nutrient delivery, etc. - bioreactors for cell expansion/proliferation for cell therapy - automatic system with high reproducibility in the final cellular products - Biomaterials processing (C1, C2, C3).	4

Total Contact Hours (All modules) **54 hours**

Reference:

1. Brown DE. Bioprocess engineering—kinetics, mass transport, reactors, and gene expression. 1994. John Wiley and Sons Inc, New York.
2. Aiba S, Humphrey A.E, Millis N.F. Biochemical engineering. 2nd ed. 1973. Academia Press.
3. Shuler ML. Bioprocess engineering. 3rd ed. 2017. Prentice-Hall.
4. Jakoby WB. Bioprocess engineering: systems, equipment, and facilities. Lydersen BK, D'Elia N, Nelson KL, editors. New York: 1st ed. 1994. Wiley.
5. Doran PM. Bioprocess engineering principles. 2nd ed. 2012. Elsevier.
6. Fynn GH. Biotechnology: a textbook of industrial microbiology: W. Crueger and A. Creuger Sinauer Associates, editors. 2nd ed. 1990. Blackwell Scientific Publications; Oxford.
7. Stanbury PF, Whitaker A, Hall SJ. Principles of fermentation technology.2nd ed. 2013. Elsevier.
8. Tsao GT. Principles of microbe and cell cultivation, S. John Pirt, editor. 1st ed. 1976 Halsted Press, Division of John Wiley and Sons, New York.
9. Doran PM. Bioprocess engineering principles. 2nd ed. 2013. Elsevier.
10. Skalak R, Chien S, Mates RE. Handbook of bioengineering. 1st ed. 1986. McGraw-Hill, New York.
11. Bailey JE, Ollis DF. Biochemical engineering fundamentals. 2nd ed. 1986. Chemical Engineering Education.
12. Denn M. Chemical engineering: An introduction. 2011. Cambridge University Press.
13. Blakebrough N. Biochemical and biological engineering science. Volume 1. 1967. Academic Press Inc.
14. Stanbury PF, Whitaker A, Hall SJ. Principles of fermentation technology. 2nd ed. 2013. Elsevier.
15. Moser A. Bioprocess technology: kinetics and reactors. 1st ed. 2012. Springer Science & Business Media.
16. Atkinson B, Mavituna F. Biochemical engineering and biotechnology handbook. 2nd ed. 1991. Stockton Press.
17. Lilly MD. Operational Modes of Bioreactors: BIOTOL Series. 1992. Butterworth—Heinemann.

Mode of Evaluation:

First semester: Two written sessional exams (internal evaluation) and the end semester written exam

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies: 29.11.2022

Semester: I

Course Code: MBT-505

Course : BIOSTATISTICS AND RESEARCH METHODOLOGY - Theory

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title:	**Biostatistics and Research Methodology (Theory)**
Course Code: MBT-505	**Course Instructor: Dr. Vani Lakshmi R**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 3	**Prerequisites: Admission to M.Sc. (BT) program**
Synopsis:	The course introduces the student to elementary concepts of Biostatistics and Research Methodology. The student will be able to analyze and interpret the findings from data-centric research.
Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	**Describe** the scales of measurement, and variable types and **identify** appropriate descriptive statistics and visualization for data from Biotherapeutics studies (C4)
CO 2:	**Illustrate** parametric and non-parametric tests in the context of statistical inference for Biotherapeutics studies (C4)
CO 3:	**Interpret** various experimental designs in the context of Biotherapeutics studies (C3)
CO 4:	**Discuss** the research process and the steps associated with real-world research (C2)
CO 5:	**Illustrate** various research dissemination methods (C3)

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO10*
CO 1	×			×		×	×	×		×
CO 2	×		×	×	×	×	×	×		×
CO 3	×		×	×	×	×	×	×		×
CO 4	×			×		×	×		×	×
CO 5	×	×				×	×			×

Course content and outcomes:

Content	*Competencies*	
Credits		**3**
Module 1: Descriptive Statistics: **No of hours**		
Scales of Measurement, Data visualisation, Measures of Central Tendency, Measures of Dispersion	**Summarise** the various scales of measurement (C2). **Illustrate** appropriate data visualisation (bar chart, pie chart, histogram, box-plot, mosaic chart, scatter diagram, frequency curves) methods for categorical and quantitative variables (C4).	8 +1 (SDL)

	Illustrate appropriate measures of central tendency (mean, median, mode) and dispersion (range, inter-quartile range, inter-quartile deviation, standard deviation and variance) for categorical and quantitative variables (C4).	
Module 2: Inferential Statistics:		
Sampling Distribution Standard Error and Confidence Intervals Parametric Tests Non-Parametric Tests	**Summarise** sampling distribution, standard error, confidence intervals and basic terminology of hypothesis testing. (C2) **Illustrate** the parametric tests (one-sample t-test, two-sample independent t-test, paired t-test, ANOVA, repeated measures ANOVA and its assumptions. (C4) **Illustrate** the non-parametric tests (Sign test, Mann-Whitney U test, Wilcoxon Signed Rank Test, Kruskal Wallis ANOVA) and chi-square tests. (C4)	14 + 1 (SDL)
Module 3: Principles of experimental design.		
Completely randomised design. Randomised block design. Factorial design. Cross-over design and repeated measures design. Randomised Control Trial.	**Describe** the concept of experimental design and understand basic principles/terminology (C2). **Illustrate** completely randomised design, randomised block design, factorial design, cross-over design and repeated measures design with examples (C3). **Describe** a Randomized Control Trial (C2).	12 +1 (SDL)
Module 4: Introduction to Research Methodology		
Research Design Literature Review Data Collection Methods Sampling Methods	**Explain** research design and types of research design (C2). **Explain** various approaches to review literature (C2). **Describe** various methods of data collection (C2). **Summarise** methods of sampling (probabilistic and non-probabilistic) and identify confounding factors in a study to minimise their effects (C2).	10+1 (SDL)
Module 5: Research Dissemination		
Scientific Writing Oral Presentation Written Presentation	**Explain** the basics of scientific writing, kinds of scientific documents – Books, research paper, review paper, book reviews, theses, conferences, project reports and research project proposals to funding agencies (C2). **Describe** the components of research paper and thesis (C2).	6+1 (SDL)

	Illustrate oral and poster presentation of research papers in conferences/ symposia and describe effective presentation skills; Scientific editing tools (C3).	

Total Contact Hours (All modules) **54 hours**

Reference:

1. Daniel, W. W., & Cross, C. L. (2018). Biostatistics: a foundation for analysis in the health sciences. Wiley.
2. Senn, S. S. (2008). Statistical issues in drug development (Vol. 69). John Wiley & Sons.
3. Kothari, C. R. (2004). Research methodology: Methods and techniques. New Age International.

Mode of Evaluation:

First semester: Two written sessional exams (internal evaluation) and the end semester written exam

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies: 29.11.2022

Semester: I

Course Code: MBT-507

Course : BIOTHERAPEUTIC DISCOVERY AND DEVELOPMENT - Laboratory Course

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title:	**Biotherapeutic Discovery and Development (Laboratory Course)**
Course Code: MBT-507	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 6	**Prerequisites: Admission to M.Sc. (BT) program**
Synopsis:	The objective of the course is to apply the principles of therapy to practices in cell and gene therapy, protein therapy, and advanced biomaterials. Students will have hands-on experience in designing experiments, execution, and analysis.
Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Understanding various methods of cell culture, cell manipulation, the impact of gene editing, protein function, and biophysical cues for biotherapeutic development.
CO 2:	Understanding and analysis of the physical and functional characterization of methods employed to discuss their relative merits and interpret data from those techniques.

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO 10*
CO 1	×	×	×							
CO 2	×	×	×	×	×	×	×	×	×	

Course content and outcomes:

Content	*Competencies*	
		6 credits
Module 1:		**No of hours**
Cell and gene therapy	Basics of cell culture, isolation, and expansion of stem cells from tissue sources, gene editing, and functional characterization. Techniques include – cell culture – cell seeding, feeding, harvest, expansion, characterization, and cryopreservation; Molecular Biology – MTT/CCK-8 assay, RNA isolation, mRNA preparation, PCR/RT PCR, western blot, flow analysis, gene editing. systems, instrumentation, and bioprocess control. substrate utilization and product formation in a bioreactor, Scale-up of Bioreactors. Downstream process: Introduction to various downstream process operations in biopharmaceutical manufacturing such as centrifugation, filtration, tangential flow filtration, cell	36

	disintegration, solvent-solvent extraction, supercritical fluid extraction, etc (P1, P2, P3, P4, P5).	
Module 2:		
Protein therapy	Modes of protein delivery and functional characterization on selected primary cells/cell lines. Techniques include – cell culture, protein therapeutic impact on functions of cells; molecular biology – MTT/CCK-8 assay, RNA isolation, mRNA preparation, PCR/RT PCR, western blot, and flow analysis (P1, P2, P3, P4).	36
Module 3:		
Functional biomaterials	Preparation of hydrogels, and nanomaterials (nanoparticles, nanofibers, etc.) with functional cells, proteins, and physical and functional characterization. Techniques include – hydrogel preparation, nanomaterials preparation, cell-biomaterial composite preparation, protein-biomaterial composite preparation, zeta potential, SEM/TEM analysis, cell culture, molecular biology – MTT/CCK-8 assay, RNA isolation, mRNA preparation, PCR/RT PCR, western blot, flow analysis (P1, P2, P3).	36

Total Contact Hours (All modules) **54 hours**

Reference:

1. David W. Russell and Joseph Sambrook. Molecular Cloning: A Laboratory Manual. 2001, 3rd Edition. CSH Publication.
2. John M Walker. Principles and Techniques of Practical Biochemistry. 2001, 5th Edition. Cambridge press.
3. Debarati Das. Essential Practical Handbook of Cell Biology & Genetics, Biometry & Microbiology: A Laboratory Manual. 2017. Academic Publishers.
4. Julio E. Celis. Cell Biology: A Laboratory Handbook. Volumes 1, 2, 3; 1994. Academic Press.
5. Buddy Ratner. Biomaterials Science: An Introduction to Materials in Medicine. 2004. Elsevier.

Mode of Evaluation:

First semester:

Two practical sessional exams within the first semester (internal evaluation) and the end semester practical exam

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies: 29.11.2022

Semester: I

Course Code: MBT-521

Course : Pharmaceutical quality control, quality assurance, and regulatory affairs – Elective Course

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title:	**Pharmaceutical quality control, quality assurance, and regulatory affairs (Elective Course)**
Course Code: MBT-521	**Course Instructor: TBD**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 3	**Prerequisites: Admission to M.Sc. (BT) program**
Synopsis:	This course is designed to impart the knowledge of quality control and assurance along with the regulatory and legislative affairs in the pharmaceutical industry

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Understand the cGMP aspects in the pharmaceutical industry
CO 2:	Appreciate the importance of documentation
CO 3:	Understand the regulatory requirements and approval process for Drugs & Cosmetics, Medical Devices, Biologicals, Herbals, and Food & Nutraceuticals in India
CO 4:	Comprehend the pharmacopoeia standards and stem cell regulation in India along with stability requirements under global scenario

Mapping of COs to POs

CO 1	x		x	x	X		x			x
CO 2	x		x	x	X		x			x
CO 3	x		x	x	X		x			x
CO 4	x		x	x	X		x	X		x
CO 1	x		x	x	X		x			x

Course content and outcomes:

Content	*Competencies*	
		3 credits
Module 1:		**No. of hours**
Introduction, cGMP, and Quality control	Concept, evolution and scopes of Quality Control and Quality Assurance. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit: protocols for the conduct of non-clinical testing, control on the animal house, report preparation, and documentation. CPCSEA guidelines. cGMP guidelines according to schedule M, USFDA Pharmaceutical Inspection Convection (PIC), WHO and EMEA. In-process quality control and finished products quality control for following dosage forms in the Pharma industry according to Indian, US,	**14**

	and British pharmacopeia: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products. Analysis of raw materials, finished products, and packaging materials.	
Module 2:		
Documentation in pharmaceutical industry	Three-tier documentation, Policy, Procedures and Work Instructions, and records (Formats), Basic principles - maintenance, retention, and retrieval of records. Content and structure of Standard operating procedures, Master Batch Formula, Batch Manufacturing Record, Quality audit plan, and reports. Specification and test procedures, Protocols, and reports. Distribution records. Concept of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	**14**
Module 3:		
Drugs, biologicals & herbals, and food & nutraceuticals acts and rules (with latest amendments)	Introduction to Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA, Other relevant provisions (rules schedules and guidelines for approval of Biologicals & Herbals, and Food & Nutraceuticals in India. Regulatory requirements and approval procedures for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities. Rules, regulations, guidelines, and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.	**14**
Module 4:		
Indian pharmacopoeia standard	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards, Bioavailability and Bioequivalence data (BA & BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study. Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies. Ethical guidelines for human participants, ICMR-DBT Guidelines for Stem Cell Research. CDSCO (Central Drug Standard Control Organization) and state licensing authority: organization & responsibility	**10**

Total Contact Hours (All modules) **52 hours**

Reference books:

1. Quality assurance guide by Pharmaceutical Procedures India, 3 rd revised edition, Volume I &II, Mumbai, 1996
2. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. Guidelines for Import and Manufacture of Medical Devices by CDSCO 10. Guidelines from official website of CDSCO

Mode of Evaluation:

First semester: Two written sessional exams (internal evaluation) and the end semester written exam

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies : 29.11.2022

Semester: I

Course Code: MBT-523

Course : 3D Bioprinting – Elective Course

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title:	**3D Bioprinting (Elective Course)**
Course Code: MBT-523	**Course Instructor: Dr. S.V. Kirthanashri**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 3	**Prerequisites: Admission to M.Sc. (BT) program**

Synopsis:	This course deals with the understanding of various types of bioprinters and bioink formulation. The fundamentals and principles of bioprinting technology along with scaffold development are covered in the course.

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	On successful completion of this course, students will be able to
CO 2:	Understand the basics of 3D bioprinting technology
CO 3:	Envision the different applications of 3D bioprinting
CO 4:	Acquire knowledge on the formulation of bioinks and scaffold fabrication for biomedical applications

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO 10*
CO 1	x	x	x	x		x	x			x
CO 2	x	x	x	x		x	x			
CO 3	x	x	x				x		x	x
CO 4	x	x	x			x		x	x	

Course content and outcomes:

Content	*Competencies*	
		3 credits
Module 1:		**No of hours**
Introduction	History of 3D printing, Additive manufacturing, Introduction to 3D bioprinting, opportunities, challenges & importance of 3D bioprinting in biomedicine, Introduction to 4D printing, various Stimulus in 4D printing, sample processing, Advancement in 4D printing.	**6**
Module 2:		
3d printers - principle & mechanism	Laser-based printers, droplet printers, extrusion printers, and stereolithography printers. Commercial bioprinters for regeneration and tablet manufacture. Comparison of various modes of 3D printers, Digital models of tissue, and organs. Biomodelling – generation of CAD design, suitability of CAD design for printability.	**12**
Module 3:		

Selection and formulation of bioink	Natural, synthetic & decellularized inks – physical parameters, solubility factors, cross-linking agents, isolation of various organs & tissue. Bioink patterns - zig-zag patterns, dot pattern, scaffold pattern. Selection of cells, the role of growth factors and cell-cell interaction. Organ 3D printing - designing of printable structures, *in vitro* evaluation, and *in vivo* implantation.	**16**
Module 4:		
Applications of 3d bioprinting	3D printing for regeneration - liver, eye, skin, esophagus. 3D printing for disease model - fibrosis. 3D printing medical devices, Tablet printing	**12**

Total Contact Hours (All modules) **46 hours**

Reference Books:

1. 3D Bioprinting. Principles & protocols. Editors Jeremy M. Crook. Humana Press. Springer. eBook ISBN978-1-0716-0520-2.
2. 3D Bioprinting: Fundamentals, Principles and Applications. Edition: 1st. Publisher: Elsevier. ISBN: 9780128030301.
3. 3D Bioprinting and Nanotechnology in Tissue Engineering and Regenerative Medicine. Elsivier. Editors: Lijie Zhang, Kam Leong, John Fisher. eBook ISBN: 9780128245538. Hardcover ISBN: 9780128245521.
4. 3D Bioprinting in Regenerative Engineering Principles and Applications. Edited By Ali Khademhosseini, Gulden Camci-Unal. CRC press. ISBN 9781138197176.

Mode of Evaluation:

First semester: two written sessional exams (internal evaluation) and the end semester written exam

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies: 29.11.2022

Semester: I

Course Code: MBT-531

Course : Journal club presentation/ assignments

Name of the Program:	**M.Sc. (bv Research) in Biotherapeutics**
Course Title: Seminar	**Soft skills**
Course Code: MBT-531	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: First Year, Semester 1**
No of Credits: 2	**Prerequisites: Admission to M.Sc. (BT) program**
Synopsis:	Students will give an oral presentation of the latest published research article in the field of Biotherapeutics and submit assignments based on advanced topics in biotherapeutics.
Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Define problems, formulate hypotheses, test hypotheses, analyse,
CO 2:	Explain, problematizing, synthesising and articulating
CO 3:	Apply and draw conclusions from data, establish hypotheses, predict cause-and-effect relationships;
CO 4:	Analyse cause-and-effect relationships
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to analyse data

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO 10*
CO 1		x								
CO 2		x								
CO 3		x								
CO 4		x								
CO 5		x								
CO 6		x								
CO 7		x								

Content	*Competencies*	*No of Hours*
Module 1:		
	• This course will include allotment of an individual seminartopic related to the semester courses of first semester	30 minutes' oral presentationfor each student

Semester II

Course Code : MBT-630

Course : Soft skills II = Tutorials/Seminars/Journal Club

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title: Soft skills	**Tutorials/Seminars/Journal Club**
Course Code: MBT-630	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: First Year, Semester 2**
No of Credits: 4	**Prerequisites: Qualified previous semester as per university regulations**

Synopsis:	This course will include allotment of an individual seminar topic related to the semester courses of second semester. This will not only enhance knowledge base of students but alsoprovide them exposure as to how to present information in a clear and concise manner. Students will also learn how to compile the literature database information.

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	How to express thoughts and ideas effectively
CO 2:	Demonstrate the ability to listen carefully and react
CO 3:	Apply one's views and present complex information in a clear and concise manner to different groups
CO 4:	Conclude on information
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to compile, write and interpret data

Mapping of COs to POs

COs	*PO1*	*PO 2*	*PO 3*	*PO 4*	*PO 5*	*PO 6*	*PO 7*	*PO 8*	*PO 9*	*PO 10*
CO 1		×								
CO 2		×								
CO 3		×								
CO 4		×								
CO 5		×								
CO 6		×								
CO 7		×								

Content	Competencies	No of Hours
Module 1:		
	This course will include allotment of an individual seminar topic and review writing related to the semester courses	30 minutes oral presentation for each student

Semester II

Course Code : MBT-699

Course : Research Project work/presentation

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title: Practical skills	**Research Project work**
Course Code: MBT-699	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: First Year, Semester 2**
No of Credits: 16	**Prerequisites: Qualified previous semester as per university rules**
Synopsis:	This course will include allotment of an individual research work (allotted in first semester) toeach student. This will not only enhance knowledge base of students but also provide them exposure as to how to conduct, analyze data and carry out a research-based task. Students will also learn how to compile and interpret results.
Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Define problems, formulate hypotheses, test hypotheses, analyse,
CO 2:	Explain, problematizing, synthesising and articulating
CO 3:	Apply and draw conclusions from data, establish hypotheses, predict cause-and-effect relationships;
CO 4:	Analyse cause-and-effect relationships
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to compile and interpret research data

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO10*
CO 1						×				
CO 2						×				
CO 3						×				
CO 4						×		×		
CO 5						×		×		
CO 6						×		×		
CO 7						×		×		

Course content and outcomes:		
Content	*Competencies*	*No of Hours*
Module 1:		
Research Project	• This course will include allotment of an individualresearch topic (allotted in first semester)	32 hours of laboratory trainingand research per week

Semester III

Course Code : MBT-631

Course : Soft skills III: Tutorials/Seminars/Journal Club

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title: Soft skills	**Tutorials/Seminars/Journal Club**
Course Code: MBT-631	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: Second Year, Semester 3**
No of Credits: 4	**Prerequisites: Qualified previous semesters as per university rules**

Synopsis:	This course will include allotment of an individual seminar related to the semester courses ofthird semester. This will not only enhance knowledge base of students but also provide themexposure as to how to present information in a clear and concise manner. Students will also learn how to compile the literature database information.

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	How to express thoughts and ideas effectively
CO 2:	Demonstrate the ability to listen carefully and react
CO 3:	Apply one's views and present complex information in a clear and concise manner to different groups
CO 4:	Conclude on information
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to compile and interpret data

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO 10*
CO 1		×								
CO 2		×								
CO 3		×								
CO 4		×								
CO 5		×								
CO 6		×								
CO 7		×								

Course content and outcomes:

Content	*Competencies*	*No of Hours*
Module 1:		
	• This course will include allotment of an individualseminar topic related to the semester courses	30 minutes OForal presentationfor each student

Semester III

Course Code : MBT-699

Course : Research Project work/presentation

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title: Practical skills	**Research Project work**
Course Code: MBT-699	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: Second Year, Semester 3**
No of Credits: 16	**Prerequisites: Qualified previous semesters as per university rules**

Synopsis:	This course will include allotment of an individual research work (allotted in first semester) toeach student. This will not only enhance knowledge base of students but also provide them exposure as to how to conduct, analyze data and carry out a research-based task. Students will also learn how to compile and interpret results.

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Define problems, formulate hypotheses, test hypotheses, analyse,
CO 2:	Explain, problematizing, synthesising and articulating
CO 3:	Apply and draw conclusions from data, establish hypotheses, predict cause-and-effect relationships;
CO 4:	Analyse cause-and-effect relationships
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to compile and interpret research data

Mapping of COs to POs

COs	*PO 1*	*PO 2*	*PO 3*	*PO 4*	*PO 5*	*PO 6*	*PO 7*	*PO 8*	*PO 9*	*PO 10*
CO 1						×				
CO 2						×				
CO 3						×				
CO 4						×		×		
CO 5						×		×		
CO 6						×		×		
CO 7						×		×		

Course content and outcomes:

Content	*Competencies*	*No of Hours*
Module 1:		
Research Project	• This course will include allotment of an individualresearch topic (allotted in first semester)	32 hours of laboratory trainingand research per week

Semester IV

Course Code : MBT-632

Course : Soft skills III: Tutorials/Seminars/Journal Club

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title: Soft skills	**Tutorials/Seminars/Journal Club**
Course Code: MBT-632	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: Second Year, Semester 4**
No of Credits: 4	**Prerequisites: Qualified previous semesters as per university rules**

Synopsis:	This course will include allotment of an individual seminar related to the semester courses ofthird semester. This will not only enhance knowledge base of students but also provide themexposure as to how to present information in a clear and concise manner. Students will also learn how to compile the literature database information.

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	How to express thoughts and ideas effectively
CO 2:	Demonstrate the ability to listen carefully and react
CO 3:	Apply one's views and present complex information in a clear and concise manner to different groups
CO 4:	Conclude on information
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to compile and interpret data

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO10*
CO 1		×								
CO 2		×								
CO 3		×								
CO 4		×								
CO 5		×								
CO 6		×								
CO 7		×								

Course content and outcomes:

Content	*Competencies*	*No of Hours*
Module 1:		
	• This course will include allotment of an individual seminartopic related to the semester courses	30 minutes' oral presentation foreach student

Semester IV

Course Code : MBT-699

Course : Research Project work /Submission of manuscript

Name of the Program:	**M.Sc. (by Research) in Biotherapeutics**
Course Title: Practical skills	**Research Project work**
Course Code: MBT-699	**Course Instructor: Dr. Raghavendra Upadhya**
Academic Year: 2023-2024	**Semester: Second Year, Semester 4**
No of Credits: 16	**Prerequisites: Qualified previous semesters as per university rules**

Synopsis:	This course will include allotment of an individual research work (allotted in first semester) toeach student. This will not only enhance knowledge base of students but also provide them exposure as to how to conduct, analyze data and carry out a research based task. Students will also learn how to compile and interpret results.

Course Outcomes (COs):	On successful completion of this course, students will be able to
CO 1:	Define problems, formulate hypotheses, test hypotheses, analyse,
CO 2:	Explain, problematizing, synthesising and articulating
CO 3:	Apply and draw conclusions from data, establish hypotheses, predict cause-and-effect relationships;
CO 4:	Analyse cause-and-effect relationships
CO 5:	Define problem in a concise manner
CO 6:	Adopt to challenging tasks
CO 7:	Students will also learn how to compile and interpret research data

Mapping of COs to POs

COs	*PO1*	*PO2*	*PO3*	*PO4*	*PO5*	*PO6*	*PO7*	*PO8*	*PO9*	*PO 10*
CO 1						×				
CO 2						×				
CO 3						×				
CO 4						×		×		
CO 5						×		×		
CO 6						×		×		
CO 7						×		×		

Course content and outcomes:

Content	*Competencies*	*No of Hours*
Module 1:		
Research Project	• This course will include allotment of an individualresearch topic (allotted in first semester)	32 hours of laboratory trainingand research per week

Mode of Evaluation:

Fourth semester: Viva voce and internal assessment

Recommended by Board of Studies: 29.11.2022

Approved by Board of Studies: 29.11.2022

Mode of Evaluation of Research Project

- **Master's Project Advisory Committee (MPAC)**
  Master's Project Advisory Committee – has the following members:
  1. Coordinator of MCBR
  2. Coordinator for the MSc program
  3. Project guide from MCBR
  4. Project co-guide from Industry/other institutions/MCBR
  5. Subject matter expert/s (optional)
     MPAC shall provide academic support for completing the dissertation, monitor progress, and help in the assessment. The MPAC should meet at least once a semester.

- **Systematic review and synopsis submission:**
  A systematic review of scientific literature in the research area of the proposed project will be performed by the student for formulating the objectives and methodology. The student will submit the synopsis of the proposed project as per the format, in consultation with the project guide/co-guide to be approved by the MPAC. This will be done within 8 weeks of joining the internship training in the second semester. The experimental research work shall commence immediately on approval of the synopsis.
- **Project Work**
  The project will be undertaken during the 2nd, 3rd, and 4th semesters and comprise 18 weeks per semester. A total of 60 credits are allotted for research work, presentation, and thesis submission distributed equally in all three semesters.

  Seminar presentations:

  The student shall make a seminar presentation before the MPAC to summarize the project work performed at the end of semester-2 and semester-3. The mid-term presentations will be made in semester 3 to appraise the progress of the work and in semester 4 to present the results/outcome.

  Conferences and workshops:

  The candidate shall attend and present in one conference/workshop/CME/ Science exhibition as approved by the MAHE towards the end of the third semester. Rules and regulations of the MAHE will be applied.

  Manuscript preparation:

  It is desirable that the candidate may prepare and submit a research/review article manuscript suitable for publication in a scientific journal or to the MPAC in the fourth semester before submitting the project dissertation.

  Preparation and submission of the dissertation

  The dissertation must be submitted by the university's stipulated date by the end of the 4th semester. The dissertation must contain a scholarly review of the

pertinent literature, give evidence of independent research, and be clearly, logically, and carefully written as per the format decided by MCBR. The thesis defense/viva-voce will happen before the examiners, approved by MAHE.

GUIDELINES FOR WRITING A DISSERTATION

The dissertation should be a minimum of 25 pages and may not exceed 200 pages. Students are required to follow the given guidelines while writing of dissertation:

1. Title Page: The layout of the title page should be as per annexure 1.
2. Work Certificate: Duly signed by the guide and/or co-guide.
3. Table of Contents: Develop a table of content guiding through the various sections of the dissertation.
4. List of Figures and Tables: If two or more figures or tables appear in the dissertation, a list of figures/tables should be included after the Table of Contents.
5. Introduction: The introduction should answer two questions: (i) Why is the focus on this particular subject? and (ii) how does the work fit into the larger context?
6. Review of Literature: A review may be a self-contained unit that rationale for primary research. A review must survey the literature in your chosen area of study.
7. Materials and Methods: The Source of chemicals used, and manufacturing details of equipment should be mentioned. Sub-headings for the various methods should be provided with appropriate references in numerical order. A detailed description of statistics applied for data analysis should be indicated.
8. Results: Describe the findings in a precise and concise manner. This is the real heart of the project and contains the original contribution of new knowledge in the chosen field.
9. Discussion: The discussion should lay out results, interpreting them to the larger field. Discussion should contain a thorough discussion of findings that demonstrate researchers' potential.
10. Conclusions: The conclusion should briefly state the research discovery and the significant ramifications of the work.
11. References: Use Vancouver style to write the reference.
12. Acknowledgements: Acknowledge those who have technically assisted with materials supply, or intellectually with suggestions, advice or expert help and financially with funding, institutional support, travel grant etc.
13. List of achievements: Conference presentations, list of papers with reprints, list of patents or other accomplishments related to the work may be included as annexure.

Annexure-1: Layout of Title page

TITLE OF DISSERTATION

(Capital, bold and inverted pyramid form)

A DISSERTATION PRESENTED BY

(**NAME**)

TO

MANIPAL CENTRE FOR BIOTHERAPEUTICS RESEARCH,

MANIPAL ACADEMY OF HIGHER EDUCATION, MANIPAL

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

MASTER OF SCIENCE BY RESEARCH

in

BIOTHERAPEUTICS

YEAR

Annexure-2: Thesis Formatting and Printing

Main Body of Paper: It should have page numbers at the bottom of each page, have one-inch margins, and be typed using 12-point font. All papers must be written in English. It should be one-sided. You should carefully proofread the thesis to avoid any spelling or grammatical errors.

Binding: Three final copies of the dissertation must be submitted to the Department before giving your presentation. Watch announcements for the specific date. To bind your dissertation, ask for spiral binding. Your name and dissertation title should be visible on the title page. The Department will keep these copies.

The MAHE library will hold a copy of the dissertations, and another copy will be retained in the Department. Ensure that when the publication is bound, the contents are not obscured or destroyed due to trimming of the pages.

Some of the essential issues related to layout are listed below:

- Sizes of page margins and line spacing
- Formats of the title page
- The contents list
- Appendices
- The reference list
- Illustrations, figures and tables
- Numbering systems for chapters and sections
- Pages
- Figure and table captions
- Equations
- Font styles for chapter and section headings
- Other text figures and table captions
- Equations
- Quoted work
- Citations and how references are formatted uniformly
- How tables, figures and equations are cited

— Whether the publication should be written in a particular tense or "person."
— Typically, the layout of a page should be as follows:
— Left margin: 40mm; Top, bottom and right margins: 25mm
— Text font: 12 point Times-Roman or Times-New-Roman
— Line spacing: 1 line

EVALUATION OF MASTER'S THESES

The master's thesis is an independent research project completed by the student. The guide and/or co-guide shall evaluate all parts of the complete thesis submitted for evaluation. The extent of the master's thesis shall be 48 credits (spread across equally in 2nd, 3rd and 4th semester), an equivalent of 18 months of full-time studies.

To qualify as an academic thesis, a master's thesis should meet all the criteria described below to at least a satisfactory extent. The grade assigned depends on the extent to which the requirements have been met.

Definition of research scope and goals

- The research scope has been defined.
- The goals of the thesis are evident.
- The research questions and hypotheses contained in the scope of research and goals are evident.
- from the thesis.

Command of the topic

- The student demonstrates command of the topic and an understanding of the scope of research.
- The student demonstrates an understanding of the relevant theoretical framework.
- The student demonstrates skills in making use of literature and other sources of information.

Methods and conclusions

- The student demonstrates the ability to choose justified methods for reaching the goals.
- The student demonstrates the ability to apply the chosen methods.

- The thesis contains references to scientific publications.
- The thesis presents well-founded conclusions drawn from the results.
- The results answer the research questions presented.

Contribution to knowledge and thesis structure

- The thesis is relevant to the set goal.
- The thesis is a well-organized logical whole.
- The thesis makes an original contribution to knowledge, i.e. it is produced by the student.

Presentation and language

- The overall appearance of the thesis is appropriate.
- The thesis contains no such grammatical or spelling errors that complicate reading.
- The thesis is written in a coherent, formal style. The thesis is a well-organised
- coherent whole.
- The given guidelines have been followed.

OVERALL ASSESSMENT AND EXAMINATIONS OF MSc (By Research) PROGRAM

Attendance and internal assessment are two valuable tools to monitor a student's academic progress. Those who do not have 75% attendance and failed to score 50% marks in the internal assessment in a particular subject cannot appear for the university examination.

Scheme of Examinations:

A candidate has to register for the examination for the subjects at the first attempt. The examinations will be held once at the end of the I semester and IV semesters or on dates that the university may fix.

- **Theory Examination:**

  Will cover all segments of the syllabus and include both short and essay questions.
- **Evaluation of Dissertation and Viva-voce examination:**

  The dissertation will be evaluated, and the Viva-voce examination will assess the candidate's knowledge at a high level of interpretation and problem-solving abilities.

- **Assessment by internal and external examiners**

  There will be evaluation by internal examiners and external examiners for the theory and laboratory courses and the project work. For the theory courses, a minimum of 30% of the total marks are maintained for internal evaluation and laboratory exercises and project work. No choice will be given in university and sessional examinations.

  (i) Internal assessment for theory courses shall comprise sessional examinations and seminar presentations assessment.

  (ii) Marks of the sessional examinations shall be published on the notice board of the Centre.

  (iii) Internal assessment of project work includes assignments, mid-semester and end semester seminar presentations, student presentations to scientific conferences/reports of attendance to scientific workshops and exhibitions and preparation of manuscripts for scientific journals.

- **Rules regarding the sessional examination:**

  There shall be one sessional examination for thirty marks each in the first semester for theory papers.

- **External/university examination:**

  Conduct of the external/university examinations for theory and practical and their assessment will be done as per the rules of the MAHE.

  Duration of Examinations

  - Duration of University Examinations

  Theory - 3 hours each.

  - Duration of Sessional Examinations:

  Theory - 2 hours each

- **Appearance for University Examinations:**

  A candidate shall register for all the subjects of a phase/year/part when he appears for the examination of that phase/year/part for the first time.

- **Minimum for Pass**

  No candidate shall be declared to have passed in any subject if the aggregate of written examination and internal assessment is less than 50%. Every candidate must obtain not less than 40% marks in the university written examination.

  A candidate who fails in any subject shall take the examination only in that subject at a subsequent university examination (theory). They must obtain the minimum passing marks in that subject as stated above.

- **Carryover:**

  M.Sc. by Research students are not allowed to carry more than two subjects from the first semesters before proceeding to project work. In order to pass all the subjects, a candidate will be permitted not more than two chances (in the second and third semesters). To defend their research project in the final examination, students must clear all their carry-over subjects.

  No grade shall be declared for a candidate who does not pass an examination on the first attempt.

- **Choice Based Credit System:**

  (i) The Choice Based Credit System (CBCS) offers the choice to students to select their preferred electives from the list of courses offered. During this period, the student must select from prescribed courses (core and elective courses) to obtain credits. Each course will carry certain credits and may comprise of lectures/tutorials/practical/fieldwork/seminar/viva/assignments/presentation/ self-study or related activities.

  (ii) A core course is a course that is to be compulsorily studied by the student as a core requirement to complete the program.

  (iii) An elective course can be chosen from a list of courses offered and provides a choice for the learner. It provides an expanded scope for the understanding of the program and aids in improving students' skill sets and proficiency towards overall development.

  (iv) A student shall choose the elective course at the beginning of the first and second academic years.

(v) Every student must present their research findings in conferences/meetings/symposiums and communicate a minimum of one research article before their final defence of the thesis.

(vi) Each semester will consist of a minimum of approximately 18 weeks of academic work corresponding to 90 teaching days. The odd semester usually starts in August, while the even semester is in January.

- **Classification of Successful Candidates:**

  Relevant marks will be given for all examinations and converted into grade points. After the University examination at the end of each semester, transcripts with grades scores will be provided for each student. The overall grading will be 'relative' in nature; however, courses with internal assessment and research project/ final thesis defence will be evaluated on an absolute scale.

- **Grading System:**

  The ten-point grading system shown below is used for awarding letter grades in each course.

Letter Grade	A+	A	B	C	D	E	AP	F/I/DT
Grade Points	10	9	8	7	6	5	0	0

AP: Audit Pass F: Failure I: Incomplete DT: Attendance Shortage

The overall performance of a student in each semester is indicated by Grade Point Average (GPA), which is a weighted average of the Grade Point obtained in semester expressed as

$$GPA = \frac{\sum_{i=1}^{n} (C_i \times G_i)}{\sum_{i=1}^{n} C_i}$$

where

n= Number of courses graded per semester

Ci = Number of course credits for the ith course

Gi = the grade point scored by the student in the ith course.

The overall performance of the student for the entire programme is indicated by Cumulative Grade Point Average (CGPA), which is the weightage average of grade points obtained across all semesters to date

$$\text{CGPA} = \frac{\sum_{i=1}^{N} (C_i \times G_i)}{\sum_{i=1}^{N} C_i}$$

where

N= Total Number of courses graded to date

****