मास्टर ऑफ टेक्नॉलजी (एमटेक) इन बयोमेडिकल इंजीनियरिंग

MASTER OF TECHNOLOGY (MTech) IN BIOMEDICAL ENGINEERING

पाठ्यचर्या &पाठ्यक्रम

CURRICULUM & SYLLABUS

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेंद्रम,

केरल- 695 011, भारत

(एक राष्ट्रीय महत्व का संस्थान, विज्ञान एवं प्रौद्योगिकी विभाग, भारत सरकार)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

KERALA - 695011, INDIA

(An institution of National importance, Department of Science and Technology, Government of India)

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1. Scope of the Program

Medical devices play an important role in modern healthcare. There is a huge and growing demand in India as well as across the globe for medical devices. India, being one of the major users of medical devices and implants, depends on imports for over 80% of its needs. The nation is striving to expand its capabilities and human resources in medical devices and implants and become self-sufficient. Data-driven medical diagnosis and treatment is an upcoming area that uses information technology to provide customized and accurate treatment. The Government of India has introduced a Production Linked Incentive scheme in medical device manufacturing to encourage domestic manufacturing, attract significant investments, reduce reliance on imports, and attain self-sufficiency (Atmanirbhar Bharat) in this industry segment as well. To achieve this goal, trained manpower is required, especially in the area of medical devices, biomedical science and technology, and their design, testing and validation. To meet this imminent demand, focused courses and training in Biomedical Engineering are to be implemented. This Master of Technology (Biomedical Engineering) course has been conceived with this background.

This course imparts knowledge and training in Biomedical Engineering with a focus on developing medical devices in the domains of Cardiovascular, Neurological, Orthopaedic, and Orthotic devices with a view to innovating solutions meeting performance, safety, and regulatory criteria. Biomedical signals and imaging and their importance in diagnosis and treatment are also covered. The specialized engineering skills required are imparted through short-term course projects wherein the student is trained to use scientific and technical knowledge and state-of-the-art tools to create an innovative solution. The whole gamut of medical device development from identifying user needs, interacting with clinicians and patients and identifying their requirements, choice of design and materials, modelling and simulation, testing and validation, in vivo models, to clinical trials are covered during the course. The importance of innovation and intellectual property are also introduced. The student will be well poised with this course to take up roles in industry, research as well as academia.

2. Program Description

Advanced knowledge in engineering principles, science, technology and its practice in Biomedical engineering will be provided by the course. Emphasis is on providing a comprehensive understanding of the medical device development lifecycle. This includes identifying user needs from the perspective of clinicians, users and patients, their design and development, validation, regulatory requirements, translation and manufacturing. The course will also address the choice

and selection of biomaterials for various applications. Biomedical signal and image analysis will also be covered and equip the student towards modern data-driven systems for diagnosis and treatment. The course aims to equip scholars to individually research, innovate and develop medical devices using a needs-based approach, manage risks, achieve performance as well as safety, successfully build, prototype and test, generate intellectual property and communicate their work effectively under a quality management framework.

3. Learning Objectives

(i) Medical Devices – what, risks, safety, performance, quality, standards, regulatory mechanisms.

(ii) Biomaterial selection and evaluation for various applications.

(iii) Biomechanics, Biosignals and Medical Imaging

(iv) Design and Design Optimization – user needs, analysis, CAD, simulation, computational methods.

(v) Prototyping, Design verification and validation, Translation, Manufacturing

(vi) In depth design principles of cardiovascular, electromechanical, polymeric, orthopaedic, and orthotic devices, instrumentation and biomedical signals and images.

(vii) Quality management systems, Innovation, Intellectual property, effective communication and management skills.

4. Eligible Candidates

Candidates with a CGPA above or equal to 6.5 (or equivalent marks) in the undergraduate level in the following categories are eligible for admission to the course.

I. B.E./B.Tech. /AMIE or equivalent in following disciplines with valid GATE score

- Biomedical Engineering
- Biotechnology
- Chemical Engineering
- Computer Science and Engineering/ Information Technology
- Electrical Engineering
- Electronics/Telecommunications Engineering
- Engineering Physics
- Instrumentation Engineering
- Mechanical Engineering
- Metallurgy & Materials Science
- Pharmaceutical Technology
- Polymer Technology

- Other Branches of Engineering

II. M.Sc. or equivalent in following disciplines with valid GATE score

- Biochemistry
- Biophysics
- Biotechnology
- Ceramics
- Chemistry
- Electronics / Electronic Sciences
- Ergonomics
- Materials Science
- Mathematics
- Molecular Biology
- Physics
- Physiology
- Other Branches of Science

III. Health Sciences with all National level post graduate entrance examination for the disciplines like NEETPG, NEETMDS, etc.

- MBBS
- BDS
- BPharm
- BVSc
- B.P.Th., B.O.Th., B.ASLP, Pharm D (Eligible only if the duration of these courses are 4 years or more)

All India level post graduate entrance examination for corresponding disciplines such as INI_CET/NEETPG/ NEETMDS JIPMER/PGI Chandigarh/ AFMC Pune/DNB Part I, AIIPMR for MBBS / BDS, GPAT/ All India level selection examination for BPharm, All India level post graduate entrance examination such as AIIPMR for MVSc., M.P.Th., M.O.Th. and M.ASLP. GATE examination for all such health science background where applicable.

Eligibility/rank certificates for all such national level entrance examinations are required. The candidate should have qualified the entrance examinations (as per the qualification criterion of the respective **exam** for that exam year and category) and the score obtained should be valid (as per the duration of validity for the respective exam) at the time of application to the MTech program.

4.1 Overseas Students

Selection will be based on educational qualifications, professional experience, the sponsoring organizations' assessments, and a telephonic interview. Applicants are required to submit two

confidential reference letters while submitting the application form. Also, the candidates have to provide certification for proficiency in English.

5. Mode of Selection

(i) **Statement of Purpose** from prospective student.

(ii) **A. Research assistantship category:** Shortlisting based on marks in the qualifying examination and valid GATE score / score in the National level entrance exam like NEET for MBBS/BDS/MVSc, as specified in 3.III above.

B. Sponsored candidates: Shortlisting based on the marks in the qualifying examination.

(iii) Test at the Institute level and interview of candidate after shortlisting.

6. Categories of Admission and Financial Support

The institute will admit students under the following categories:

6.1 Research Assistantship

Six students will be admitted in this category. This number may be increased in the future. An amount of Rs. 12,400/- per month will be paid for GATE/ other national Eligibility test qualified candidates for a period of 24 months. Students receiving assistantship should work in laboratories specified by the department for at least 8 hours per week. Amount will be released based on the attendance in the lab work.

6.2 Sponsored Candidates

Academic institutes, research institutes and industries can sponsor candidates for the program. Four seats are reserved for sponsored candidates. GATE or National level eligibility test is not mandatory for sponsored candidates.

7. Fee Structure

Admission Fee (₹)	
Application fee	1,500 *
Admission fee	1,000
Caution deposit	10,000
Library	1,000
Student welfare fund	1,000
Miscellaneous fee (Identity card, etc.)	500
Total (A)	**15,000**

*Tuition Fee (₹) – To be paid semester-wise	
Semester 1	25,000
Semester 2	25,000
Semester 3	25,000
Semester 4	25,000
Total (B)	**1,00,000**

Exam Fee (₹)	
Semester 1	1,000
Semester 2	1,000
Thesis evaluation	5,000
Total (C)	**7,000**

Total Fee for the MTech BME program (A+B+C) = ₹ 1,22,000 (INR One lakh twenty-two thousand only).

8. Course Structure

- MTech Biomedical engineering curriculum is interdisciplinary and is of 4 semesters duration.
- Each academic year has 2 semesters of roughly 15 weeks each (5 days working weeks, omitting the days of evaluation/exams).
- The courses will consist of CORE courses in Biomedical engineering, and is common to all students in semester one.
- Specialisation core courses will be offered in second semester and Electives will be chosen based on the student's research interest under the guidance of the Research Advisor.
- In the first year the students to get a practical exposure to Biomedical engineering, would have to do two laboratory internships.
- MTech program sets aside the last two semesters for mentored thesis research. Students will start working on a research area in the third semester of study under the supervision of a guide. Research will be supervised by a Research Advisory Committee (RAC) composed of Research Advisor/Guide (or Mentor), Co–Advisor and a nominee of the Head of Department as ex–officio member. The guide may initiate the steps to constitute RAC which may be recommended by Head of Department and approved by the Dean (Academic affairs). Scholars are expected to carry out their research activity on campus.

Research work off-campus will be permitted to sponsored candidates in case an MoU exists that directly facilitates academic activities.

- The research area could be an unmet clinical need identified with the help of a clinical faculty or a resident. This unmet need must be researched in depth to arrive at a solution. The Co-Advisor could be a clinical faculty associated with the clinical resident who is also working simultaneously on the clinical aspects in the same area.
- For identifying research problems, the students are encouraged to contact clinicians, industries including startups, in case an MoU exists with the organisation for collaboration.
- The medium of instruction, examination and project report for all courses is English. The syllabi and curricula of the program are subject to revision from time to time. On course commissioning a Syllabus Revision Committee (SRC) will be formed from participating faculty under the Head of Department. SRC will meet once a year and recommend changes in syllabus and course systems for incoming admissions as necessary. Recommendations from SRC on the course conducted in the department will be passed on to the Academic Affairs for approval through proper channel for implementation.
- Currently maximum number of students admitted would be 10, considering the faculty strength, lab space and facilities. Four seats can be reserved for sponsored candidates. A "No Objection Certificate" from their employers indicating grant of permission to undertake course and commitment to meet expenses will be required.

9. Degree Requirements

MTech (Biomedical engineering) program follows a credit-based system for the successful completion of the degree program. Each course is assigned credits, and continuous assessment is used to assign a letter grade to a student enrolled in that course based on a relative grading scheme. A cumulative grade point average (CGPA) is calculated using the student's letter grades. The following are the minimum requirements for the award of a MTech degree:

- Each student should acquire a minimum of **75 credits** for MTech program.
- All the courses of the first year must be successfully completed.
- Successful completion of the thesis by research is mandatory for the award of the MTech degree.

- Scholars shall be encouraged to attend conferences / seminars in the area of their work by Mentor.
- A prepared manuscript for publication and / or patent application is to be submitted with thesis.

10. Coursework and Assessment

The progress of the students will be assessed using:

(i) Written reports
(ii) Oral presentations
(iii) Laboratory reports
(iv) Examinations
(v) Thesis

11. Assessment Guidelines

(i) Marks for courses will be awarded on the basis of written assessment and internal assessment. This can be utilized to assess student preparation, provide training in reporting and presentation skills.

(ii) Written Assessment: This will be held after completion of required class hours. A written assessment will be held for a course which carries a credit value of 2 or above. The courses with credits less than 1 will be clubbed together for a single written assessment.

(iii) Admission to written assessment (or written examination) is restricted to students who secure 80% attendance. Lack of attendance due to medical grounds will be condoned on production of a medical certificate from a licensed medical practitioner. Written assessment will be for 60% to 80% of the total marks allotted for the course.

(iv) Examination/assessment format: To ensure uniformity and quality content written examinations shall be carried out under the following guidance. Exams shall consist of 4 to 5 essays for 10 marks each, 5 to 8 detailed questions for 5 marks each and can also include 5 to 10 brief essay questions of 2 to 3 marks each. Choice may be provided to the students in question paper by faculty based on course diversity.

(v) Internal assessment Assignments: At least one oral presentation will be assigned based on subject area and one assignment in written / typed form. 20-40 marks per module is assigned to the same. 10-15 marks for oral presentation / seminars and 10-25 marks for

project work. Marks can be further allotted based on presentations and assignments by faculty. For example, 100 marks is total mark available for assessment to obtain 3 credits for a particular course. Then 60 - 80 marks will be allotted to written exam and 20 - 40 marks will be allotted to internal assessment.

(vi) Academic Review: Scholars should be made aware that academic activity will be reviewed thoroughly, and plagiarism or unethical practices will not be tolerated in any form. In case of unethical activity, adverse reports on plagiarism analysis the mentor of the student, RAC & HOD shall be notified. Further action as required will be recommended by the RAC.

(vii) Thesis: This shall be a comprehensive document covering research work from inception, literature review to reporting of results. Format of MTech thesis and guidelines as published with updates from time to time on SCTIMST website should be followed.

(viii) The Thesis will be evaluated by two examiners nominated by the HOD as well as the research mentor.

(ix) Submission of thesis will be on the last working day of the penultimate month of the 4th semester. This will provide a three-week window for DAA to provide it for review and gather comments from two examiners before the *viva voce*.

12. Assessment Criteria & Evaluation

PERCENTAGE OF MARKS	LETTER GRADE
90 and above	S - Outstanding
80 to < 90	A - Excellent
70 to < 80	B - Very Good
60 to < 70	C - Good
50 to < 60	D - Satisfactory
40 to < 50	E - Poor
<40	F - Fail
Incomplete	I
Withdrawal	W

12.1 Marks Awarded for Courses

For each course the maximum marks awarded on evaluation would be 100 and this may be gained through the following ways of assessment:

- Written Exam : 60 - 80 marks (each course exam)
- Seminars/Assignment : 10 - 15 marks (each course)
- Course Project : 10 - 25 marks (each course)

Laboratory Internship : 100 marks (each report and presentation)

Marks for Research Project Report : 70% (assessed by Monitoring Committee including the mentor)

Marks for Research Thesis Viva : 30% (based on the defence of the thesis)

12.2 Grade Points

GPA - Grade Point Average, Semester wise – SGPA, Cumulative - CGPA

$$GPA = \frac{\sum_i (C_i \,.\, GP)}{\sum_i C_i}$$

where C_i is the credit of the course;

GP is the grade point of that course, and Σ_i is the sum of the credits of all registered courses successfully cleared during that semester.

Letter Grades

Grade	Grade points
S	10
A	9
B	8
C	7
D	6
E	4
F	0

For converting GPA into percentage, use the formula:
'Percentage = 55 + 10 (GPA - 6)'

Grades 'S' to 'E' indicate successful completion of the course

Attendance Code

Attendance rounded to	Remarks	Code
≥ 95%	Very good	VG
85 - 94%	Good	G
< 85%	Poor	P

13. Essentials for Completing Courses

(i) Students are expected to attend all the classes. Students with overall 80% attendance or above will only be permitted to write the end semester examination. Attendance will be recorded in every class.

(ii) To attend the following semester a student must have completed ALL prerequisite courses (if any) with an E grade or better.

(iii) A student with an F grade in a course may be given a repeat final examination. An F grade may be improved at best to a E grade as a result of the repeat final exam. Under-performing students may be given remedial classes before the repeat final examination.

(iv) Repeat of a course is not permitted if the student has obtained a grade E or above in the same course.

(v) The incomplete grade I is a transitional grade which will be given to the students who miss the end semester examinations under exceptional circumstances (e.g., serious medical reasons) as determined by the MTech course coordinator in consultation with the Head of Department (if applicable) and approved by the Dean (Academic Affairs). Make-up examination will be given to these students provided they meet 80% attendance and other academic requirements as per the rules and regulations of the institute. The actual grade obtained after the make-up examination will be taken and will reflect in the transcript replacing the I grade. In case a student obtains an F grade in the make-up final examination, he/she will be eligible to write the repeat final examination. Absence in the make-up examination will automatically lead to zero marks in that examination and the final grade in that course will be determined based on the other examinations taken in that course. If the absence of a student in an examination is not approved by the Dean (Academic Affairs) (e.g., a deliberate attempt to skip the examination), he/she will be awarded zero marks in that particular course examination. The final grade in that course will be determined based on the other examinations of that course taken by the student.

(vi) Withdrawal of a registered course in a semester is usually permitted/enforced under very special cases, e.g. due to prolonged illness. W grade is given in these circumstances and the student is asked to repeat the concerned course with same course number taking all examinations when offered next. The new grade obtained by the student will be taken into consideration and appear in the transcript. However, the previous W grade will also appear in the transcript.

(vii) W grade will not have any effect in the calculation of CGPA. If a student has W grade in a registered course in a particular semester, CGPA will be calculated based on the grades obtained in other courses of that semester.

(viii) If a student does not clear a CORE course even after writing (or skipping) the repeat final examination, he/she is required to repeat the course with the same course number when offered next taking all examinations. Until the course is repeated and passed by the student, it is treated as a backlog in the student's records. Both the grades, the new grade and the previous F grade, will appear in the grade transcripts.

(ix) An F grade obtained in a course will contribute to the CGPA until:

i. The course with the same course number is completed with a E grade or better (applicable for foundation and core courses) OR

ii. Substituted with an alternative course of the respective Department and completed with an E grade or better (applicable only for minor/elective/additional courses).

(x) A maximum of one backlog course from the first year may be allowed, at the discretion of the Dean (Academic Affairs) and the Director, before a student can choose a major and proceed to the second year.

(xi) A student who has more than two F and/or W grades in a particular semester of the first four semesters will have to repeat ALL the courses of that semester. Only the new grades obtained in all the courses will be taken into consideration and the previous grades will be converted to W grades.

(xii) The student gets elevated gradually to each semester(s) by completing / attempting all the courses of previous semester(s) by registering and writing the end semester examinations as per rule and meeting other academic requirements as per Course Diary.

14. Details of Courses and Credits

14.1 Semester-Wise Credit Distribution

Semester	I	II	Summer Internship	III	IV	Total
Credits	18	19	4	17	17	75

14.2 Assignment of Credits to Courses

Course code	COURSE NAME	L	T	P	C

SCT XXX	Course 1	2	0	2	3

L: Lecture, T: Tutorial, P: Practical /Lab, C: Credits
One lecture or tutorial hour per week for a 15-week long semester is assigned one credit.
Two laboratory/practice hours per week for a 15-week long semester is assigned one credit.

14.3 Course Distribution

This program offers 5 program core courses, 2 specialization core courses, and 3 elective courses, one clinical attachment, one laboratory module, 2 laboratory internships, summer internship and 2 one-credit courses on research methodology and safety in biomedical laboratories.

14.4 Semester-wise Distribution of Courses and Credits

SEMESTER 1

Course Code	Course Name	L	T	P	C
SCT 501	Anatomy and Physiology for Engineers #	2	1	0	3
MDE 501	Immersion to Engineering and Technology #	2	0	2	
BST 501	Biomaterials	2	0	2	3
MDE 502	Fundamentals of Medical Devices	2	0	2	3
MDE 503	Medical Device Technology	2	0	2	3
BMT 501	Research Methodology	1	0	0	1
SCT 551	Clinical attachment	0	0	4	2
BMT 551	Laboratory internship 1	0	0	4	2
BMT 502	Safety in Biomedical Laboratories	0	1	0	1
	Total for Semester 1				**18**

Mandatory bridge course – Either one of these courses should be selected based on the educational background of the student.

SEMESTER 2. SPECIALISATION - MEDICAL DEVICES ENGINEERING

Course Code	Course Name	L	T	P	C
MDE 612	Computational Modelling in Biomedical Engineering	2	0	2	3
MDE 611	Medical Device Design and Production	2	0	2	3
	Elective 1				3

	Elective 2				3
	Elective 3				3
MDE 551	Laboratory Module	0	1	2	2
MDE 552	Laboratory internship II (Mini Project)	0	0	4	2
	Total for Semester II				**19**

SEMESTER 2. SPECIALISATION - MEDICAL DEVICES ENGINEERING: ELECTIVE COURSES

Course Code	Course Name	L	T	P	C
MDE 511	Medical Instrumentation and sensors	2	0	2	3
MDE 512	Biomechanics	2	1	0	3
MDE 513	Biomedical Signal and Image processing	2	0	2	3
MDE 613	Advanced Polymer Technology	2	0	2	3
MDE 514	Orthopaedic Implant Technologies	2	1	0	3
MDE 515	Artificial Intelligence and Connected Health	2	0	2	3

SEMESTER 2. SPECIALISATION - APPLIED BIOSCIENCES

Course Code	Course Name	L	T	P	C
APB 611	Biological & Safety Evaluation	2	0	2	3
APB 612	General Pathology and Implant Biology	2	0	2	3
	Elective 1				3
	Elective 2				3
	Elective 3				3
APB 551	Laboratory Module	0	1	2	2
APB 552	Laboratory internship II (Mini Project)	0	0	4	2
	Total for Semester II				**19**

SEMESTER 2. SPECIALISATION - APPLIED BIOSCIENCES: ELECTIVE COURSES

Course Code	Course Name	L	T	P	C
APB 511	Applied Biochemistry & Physiology	1	1	2	3
APB 512	OMICS (Genomics, Proteomics, Metabolomics)	2	0	2	3
APB 613	Tissue Engineering & Regenerative Medicine	2	1	0	3
APB 614	Tissue-based Medical Devices	2	1	0	3
APB 513	Fundamentals of Pharmacology	2	1	0	3
APB 615	In-vivo Functional Safety Evaluation	1.5	1	1	3

SEMESTER 2. SPECIALISATION - BIOMATERIALS

Course Code	Course Name	L	T	P	C
BST 611	Polymeric Biomaterials	2	1	0	3
BST 612	Biomaterials Processing Techniques	2	0.5	1	3
	Elective 1				3
	Elective 2				3
	Elective 3				3
BST 551	Laboratory Module	0	1	2	2
BST 552	Laboratory internship II (Mini Project)	0	0	4	2
	Total for Semester II				**19**

SEMESTER 2. SPECIALISATION - BIOMATERIALS: ELECTIVE COURSES

Course Code	Course Name	L	T	P	C
BST 511	Nano Biomaterials	2	1	0	3
BST 613	Drug Delivery Systems	2	1	0	3
BST 614	Orthopaedic and Dental Materials	2	1	0	3

APB 615	In-vivo Functional Safety Evaluation	1.5	1	1	3
APB 613	Tissue Engineering & Regenerative Medicine	2	1	0	3

SUMMER INTERNSHIP

Course Code	Course Name	C
BMT 552	Industrial internships / Hospital internship/ Laboratory internship	4

Students are expected to do summer internship and submit a report for obtaining the credits. The internships may preferably be done with start-ups, industries, hospitals, research institutes, academic institutes, or laboratories of SCTIMST in the order of preference.

SEMESTER 3

Course Code	Course Name	C
TQM 501	Technology, Quality & Regulatory Management of Medical Devices	3
BMT 701	MTech Thesis Research – Work Status Report & Seminar	14
	Total for Semester 3	**17**

SEMESTER 4

Course Code	Course Name	C
	Comprehensive Course Viva	**2**
BMT 702	MTech Thesis Research – Project Report & Viva Voce	15
	Total for Semester 4	**17**

15. Program Outcome

The program is expected to equip students with the knowledge and skills needed to identify unmet clinical needs and design medical devices. The following attributes are to be demonstrated by a graduate upon completing the program. The identified program outcome (PO) is listed below:

PO1: The ability and skills needed to identify unmet clinical needs and design medical devices.

PO2: The ability to identify appropriate materials, methods, design tools, and processes for the development, fabrication, and evaluation of medical devices.

PO3: Ability to understand methods to be followed in the biological evaluation of medical devices.

PO4: Understand the regulatory mechanisms underlying for taking a medical device to market.

PO5: Gain in-depth knowledge of the processes involved in the translation of medical technologies from concept to commercialization.

16. Syllabus and Course Outcomes

16.1 Semester 1 - Courses

16.1.1 Anatomy and Physiology for Engineers

<table>
<tr><td>Course Title</td><td>Anatomy and Physiology for Engineers</td><td>Course Code</td><td colspan="4">SCT 501</td></tr>
<tr><td>Department</td><td>Medical Devices Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td>Faculty</td><td>From Hospital Wing, AMC, Visiting faculty, Dr. Kamalesh Gulia</td><td colspan="5">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course objectives</td><td colspan="6">The course introduces the basic fundamentals of various engineering principles for non-engineers such as biologists and clinicians working in medical device technology.</td></tr>
<tr><td>Course Outcome:</td><td colspan="6">At the end of this course, the students will be able to remember the important terms used in anatomy and understand the medical terminologies. They will also gain a</td></tr>
</table>

	basic understanding of human physiology and will be able to apply the knowledge for the purpose of developing medical devices.

CO	Course Outcome	Bloom Knowledge Level (KL)*
CO1	Gain a preliminary understanding of cells, tissues, homeostasis, and language of anatomy	K2 & K3
CO2	Understand the anatomy and physiological principles of the nervous, sensory, cardiovascular, respiratory systems, urinary, Digestive, skeletal, and muscular systems	K2 &K3
*K1: Remember, K2: Understand, K3: Apply, K4: Analyze, K5: Evaluate, K6: Create		

Syllabus: Anatomy and Physiology for Engineers

Module	Topics (In detail)	No. of hours (L)	Tutorial
Module 1	Introductory Biology Cell - structure and functions, genes, and chromosomes. Functional organization of body– cells, tissues, organs & systems – Types; Homeostasis – intracellular & extracellular fluids - homeostatic control systems – negative & positive feedback and feed-forward mechanisms.	06	
	Tutorial: Anatomical and medical terminology, Structure of the human cell, Organs, and organ systems		03
Module 2	Nervous and Sensory System Nervous system – types of neurons and synapses – Mechanisms of Nerve impulse. Organization of nervous system - Central nervous system, peripheral nervous system, Autonomous nervous system Sensory System- types-special and somatic, physiology of pain, Muscle spindle, Golgi tendon organ and related reflexes Motor system- Upper and lower motor neurons, Definition of hemiplegia, quadriplegia, paraplegia. Brown sequard syndrome- features	06	

	Special senses – Vision, Hearing and vestibular apparatus, touch, smell and taste. Cross-function of nervous and sensory system		
	Tutorial: Structure of neuron and neuroglial cells, Brain and spinal cord, Functions of the parts of the brain, Organs of general sense - Vision, hearing, taste, touch, and smell		03
Module 3	Cardiovascular and Respiratory System Heart – Anatomy– pump – valves - major arteries & veins – cardiac muscle Conduction system – SA node and ventricular action potential and ECG, special properties of cardiac muscle, pacemaker – normal & ectopic – cardiac action potential Cardiac rhythm & rate – normal & abnormal, Cardiac cycle, myocardial ischemia & infarction, atherosclerosis – Heart sounds & murmurs, cardiac output – stroke volume Blood: Components of Blood and functions – plasma– haematocrit – plasma proteins – erythrocytes – haemoglobin – anaemia – blood typing – transfusion reaction – universal donor & acceptor – leukocytes – functions & types – platelets– blood clotting. Respiratory: Parts of Respiratory Systems – Gas exchange and transport, Mechanics of breathing, regulation of respiration, Cross-function of cardiovascular and respiratory system	06	
	Tutorial: Structure of the heart and blood vessels, Systemic arteries and veins, Nasal cavity, Larynx, Trachea and bronchi, Lungs		03
Module 4	Digestive, Endocrine, and Urinary Systems Digestive System: Anatomy and physiology of Gastrointestinal tract - Digestion and Absorption mechanism. Function of liver, gall bladder, intestine Endocrine system: Endocrine glands and Hormones – Types - hormone receptors – Adenohypophysis and neurohypophysis, Functions and regulation of - Hypothalamus, pituitary, thyroid, parathyroid, Adrenal and endocrine pancreas. Urinary System: Kidneys – functional anatomy of kidney and nephron	09	

	Basic renal processes –glomerular filtration, mechanism-forces involved, factor affecting forces, tubular reabsorption & secretion – urine excretion & plasma clearance – micturition reflexes, cross function of digestive, endocrine and urinary systems		
	Tutorial: Kidneys, Ureters, Urinary bladder, Urethra, Mouth, Pharynx, Oesophagus, Stomach, Intestines, Liver, Gallbladder, Pancreas, Spleen, Hypophysis, Adrenal glands Thyroid Gland, Islets of Langerhans		03
Module 5	Skeletal and Muscular Systems Muscular system: Parts of Muscle, types, Muscle contraction and relaxation. Skeletal system: Types of Bone and function, Physiology of Bone formation, Types of joints and function, Joint movements, Types of cartilage and function. Cross function of skeletal and muscular systems	04	
	Tutorial: Long and short bones, vertebral column, rib cage, hand and feet, Skeletal muscles, ligaments, knee, hip, and ankle joints,		02

Text Books:

1. Arthur C Guyten, John E. Hall. Textbook of Medical Physiology, Elsevier Saunders; 13th edition
2. N. Elaine Marieb, Essentials of Human Anatomy and Physiology, Pearson, 10th edition
3. Elaine Marieb, Katja Hoehn, Human Anatomy & Physiology, Pearson, 11th edition

Assignments:

- Two assignments
- Seminars – Two per group.
- Evaluation: Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Clinical faculty	Clinical faculty	Clinical faculty
Module 2	Clinical faculty	Clinical faculty	Clinical faculty
Module 3	Clinical faculty	Clinical faculty	Clinical faculty
Module 4	Clinical faculty	Clinical faculty	Clinical faculty

Module 5	Clinical faculty	Clinical faculty	Clinical faculty

16.1.2 Immersion to Engineering and Technology

Course Title	Immersion to Engineering and Technology	Course Code	MDE 501			
Department	Medical Devices Engineering	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	0	2	3
Faculty	Er. Sarath S Nair, Er. Vinodkumar V., Er. Anoop G, Er. Jithin Krishnan, Er. Saurabh S Nair, Er. Neethu S	Description: L: Lecture, T: Tutorial, P: Lab, C: credits				
The course introduces the basic fundamentals of various engineering principles for non-engineers such as biologists and clinicians working in medical device technology.						
The students will learn: • Fundamental engineering principles • Material properties and selection criterion for medical devices • Mechanical concepts for design • Electrical concepts and components • Electronic components and design • Fundamentals of digital systems, Microcontroller architecture, programming methods.						

Course Outcome (CO):

CO	Course Outcome	Bloom Knowledge Level (KL)
CO1	Engineering Concepts	K1 & K2
CO2	Engineering Materials	K1 & K2
CO3	Basic Mechanical Engineering	K1, K2 & K3
CO4	Basic Electrical and Electronics Engineering	K1, K2 & K3
CO5	Digital Electronics	K2, K3 & K4

Syllabus:

Module	Topics (In detail)		No. of hours
Module 1	Engineering Concepts	Introduction to the engineering profession, engineering design, units and dimensions, engineering drawings, engineering marvels, Errors, uncertainty, tolerances, GPP, GMP & GLP, basic engineering principles, Free body	4

		diagrams mechanics and dynamics, physiological phenomenon - electrical & mechanical analogy.	
Module 2	Engineering Materials	Material related failures in medical devices, Material selection, electrical, mechanical and thermal properties of materials, magnetic materials, dielectric materials, Smart materials: Sensors and actuators, piezoelectric, magnetostrictive and electrostrictive materials, basic laws, stress strain curves, failures, corrosion - causes and prevention, basic machining operations, precision engineering. Basics of heat treatment and general manufacturing process	6
Module 3	Basic Mechanical Engineering	Structural dysfunction in medical devices - Stress and Deflection, Types of Stress - Tensile, Shear stress, Shear Force, Bending Moment, specific weight, specific gravity, Centroid and Moment of Inertia, Hemodynamics - Introduction to fluid mechanics, properties of fluids, viscosity, kinematic viscosity, Newton's Laws, types of fluids, Surface Tension, Capillarity, Vapour pressure fluid kinematics, streamlines, classification of flows, flow continuity, fluid dynamics, forces acting on fluids in motion Euler's equation, Bernoulli's Equation, Momentum equation, boundary layer, Reynold's number, losses in flow, Vibrations & Damping, Basic concepts and Modes of heat transfer,	7
Module 4	Basic Electrical and Electronics Engineering	Conduction systems in human - electrical & biochemical, Electricity, Voltage, current, capacitance, inductance, impedance, network theory, active and passive components, Semiconductors, electronic components, diode, transistors, Operational amplifiers.	7
Module 5	Digital Electronics	Number systems, fundamental logic gates, Combination and arithmetic circuits, sequential circuits, logic families, CPLD, microprocessors, microcontrollers.	6

Text Books:

1. Moaveni S. Engineering fundamentals: An introduction to engineering, Cengage Learning; 2019.
2. Lightsey B. Systems engineering fundamentals. Defense acquisition univ ft belvoir va. 2001.
3. Agrawal, Basant. Basic Mechanical Engineering. John Wiley & Sons, 2008.
4. Hambley, Allan R. Electrical engineering: principles and applications. Pearson Prentice Hall, 2011.
5. Mehta, V. K., and Mehta Rohit. Principle of Electrical Engineering and Electronics. S. Chand Publishing, 2014.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Engineering Concepts	Sarath S. Nair	Vinodkumar V.	Saurabh S. Nair
Engineering Materials	Anoop G. / Vinodkumar V	Saurabh S. Nair	Sarath S. Nair
Basic Mechanical Engineering	Saurabh S. Nair /Anoop G	Sarath S. Nair	Vinodkumar V.
Basic Electrical and Electronics Engineering	Sarath S. Nair	Jithin Krishnan	Neethu S.
Digital Electronics	Jithin Krishnan	Sarath S. Nair	Neethu S.

Lab Sessions (15 weeks - 2 hours each week)

Sl. No.	Module	Sessions
1	Module 1	Drawing & Dimensioning Measuring Instruments familiarisation
2	Module 2	Material Characterization Strength of materials testing using UTM Corrosion Testing
3	Module 3	Roughness Testing Hardness Testing Mechanical Inspection Pressure measurement
4	Module 4	Measuring Instruments Familiarization Component Identification Soldering Practices Circuits realization
5	Module 5	Electronic simulation Digital Circuits simulation Programming Integrated circuits

16.1.3 Biomaterials

Course Title	Biomaterials	Course Code	BST 501			
Department	Department of Biomaterial Science and Technology	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2.5	0.5	0.5	3
		Description: L: Lecture, T: Tutorial, P: Lab, C: credits				
Faculty	Dr. HK Varma; Dr. Manoj Komath; Dr. Lizymol PP, Dr. Shiny Velayudhan; Dr. Manju					

	S; Dr. Francis B. Fernandez, Dr. Sabareeswaran A, Dr. Anil Kumar PR, Dr. Anugya Bhatt.	

Course Objectives:

The proposed course is intended to provide a comprehensive view of the materials used in biomedical devices and implants. Initially, the definitions, classification and applications of biomaterials are introduced. The course covers the essentials of processing, characterization and physico-chemical properties of biomaterials. An overview of the biological characterization strategy adopted for translating the biomaterials also is included.

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BST 501 – CO1	Gain understanding of materials in biomedical applications, material classification, application-oriented material selection	K2 & K3
BST 501 – CO2	Understand properties of biomaterials, polymers, ceramics, biopolymers, nanomaterials, composites, smart and meta materials.	K2 & K3
BST 501 – CO3	Understand tools and planning for material characterization. Be able to develop strategies for planned material characterization	K1, K2, K4, K5
BST 501 – CO3	Gain familiarity with the modality of the biological testing of biomaterials. Test methods corresponding to ISO 10993 will be introduced.	K1 & K2

Syllabus:

Module	Topics (In detail)	No. of hours		
		L	T	P
Module 1	Essentials of Materials for Biomedical Applications: Definition of Biomaterials, Structure and properties of biomaterials, Processing of biomaterials, Nano-biomaterials and Tissue Engineering Scaffolds, Concept of Biocompatibility, Significance of biomaterials in the field of Medicine. Current topics of interest in biomaterials and applied biomaterials.	6	2	
		Effective hours for credit = 7		

<table>
<tr><td rowspan="2">Module 2</td><td rowspan="2">Metals, Ceramics, Polymers and Composites used for medical applications

Bio-inert, Bioresorbable and Bioactive materials; Nano-biomaterials, Smart materials and Biosensor materials; Biopolymers, natural biomaterials; Surface properties and bulk properties of biomaterials, Structure-property relationships; General aspects of the processing of biomaterials; Biological response to material surfaces; patterned surfaces for optimizing biological response</td><td>8</td><td>3</td><td>3</td></tr>
<tr><td colspan="3">Effective hours for credit = 11</td></tr>
<tr><td rowspan="2">Module 3</td><td rowspan="2">Characterization of Biomaterials:

Strategies, Instrumentation - i) Surface, morphological and phase characterization Micromorphological study using microscopic techniques scanning electron microscopy (SEM), transmission electron microscopy (TEM) and atomic force microscopy (AFM); Phase analysis using X Ray Diffractometry (XRD); (ii) Characterisation strategies - Physico-chemical (Chromatography, Electrophoresis, Contact angle measurements. Dynamic light scattering), thermal (thermogravimetric analysis, differential scanning calorimetry) and mechanical (Modulus, Hardness, Fatigue). Developing a characterization strategy and work plan. (iii) Characterization Instrumentation - Principle, instrumentation, sampling and data interpretation of spectroscopic techniques. UV-Visible, FTIR, NMR, Raman spectroscopy, Mass spectroscopy, Atomic spectroscopy for elemental analysis, X-Ray photoelectron spectroscopy (XPS) and Energy Dispersive Analysis (EDS).</td><td>8</td><td>3</td><td>5</td></tr>
<tr><td colspan="3">Effective hours for credit = 12</td></tr>
<tr><td rowspan="2">Module 4</td><td rowspan="2">Biological testing of Biomaterials

Biological testing of biomaterials, In vitro and in vivo assessment of tissue compatibility. Cellular assays, Cytotoxicity, Adhesion, Migration, Proliferation, Differentiation, Functional evaluation of blood materials interaction, Microscopic methods.</td><td>12</td><td>4</td><td>2</td></tr>
<tr><td colspan="3">Effective hours for credit = 15</td></tr>
</table>

Text Books:

1. Biomaterials Science - An introduction to Materials in Medicine, Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen and Jack E. Lemons, 2nd Ed. Academic Press, London, 2004.
2. Biomaterials: An Introduction, J. Park and RS Lakes, 3rd Edn., Springer Science, New York, 2007.
3. Biomaterials Science: An Introduction to Materials in Medicine, by (Eds) William Wagner, Shelly Sakiyama-Elbert, Guigen Zhang, Michael Yaszemski, Academic Press Inc; 4th Edition, 2020.
4. Text book of Polymer Science, F.W.Billmeyer Jr. III Edn. Wiley Interscience Publishers, Canada 2002.
5. Biomedical Polymers - Designed to degrade systems, Shalaby W. Shalaby, Hanser Publishers, New York, 1994.
6. Infrared and Raman Spectroscopic Imaging, Reiner salzer and Heinz W.Siesler, Wiley VCH, 2009.
7. Electron Microscopy: Principles and Fundamentals. S. Amelinckx , Dirk van Dyck, J. van Landuyt, Gustaaf van Tendeloo (Editors), Wiley, Germany, 2008.
8. Bone tissue engineering, Hollinger, Jeffrey O, et al. (Editors), CRC Press, London, 2000.

9. Dental Materials and their selection (III Edition) Ed., William J.O'Brien, Quitessence Publishing Co., Canada 2002.
10. Science of dental materials, Philips, XI edn by Anusavice K.J., Saunders Publishing Co., USA, 2004.
11. Dental Materials, Foundations and Applications, Editor: John M Powers and John C Wataha; Elsevier 2017
12. Dental Materials, properties and manipulation, Editor: Robert G Craig, John M Powers and John C Wataha; Elsevier 2017
13. Polymeric Dental Materials, Editor: Michael Braden, Richard L. Clarke, Sandra Parker and John Nicholson; Springer 1997
14. Biocompatibility, Interactions of biologicals and Implantable Materials Volume 1. Polymers, F.Silver and C. Doillon, VCH Publishers, New York, 1989.
15. Host response to Biomaterials. Stephen F Badylack, Elsevier, 2015.
16. ISO standards, ISO 10993 Biological Evaluation of Medical Devices series. Parts 1 to 23.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
1	Dr. H K Varma/ Dr. Lizymol PP/Dr. Manoj Komath	Dr. Shiny Velayudhan / Dr. Manju S.	Dr. Francis Fernandez
2	Dr. Lizymol PP/ Dr. R.S. Jayasree/Dr. M.R. Rekha	Dr. H K Varma/ Dr. Manoj Komath	Dr. Manju S. / Dr. Shiny Velayudhan
3	Dr. H K Varma/ Dr. Manoj Komath/Dr. Lizymol PP	Dr. Shiny Velayudhan / Dr. Manju S.	Dr. Francis Fernandez / Dr. Manoj Komath
4	Dr. Sabareeswaran A., Dr. Anil Kumar PR	Dr. Anil Kumar PR, Dr. Anugya Bhatt.	Dr. Anugya Bhatt, Dr. Sabareeswaran A.

16.1.4 Medical Device Technology

<table>
<tr><td>Course Title</td><td>Medical Device Technology</td><td colspan="2">Course Code</td><td colspan="3">MDE 503</td></tr>
<tr><td>Department</td><td>Medical Devices Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering

MTech Clinical Engineering</td><td>2</td><td>0</td><td>2</td><td>3</td></tr>
<tr><td>Faculty</td><td>CV Muraleedharan, Sujesh S, Subhash N N, Arvind Kumar Prajapati, Vinodkumar V, PR Umashankar, DS Nagesh, Easwer H V, S Balram, Amrutha C</td><td colspan="5">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">The objective of this course is to familiarize the students with techniques in medical device development.</td></tr>
</table>

	It aims to equip the students with standard concepts and tools to an advanced level that will enable them to to tackle the various aspects of medical device development.
The students will learn:	• To classify the devices based on risk assessment and regulatory requirements • To deal with the development planning and to document the device characteristic documentation (DCD) • Design and design verification strategies • Prototyping • Preclinical in vitro and in vivo evaluation strategies • Manufacturing under QMS platform • Clinical evaluation

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
MDE 503 – CO1	Gain expertise in the risk based regulatory classification and apply the expertise by classifying a medical device	K2 & K3
MDE 503 – CO2	Develop and document the device characteristic document (DCD)	K2 & K3
MDE 503 – CO3	Understand various stages in medical device design and design verification, and apply the knowledge on a medical device case study	K1, K2 & K3
MDE 503 – CO4	Understand methods of prototyping medical devices	K2 & K3
MDE 503 – CO5	Understand various analytical, and Preclinical evaluations required for design verification and Identify the in-vitro tests required for a medical device.	K2, K3 & K4
MDE 503 – CO6	Understand manufacturing under quality management system (QMS)	K2, K3, K5
MDE 503 – CO7	Understand the requirements of Clinical evaluation	K2 & K3

Syllabus:

Module	Topics (In detail)	No. of hours	
		Lecture	Practical
Module 1	Classification Classification based on nature and duration of contact, International harmonized norms, active devices, IVD, medical instrumentation. Classify a medical device, identify applicable	6	6

	standards and tests required for a suitable certification such as CE, FDA or Indian Design & Reliability Design control, design history, human factors engineering, design validation. Study a medical device and identify the design steps involved. Make a specification for the device and describe how the design meets the specification. Basic concepts, graphical methods of reliability analysis, reliability prediction, Failure Mode Evaluation and Analysis (FMEA), Fault Tree Analysis, Medical device risk analysis. For the device of session 2 (or another device), do a reliability analysis and risk management study using the concepts studied such as FMEA		
Module 2	Design strategies Strategies for medical device design. Case study of one medical device-User needs, Design Input, Design Process, Design Output, Medical device. Verification & Validation.	3	2
Module 3	In vitro evaluation, in vivo evaluation Techniques of in vitro evaluation, simulation, analytical modelling, life testing, performance evaluation, safety evaluation, One case study. For the device, identify the in-vitro tests required and carry out a study of a single test. Animal models, selection, Ethics in animal evaluation, One case study in animal evaluation. Case study of pre-clinical evaluation of a medical device.	5	4
Module 4	Manufacturing, Quality Systems GMP Basics, Drug vs devices, validation and verification, manufacturing traceability and documentation, personnel and training. Facility Management: Clean rooms, clean room procedures, water quality management, air quality management, Environmental monitoring, Production equipment – selection and management.	7	2
Module 5	Packaging and sterilization Device cleaning – fundamentals, methods of cleaning (ultrasonic cleaning, solvent degreasing), cleaning validation; Medical device packaging – Packaging requirements, packaging	3	2

	materials, packaging equipment, package validation, accelerated aging; Sterilization – Basics, Techniques (Steam, ETO, radiation, chemical, filtration), Process design, Sterilizer qualification, process validation, bioburden, sterility and pyrogenicity.		
Module 6	Clinical Evaluation Clinical evaluation standards, ISO 14155. Case study of clinical evaluation of a medical device.	2	2
Module 7	Regulatory compliance Horizontal and vertical standards, Standard making bodies (ISO, ASTM, AAMI, EN, BIS), Regulatory mechanisms (FDA, CE and Indian regulatory mechanisms), How to select suitable standard(s) for device qualification, Product litigation. Comparison of CE / FDA regulatory mechanisms	3	2

Text Books:

1. Reliable Design of Medical Devices. Richard C. Fries (Access No: 610.28 FRI).
- Medical device design: innovation from concept to market. Ogrodnik P. J. (BM 610.28 OGR)
- Design for six-sigma for medical devices: a roadmap for safety and effectiveness. Basem, Khalid (610.28 HAI).
- Safety Evaluation of Medical Devices. Shayne Cox Gad (610.28 GAD).
- Clinical Evaluation of Medical Devices. Karen Becker Witkin (610.28 WIT)
- International Medical Device Clinical Investigations. Pieterse et. al. (610.28 PIE)
- Medical Device Packaging Handbook. Joseph D O'Brien (610.28 OBR)
- Replacement Cardiac Valves. Endre Bonar, Frater (610.28B, BOD) (for case study).
- Design of Biomedical Devices and Systems. Paul King; Richard C. Fries. (610.28 KIN)
- The Medical Device R & D Handbook. Theodore R. Kucklick. (610.28 KUC).
- Cleanroom Technology: fundamentals of design, testing and operation, W. Whyte, (614.48WHY).

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
1	CV Muraleedharan	Dr. Sujesh S	Subhash N N
2	Arvind Kumar Prajapati	Subhash N N	Dr. Sujesh S

3	Vinodkumar V, Dr. PR Umashankar	Sarath S Nair	Dr. Sachin J Shenoy
4	D.S. Nagesh	C.V. Muraleedharan	D.S. Nagesh
5	Arvind Kumar Prajapati	Vinodkumar V.	D.S. Nagesh
6	Easwer H.V.	Clinical faculty	C.V. Muraleedharan
7	Amrutha C.	S. Balram	C.V. Muraleedharan

16.1.5 Fundamentals of Medical Devices

Course Title	Fundamentals of Medical Devices	Course Code	MDE 502			
Department	Medical Devices Engineering	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	0	2	3
Faculty	Er. Muraleedharan CV, Er. Nagesh DS, Dr. Ramesh P., Dr. Roy Joseph, Dr. Sujesh, Er. Vinodkumar V, Dr. Sivakumar K.G.V, Dr. Manoj G, Er. Arvind Kumar Prajapati, Er. Subhash NN, Er. Sarath S Nair, Er. Jithin Krishnan, Er. Anoop Gopinathan	Description: L: Lecture, T: Tutorial, P: Practical, C: credits				
Course Objectives:	The objective of this course is to familiarise students with a variety of medical devices based on human body systems					
Course Outcome: At the end of the course, the student will be able to learn about various medical devices based on their application to the body systems. They will also understand the basic scientific and engineering principles behind these devices.						

CO	Course Outcome	Bloom Knowledge Level (KL)
CO1	Understand medical devices and their classification	K1, K2, K3 & K4
CO2	Gain knowledge on variety of Neuro devices	K2, & K3
CO3	Understand variety of extracorporeal devices	K2, & K3
CO4	Gain knowledge on variety of cardiovascular devices	K2, & K3
CO5	Gain knowledge on variety Products for kidney, liver, and soft tissues	K2, & K3
CO6	Understand the variety of orthopaedic devices	K2, & K3
CO7	Understand variety of In-vitro diagnostic devices	K2, & K3

Syllabus:

Module	Topics (In detail)	No. of hours (L)	Practical (P)
Module 1	Introduction Strategies for device characterisation- 1) Nature of body contact 2) construction-based and In-vitro diagnostic devices Basics of materials-metal, ceramics, polymer, elastomers, and tissue-derived materials	03	
	Practical: Medical device classification with an example		03
Module 2	Neuro devices • Stimulators – Deep Brain Stimulator, intracranial electrodes, Spinal cord stimulator, Optical peripheral nerve stimulator, Transcranial magnetic stimulation • Implant: Neurolink, aneurysm clip, cranial implants • Monitoring system: EEG system, EMG monitoring system • Flow management devices: hydrocephalus shunt • Assist- Wheelchairs, Crutches, Prosthetics, Splints, Voice recorder, Walkers • Rehabilitation – treadmill, unweighting system, AR/VR-based neuro rehab devices	05	
	Practical: Case study		05
Module 3	Extracorporeal devices • Normal skin contact type –vein viewer, anaesthesia machine. • Skin breached –para corporeal LVAD, hemoconcentrator. • Others: centrifugal blood pump, blood flow meter, blood & IV Fluid Warmer, cardiotomy reservoir, Bubble oxygenator, membrane oxygenator.	05	
	Practical: Case study		05
Module 4	Cardiovascular devices • Flow management devices- mechanical heart valve, coronary artery stent, atrial septal defect (ASD) occluder, annuloplasty ring, flow-diverter stents, Bio-prosthetic heart valve	05	

	• Rhythm Management- Implantable Cardioverter Defibrillators, Pacemakers, cardiac defibrillator • Monitoring- ECG electrodes, PMS		
	Practical: A case study on TTK Chitra™ heart valve.		05
Module 5	Products for kidney, liver, and soft tissues • Products-Leukocyte (WBC) Reduction Filter, 3D Printing of Liver Tissue Constructs, Radiopaque Liquid Embolization Device, Oral Insulin Delivery System, 3 D Printing of Skin Tissue products, dialyser.	04	
	Practical: Case study		04
Module 6	Orthopaedic devices • Spine - Spinal fixation devices, dynamic implants, lumbar spine cages, cervical plates, cervical cages, Bioceramic cages, spine jacks, idiopathic scoliosis devices • Joints- knee, hip, and ankle implants • Instruments - Surgical instruments	04	
	Practical: Case study		04
Module 7	1. In-vitro diagnostic devices • Immunodiagnostic kits for the diagnosis and management of Heart Failure disease, sepsis, infectious diseases, Multiple sclerosis, Infertility • Molecular Diagnostic Kits for Infectious diseases, Human Papiloma Virus, Tuberculosis • Reagents for sample preparation - Nucleic acid Extraction Kits, Antibody conjugation kits, Antigen-Antibody stabilisation kits, Reagents for enhancing the sensitivity	04	
	2. Practical: Case study		04

Text Books:

1. Medical Devices Rules, 2017, Ministry of Health and Family Welfare, Govt. of India.
2. Replacement Cardiac Valves. Endre Bonar, Frater (610.28B, BOD) (for case study).
3. Design of Biomedical Devices and Systems. Paul King; Richard C. Fries. (610.28 KIN)
4. Medical device design: innovation from concept to market. Ogrodnik P. J. (BM 610.28 OGR)
5. Lyshevski, Sergey Edward. Electromechanical systems and devices. CRC Press, 2008.
6. Lyshevski, Sergey Edward. Nano-and micro-electromechanical systems: fundamentals of nano- and microengineering. CRC press, 2018.
7. Bhansali, Shekhar, and Abhay Vasudev, eds. MEMS for biomedical applications. Elsevier, 2012.

8. Allen, James J. Micro electro mechanical system design. CRC press, 2005.
9. Bioconjugate techniques by Greg T Hermanson
10. Lateral Flow Immunoassay, Raphael Wong, Harley Tse
11. In-Vitro Diagnostic Devices by Chao-Min Cheng, Chen-Meng Kuan , Chien-Fu Chen

Evaluation:

- Assignment: Medical device classification : 25 marks
- Seminars: two per group : 15 marks
- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Er. Muraleedharan C V	Dr. Sujesh	Er. Arvind Kumar Prajapati
Module 2	Er. Muraleedharan C V	Er. Jithin Krishanan	Er. Neethu S
Module 3	Er. Nagesh D S	Er. Vinodkumar V	Er. Sarath S Nair
Module 4	Dr. Sujesh	Er. Muraleedharan C V	Er. Annop Gopinathan
Module 5	Dr. Ramesh P	Dr. Roy Joseph	Dr. Anil Kumar P.R.
Module 6	Er. Arvind Kumar Prajapati	Er. Subhash NN	Dr. Siva Kumar K.G.V.
Module 7	Dr. Manoj	Dr. Anoop Kumar T.	Er. Saurab S Nair

16.1.6 Research Methodology

<table>
<tr><td>Course Title</td><td>Research Methodology</td><td>Course Code</td><td colspan="4">BMT 501</td></tr>
<tr><td>Department</td><td></td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>Faculty</td><td>Dr. Manoj Komath, Dr. Anil Kumar PR, Dr. Mohanan PV</td><td colspan="5">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">1. To introduce the basic concepts in research methodology, essential for pursuing scientific research.
2. This course addresses the issues inherent in selecting a research problem and discuss the techniques and tools to be employed in to prepare and framing Research proposals, completing a research project and report writing.
3. The course stresses upon the importance of scientific conduct and ethics in research and publication, in order to bring in honesty and research integrity.</td></tr>
</table>

Course Outcome:

At the end of this course, the students will acquire fundamental knowledge of basics of philosophy of science and ethics, research integrity, publication ethics. The student will be able to avoid research misconduct and plagiarism.

CO	Course Outcome	Bloom Knowledge Level (KL)
BMT 501 – CO1	Gain a preliminary understanding of scientific methodology	K1, K2
BMT 501 – CO2	Gain fundamental knowledge in research methodology such as identification of research problem, formulation of hypothesis and design of experiment	K1, K2
BMT 501 – CO3	Develop integrity in research and scientific communication	K1, K2, K3

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Research Methodology, Experimental design. Essential roles and responsibilities of a researcher, selecting topic, Literature survey, Formulating the Research Questions, Development of Hypothesis, Basics of experimental design, Preparing a research project proposal.	3		
Module 2	Tools and Techniques of Research Research Design (Components, Experimental group, Variable, Control), Types of Research Designs and Approaches (Groups in research design, Group Equivalence, General Controlling Artefact and Bias, Data Collection), Assessment Methods and Measurement Strategies (Validity, Data Preparation, Analyses, Recording observations and documentation), Interpretation of the research data	5		
Module 3	Research communications (Types of manuscripts, Best practices and guidelines, Peer review, Conflict of interest) and Research metrics (Impact factor, H index, i10 index, etc). Responsible use of scientific data, Handling images. Publication Ethics: Definition, Introduction and Importance. Redundant Publication: duplicate and overlapping publications, salami slicing, Conflicts of interest, Predatory Publishers and Journals	4		
Module 4	Scientific Conduct and Ethics	3		

	Intellectual honesty and research integrity, Scientific misconducts (Plagiarism, Falsification, Fabrication, Fraud, Inappropriate Authorship, Selective reporting and misrepresentation of data) and Publication misconducts			

Text Books:

1. Research Methodology and Scientific Writing, by C. George Thomas (Edition Number 2); Springer (2021)
2. Research Methodology – Methods and Techniques by CR Kothari and Gaurav Garg, New Age, New Delhi (2019).
3. Style and Ethics of Communication in Science and Engineering, by Jay D. Humphrey and Jeffrey W. Holmes, Morgan & Claypool (2009)
4. D. B. Resnik, what is ethics in research & why is it important. National Institute of Environmental Health Sciences, 1-10, 2011. Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm
5. P. Chaddah, Ethics in Competitive Research: Do not get scooped: do not get plagiarized, 2018 ISBN:978-9387480865
6. Patwardhan B., Desai A., Chourasia A, Nag S., Bhatnagar R. 2020. Guidance Document: Good Academic Research Practices. New Delhi: University Grants Commission.
7. Academic Integrity and Research Quality, https://www.ugc.ac.in/e-book/Academic and Research/mobile/index.html

Evaluation

- Two assignments
- Two Seminars.
- Total 100 marks. Written exam - 60 marks, Assignment and Seminar - 40 marks.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Anil Kumar PR	Dr. Manoj Komath	Dr. Mohanan PV
Module 2	Dr. Manoj Komath	Dr. Anil Kumar PR	Dr. Mohanan PV
Module 3	Dr. Manoj Komath	Dr. Anil Kumar PR	Dr. Mohanan PV
Module 4	Dr. Mohanan PV	Dr. Anil Kumar PR	Dr. Manoj Komath

16.1.7 Clinical Attachment

SCT 551	Clinical Attachment in Hospitals	2 credits

16.1.8 Laboratory Internship 1

BMT 551	Device Development and Evaluation Study	2 credits

16.1.9 Safety in Biomedical Laboratories

<table>
<tr><td>Course Title</td><td>Safety in Biomedical laboratories.</td><td>Course Code</td><td colspan="3">BMT 502</td></tr>
<tr><td>Department</td><td>Technology and Quality Management</td><td rowspan="2">Credits</td><td>L / T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>1</td><td>0</td><td>1</td></tr>
<tr><td>Faculty</td><td>SSN, JKN, Safety officers</td><td colspan="4">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="5">This course is intended to provide knowledge on safety in laboratories, safe laboratory practices and safety in hospitals and also patient safety, especially with active medical devices.</td></tr>
<tr><td>The students will learn:</td><td colspan="5">• Basic concepts of electrical safety, patient, different type of shocks.
• Understand the importance of biological safety, chemical safety, radiation safety and fire safety.</td></tr>
</table>

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BMT 502 – CO1	Understand and apply the concepts of Electrical Safety, Chemical Safety, Radiation Safety and Biological safety in laboratories	K1, K2 & K3
BMT 502 – CO2	Understand and apply concepts of safety in medical devices.	K1, K2 & K3

Syllabus:

Module	Topics (In detail)	No. of hours

		Lecture/ Tutorial
Module 1	Electrical Safety Electrical current, voltage, skin impedance, Microshock, Macroshock, electrocution.	3
Module 2	Chemical safety. Handling chemicals safely in laboratories, toxicity.	3
Module 3	Chemical safety. Handling chemicals safely in laboratories, toxicity.	3
Module 4	Radiation safety. Ionising radiation, harmful effects, prevention.	3
Module 5	Medical Device safety Safety in medical devices, patient safety, operator safety, precautions.	3

Text Books:

1. SCTIMST Safety Hand book.
2. CRC Handbook of Laboratory Safety, 5Th Edition by Furr A K, Crc Press
3. Chemical Safety in the Laboratory by K. Hall, Taylor & Francis
4. Principles of Electrical Safety by Peter E. Sutherland, Wiley India, 2018.
5. Patient Safety Now 1st Edition 2022 by Woodward, Suzette, Taylor and Francis Ltd

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
1 - 5	Safety officers	Deputy safety Officers	
5	Er. Jithin Krishnan	Er. Sarath S Nair	Er. Vinodkumar V.

16.2 Semester 2: Specialization – Medical Devices Engineering

16.2.1 Computational Modelling in Biomedical Engineering

Course Title	Computational Modelling in Biomedical Engineering	Course Code	MDE 612			
Department	Medical Devices Engineering	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	0	2	3

		Description: L: Lecture, T: Tutorial, P: Lab, C: credits
Faculty	Sujesh S, Ranjth G., Saurabh S. Nair, Subhash NN, Sarath S Nair, Jithin Krishnan.	
Course Objectives:		
The course introduces the student to computational modelling in the design and in silico verification of medical devices. The student is introduced to various algorithms and tools which are commonly used in the computational modelling of medical devices and biological tissues. This course is designed to provide students with a foundational understanding of computational methods and numerical techniques used in solving biomedical problems in mechanical engineering, fluid dynamics, thermal analysis, and electromagnetics.		
Course Outline:		
• Overview of Numerical Solutions and Linear Algebra • Structural, Fluid, Electromagnetic and Thermal and multiphysics modelling. • Electronic design automation, electronic circuit modelling and analysis. • Medical Device modelling – different active and passive medical devices • Optimization, Validation and Quality of results.		

Course Outcome:

MDE 612 - CO	Course Outcome	Bloom Knowledge Level (KL)*
MDE 612 – CO1	Translate a physical problem into a mathematical model	K2 & K3
MDE 612 – CO2	Gain expertise in numerical modelling and solving.	K2 & K3
MDE 612 – CO3	Understanding the physics of medical device modelling.	K2 & K3
MDE 612 – CO4	Medical device model – design and evaluate in silico	K3, K4 & K5
MDE 612 – CO5	Medical device model – optimize, ensuring the quality of results	K3, K4 & K5
*K1: Remember, K2: Understand, K3: Apply, K4: Analyze, K5: Evaluate, K6: Create		

Syllabus:

Module	Topics (In detail)	No. of hours		
		L	T	P
Module 1	Introductory Math - Numerical Solution to Differential Equations, Linear Algebra Biophysical Modelling - Multiphysics	6		6
Module 2	Structural Models – Material Models, Load and Boundary conditions, FEM.	6		6
Module 3	Fluid Flow Models – Eulerian and Lagrangian approaches, turbulence, blood flow. Thermal Models	6		6
Module 4	Electromagnetic Models – Low frequency, High frequency. Electronic Circuit Models	6		6

Module 5	Medical Device Models – active and passive, Case Studies – 3 devices, Model validation, Design optimization, Quality of results	6		6

Text Books:

1. Numerical analysis: mathematics of scientific computing. David Kincaid, et. al.; American Mathematical Society; 2009.
2. Engineers Guide to MATLAB: with application from mechanical, aerospace, electrical, and civil engineering, Edward B. Magrab; 2011; Prentice Hall.
3. Computational fluid dynamics: the basic with applications. John D. Anderson; 1995; McGraw Hill Education
4. Computational Fluid Dynamics: An Introduction by John F. Wendt
5. Computational Fluid Dynamics for Engineers by Bengt Andersson, Ronnie Andersson, Love Håkansson, Mikael Mortensen, Rahman Sudiyo, Berend van Wachem
6. Computational fluid dynamics: the basics with applications by John Anderson

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Sujesh S	Er. Ranjith G	Er. Saurabh S Nair
Module 2	Er. Subhash NN	Er. Anoop Gopinathan	Dr. Sujesh S.
Module 3	Er. Saurabh S Nair	Er. Ranjith G	Er. Anoop Gopinathan
Module 4	Er. Jithin Krishnan	Er. Sarath S Nair	
Module 5	Er. Ranjith G	Dr. Sujesh S	Er. Sarath S Nair

16.2.2 Medical Device Design and Production

Course Title	Medical Device Design and Production	Course Code		MDE 611		
Department	Medical Devices Engineering	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	0	2	3
		Description: L: Lecture, T: Tutorial, P: Practical, C: credits				
Faculty						

Course Objectives:
The objective of this course is to equip participants with the knowledge and skills needed to manage biomedical technology projects effectively. It covers the identification of research ideas, project planning, development phases, standardization, preclinical evaluation, technology transfer, clinical evaluation, and commercialization. Students will learn to address unmet needs, understand about / conduct studies on regulatory processes, which are essential for understanding the challenges and

processes of the Medical Device Development along various stages of Technology Readiness Level (TRL).
Course Outcome:
• Identify Promising Research Ideas: Students will learn how to recognize research ideas with practical applications in the field of biomedical technology. • Effective Project Planning: They will acquire skills in developing comprehensive project plans tailored to biomedical technology projects. • Understanding Development Phases: Students will understand how to understand the various phases of device development, from conceptualization to practical implementation. • Understanding various manufacturing methods: Students will understand various manufacturing methods like moulding, casting, additive manufacturing, machining techniques and also sterilisation of Medical Devices. • Emphasis on Standardization: The course will teach the importance of standardization and the documentation required in the biomedical industry. • Preparation for Preclinical Evaluations: Students will learn how to prepare for and manage preclinical evaluations, ensuring compliance with regulatory requirements. • Facilitate Technology Transfer: They will gain insights into facilitating smooth technology transfer processes and industry training. • Clinical Evaluations: The course will cover the process of performing clinical evaluations and maintain comprehensive device history documentation. • Successful Commercialization: Students will be equipped to oversee the successful commercialization of biomedical devices, including post-market surveillance to ensure their effectiveness and safety in real-world applications.

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
CO1	Identify and evaluate research ideas with practical applications in the biomedical field.	K2
CO2	Develop effective project plans for biomedical technology initiatives.	K2 & K3
CO3	Understand the various phases of device development, from concept to commercialization.	K2, K3& K4
CO4	Understand the importance of standardization and documentation in the industry.	K2, K3 & K4
CO5	Prepare and manage preclinical evaluation processes, including regulatory compliance.	K2, K3 & K4
CO6	Understand facilitation of technology transfer processes	K2 & K3
CO7	Understand about clinical evaluations and maintain comprehensive device history documentation.	K2 & K3
CO8	Successfully oversee the commercialization of biomedical devices, including post-market surveillance.	K2

Syllabus:

Module	Topics	No. of hours
Module 1	Identify research idea which shows the potential application	
Unmet need identification, Statistics, Global Disease Burden, Stake Holders, Prior Art/ Current Art, Concept Development and Testing, Identification and Listing of Alternatives, Selection of Concepts of Alternatives, Initial Proof of Concept, Technology Readiness Level		3
Module 2	Project Planning	
Device Characteristics Identification, Design Team Formation, Defining Medical Problems, Define Engineering Problems, Test Plan Preparation, Material Identification, Quality Function Deployment		4
Module 3	Development and Standardization Phase	
Generating Solution Concepts, Preliminary Design Generation, Proof of Concept, Crafting 2D/3D design and drawings, Rapid Prototyping, Machining, Molding, Design Verification, Sub System Assembly, Main Integration, Benchtop Functional Testing, Detailed Designing for Usability and Manufacturability, Design History File, Device and Material Evaluation Matrix, Biocompatibility Evaluations as per ISO 10993, Intellectual Property		4
Module 4	Preclinical Evaluation Phase	
Device Validation, International Standards and Guidelines – Vertical and Horizontal Standards, Test System Identification and Preparation, In Vitro testing, Animal Models identification, Ex Vivo, In Vivo evaluations, Biological Safety and Performance Evaluations		4
Module 5	Technology Transfer for Production Phase	
Risk Management practices – hazard identification, Risk Analysis, ISO 14971 requirement, Failure Mode Effect Analysis, Design Revisions, Device Master Record - Work Procedures, Test Report Preparation, Comparison with Predicate Devices, Safety and Effectiveness Compilation, Finalisation of Production Drawing, Development of Jigs and Fixtures, ISO 13485 requirements, Good Manufacturing Practices, Cleanroom Practices, Manufacturing for Testing		4
Module 6	Clinical Evaluation Phase	
Regulatory Aspects, Clinical Trial Protocol, Clinician's Brochure, Investigators Brochure, Cohert Identification, End Points Determination, Ethics Committee Approval, Regulatory Submissions, Single Centric and Multi Centric Evaluations, Report Generation		4
Module 7	Commercialization Phase	
Business Plan Creation, Import Export Data, Pricing, Technical Documentation, Post Market Surveillance, Design Controls		2

Tutorial Sessions

Seminars and Case Studies of Each Phase

Textbooks:

1. International Organization for Standardization. ISO 13485:2016. Medical devices - Quality management systems - Requirements for regulatory purposes. Geneva: ISO; 2016
2. International Organization for Standardization. ISO 14971:2019. Medical devices - Application of risk management to medical devices. Geneva: ISO; 2019.
3. International Organization for Standardization ISO I. 10993-1: 2009. Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process. International Organization for Standardization, Geneva. 2009.
4. Tranquillo J, Goldberg J, Allen R. Biomedical Engineering Design. Academic Press; 2022 Feb 19.
5. Wagner WR, Griffith LG, Sakiyama-Elbert SE, editors. Biomaterials science: an introduction to materials in medicine. 4th ed. London: Academic Press; 2020.
6. Ashby MF, Shercliff H, Cebon D. Materials: engineering, science, processing and design. 4th ed. Oxford: Butterworth-Heinemann; 2018
7. Black JT, Kohser RA. DeGarmo's materials and processes in manufacturing. 12th ed. Hoboken: John Wiley & Sons; 2017.
8. Hartman NW, Bertoline GR, Wiebe EN, Ross WA. Technical graphics communication. 4th ed. New York: McGraw-Hill Education; 2008.
9. Mastro PF. Plastic product design. Hoboken, NJ: Wiley-Scrivener; 2016
10. Yock, Paul G., ed. Biodesign. Cambridge University Press, 2015.
11. Cross, Nigel. Engineering design methods: strategies for product design. John Wiley & Sons, 2021.
12. Kumar V. 101 design methods: A structured approach for driving innovation in your organization. John Wiley & Sons; 2012 Oct 9.
13. Tobin E. The medical device engineers' handbook. (No Title). 2016.
14. Elahi B. Safety risk management for medical devices. Academic Press; 2021 Nov 11.
15. Rodríguez-Pérez J. Quality risk management in the FDA-regulated industry. 2nd ed. Milwaukee, WI: ASQ Quality Press; 2017
16. Davim JP, editor. The design and manufacture of medical devices. Elsevier; 2012 Oct 16.
17. Lam RH, Chen W. Biomedical Devices. Materials, Design, and Manufacturing. Springer, Reading, Massachusetts, 2019 Jan;1.
18. Shanmugam PS, Thangaraju P, Palani N, Sampath T, editors. Medical Device Guidelines and Regulations Handbook. Springer; 2022 Apr 22.
19. Annacchino M. New product development: from initial idea to product management. Elsevier; 2003 Oct 16.
20. Singh BK. Advanced Geometric Dimensioning and Tolerancing. New Delhi: Blue Rose Publishers; 2021. 146 p
21. Groover M, Zimmers E. CAD/CAM: Computer-Aided Design and Manufacturing. New Delhi: Pearson Education; 2013. 510 p.
22. Matisoff BS. Handbook of electronics packaging design and engineering. Springer Science & Business Media; 2012 Dec 6.
23. Lau JH. Semiconductor advanced packaging. Springer Nature; 2021 May 17.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Er D S Nagesh	Er Anoop Gopinathan	Er Sarath S Nair
Module 2	Er Subhash N N	Er Sarath S Nair	Er Nagesh D S
Module 3	Er Anoop Gopinathan	Er Sarath S Nair	Er Subhash N N
Module 4	Er Sarath S Nair	Er D S Nagesh	Er Subhash N N
Module 5	Er D S Nagesh	Er Amrutha C	Er Sarath S Nair
Module 6	Er Amrutha C	Er Sarath S Nair	Er D S Nagesh
Module 7	Er Sarath S Nair	Er Subhash N N	Er Anoop Gopinathan

16.2.3 Biomechanics

<table>
<tr><td>Course Title</td><td>Biomechanics</td><td>Course Code</td><td colspan="4">MDE 512</td></tr>
<tr><td>Department</td><td>Medical Devices Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td></td><td></td><td colspan="4" rowspan="2">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Faculty</td><td>Adjunct faculty/Professors of Practice/ faculty of BMT Wing</td></tr>
<tr><td>Course Objectives:</td><td colspan="5">The objective of this course is to familiarise students with the fundamentals of mechanical principles behind human body movement and enable them to apply these principles in medical device development</td></tr>
<tr><td colspan="6">Course Outcome:

At the end of the course, the student will be able to learn mechanics behind human body movement. They will also learn mathematical models for muscles, tissues, tendons and apply them to address real world problems.</td></tr>
</table>

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
CO1	Understand and apply the fundamental concepts of biomechanics applicable to the study of human motion in problem-solving scenarios	K2 & K3
CO2	Understand the muscle architecture and mechanics	K3 & K4

CO3	Gain knowledge on properties of muscle and tendon	K3 & K4
CO4	Understand and apply engineering tools that are used to analyze human movement	K4, K5
CO5	Understand and solve equations of motion for simple models of human movement	K2, K4
CO6	Apply biomechanics principles to clinical and biomechanical translational research	K2, K5

Syllabus:

Module	Topics (In detail)	No. of hours	
		Lecture	Tutorial
Module 1	Introduction to Biomechanics Elements of the human musculoskeletal system. Movements in the sagittal, frontal and transverse planes. Movements occurring about the medio-lateral, antero-posterior and longitudinal axis. Muscle, bones and joints with the terminology. Degrees of freedom at a joint based on its anatomy. Anthropometry Structure of bones – Composition and properties of bones and relationship to structure, Elastic properties of bones, Modelling and Remodelling of bones (Wolfe's law of bone remodelling), bone fractures, common sports injuries, Review of forces, torques, equilibrium and levers.	06	
	Tutorial: 2-D and 3-D problems on anthropometry, forces, torques and levers		03
Module 2	Skeletal muscles Muscle architecture, Muscle fascicles and their arrangement, fibre architecture in fascicles, Muscle as a fibre reinforced composite, Muscle centroids, muscles microscopic view (Physiological & Anatomical) Effect of exercise on muscles and co-ordination, active/tetanized muscles	04	
	Tutorial: Demonstrate muscle model and explain its part, solve 2-D muscle-related problems		02

Module 3	Properties of muscle and tendon Properties of tendons – Viscoelastic behaviour of tendons, Tendon interaction with surrounding tissues Mechanical properties of passive muscles, Mechanics of Active muscle: Muscle force production and transmission, Sliding filament theory, History effects in muscle mechanics – Hill's model (derivation)	04	
	Tutorial: Demonstrate the viscoelastic behaviour of tendons and the behaviour of active muscle		02
Module 4	Mathematical models for muscle How muscles generate forces and their effect on the structures surrounding them. Functional relations (Force - length, Force – Velocity curves), sliding filament model, Muscle coordination – Problem of motor redundancy – Approach to studying muscle force production using optimization (forward and inverse) Exemplary behaviour: Dynamics of Reaching – Inverse dynamic modelling	06	
	Tutorial: Assignment on one muscle model		03
Module 5	Kinematics and kinetics Defining body orientation, Free body diagram, Transformation matrices, Rotation matrices, Multiple Transformations, Inverse kinematics, Kinematic equations of motion, Velocity of Kinematic chain, Acceleration of kinematic chain, interaction torques, computation of interaction torques.	04	
	Tutorial: problems on matrices, velocity, acceleration, and interaction torque		02
Module 6	Motion of human body Mechanics of standing, walking, running, jumping, throwing a ball and other types of motions, physics of sports, Motion Capture, Link-Segment Models, Dynamic Measurement Methods, Human walking- Gait, Characteristics of normal and pathological gait, Applications to the design of assistive devices	06	
	Tutorial: Apply learnings in biomechanical translational research		03

Text Books:

1. Principles of Biomechanics by Robert L. Huston, CRC Press

2. Berne & Levy Physiology, 6th Updated Edition, Bruce M. Koeppen and Bruce A. Stanton, Mosby, 2009 edition.
3. Fundamentals of biomechanics, by Knudson DV, Knudson DV, New York: Springer; 2007 May 28.
4. Biomechanics and Motor Control of Human Movement, by David A. Winter. (2009), Fourth Edition. Published by John Wiley & Sons, New York.
5. Atlas of Human Anatomy by Frank H Netter, Saunders Elsevier
6. Physics of the Human Body, by Irving P. Herman, Springer, New York, NY, November 2006
7. Fundamentals of Neuromechanics by Valero Cuevas,
8. Kinetics of human motion, by Zatsiorsky, Vladimir M, Human Kinetics, 2002.
9. Kinematics of Human Motion, Zatsiorsky, Vladimir M, Human Kinetics, 2002.
10. Biomechanics of skeletal muscles, 5. Zatsiorsky, Vladimir, and Boris Prilutsky, Human Kinetics, 2012.

Evaluation:

- Assignment/ Seminars: - 3 assignments
- Total 100 marks. Written exam - 60 marks, Assignment and Seminar - 40 marks.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Er. Arvind Kumar Prajapati	Er. Subhash NN	Dr. Siva Kumar KGV
Module 2	Er. Subhash NN	Er. Arvind Kumar Prajapati	Dr. Siva Kumar KGV
Module 3	Er. Arvind Kumar Prajapati	Er. Subhash NN	Dr. Siva Kumar KGV
Module 4	Er. Subhash NN	Dr. Siva Kumar KGV	Er. Arvind Kumar Prajapati
Module 5	Er. Arvind Kumar Prajapati	Er. Subhash NN	Dr. Siva Kumar KGV
Module 6	Er. Subhash NN	Er. Arvind Kumar Prajapati	Dr. Siva Kumar KGV

16.2.4 Orthopaedic Implant Technologies

<table>
<tr><td>Course Title</td><td>Orthopaedic Implant Technologies</td><td colspan="2">Course Code</td><td colspan="3">MDE 514</td></tr>
<tr><td>Department</td><td>Medical Devices Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td rowspan="2">Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td>Faculty</td><td>Er. Arvind Kumar Prajapati, Er. Subhash NN, Dr. Siva Kumar K.G.V.</td><td colspan="5">Description:
L: Lecture, T: Tutorial, P: Practical, C: credits</td></tr>
</table>

Course Objectives:	The objective of this course is to familiarize students with a comprehensive understanding of Orthopaedic implants and prostheses
Course Outcome: At the end of the course, the student will be able to learn about human joints and associated devices. They will also gain a detailed understanding of the implants and prosthesis design, evaluation, and manufacturing.	

CO	Course Outcome	Bloom Knowledge Level (KL)
CO1	Gain knowledge on orthopaedic implants and prosthesis	K2, K3
CO2	Understand the mechanics of various joints	K2, K4, & K5
CO3	Gain knowledge in Implant and prosthesis design	K4, K5
CO4	Understand the evaluation of Implant and prosthesis	K4, K5
CO5	Understand the different alloy systems and their use in orthopedic implants	K4, K5
CO6	Understand the different manufacturing processes used in implant-making	K2, K3

Syllabus:

Module	Topics (In detail)	No. of hours	Tutorial
Module 1	Introduction History of orthopaedic implants and prosthesis, Need for implants and prosthesis, Basics of Musculoskeletal system Bone, Muscle, Ligament, Tendon, Cartilage and Meniscus, Structure, and functional anatomy of Synovial Joints – Hip, Knee, Shoulder, Elbow, and spine	03	
	Tutorial: Learn a variety of joints using 3D human anatomy models		03
Module 2	Mechanics of joint Concepts of Stresses and Strain, Bone Structure - Cancellous and Cortical Bone, Mechanical Behaviour of Bone Adaptation and Viscoelasticity, Bone Anisotropy. Mechanics of Joint – Hip, Knee, Shoulder, Spine, Medical conditions for implant and prosthesis, Cemented and Cementless implant fixation, Failure mechanisms of implants and prosthesis, Bone Fracture Healing, Principle of	07	

	Mechanobiology, Bone ingrowth/outgrowth around implants, Bone Remodelling – formulation		
	Tutorial: Identify the medical condition of one of the joints		03
Module 3	Implant and prosthesis design Introduction to types of Design, Stage-Gate and Spiral Design, Stages in New Product Development, Reverse Engineering and Redesign. 1. Phase 1 or Conceptual design- Identifying Customer Needs, Customer Need Analysis, Need - Metric Matrix, HoQ, Functional Decomposition, FAST Method, Function Structure (Flow Method), Flow Method, Establishing Target Specifications. Concept Development, Intuitive Methods, Logical Method- TRIZ, Concept Selection 2. Phase 2 or Embodiment design- Product Architecture, Configuration design, Parametric design 3. Phase 3 or Detailed design 4. Phase 4 or planning for manufacturing, distribution, and use.	08	
	Tutorial: Generate ideas for medical conditions using concept generation methods and score them		03
Module 4	Implant and prosthesis evaluation Design controls, design history, Implant and prosthesis design parameters, Modelling techniques and analysis, Geometric Dimensioning and Tolerancing (GD&T), Finite Element Analysis of implant and prosthesis, Experimental validation of numerical models, Prototyping, Failure Mode Evaluation and Analysis (FMEA), Fault Tree Analysis, reliability analysis and prediction	06	
	Tutorial: Finalize the specification and determine the evaluation parameters		03
Module 5	Materials for implants and prostheses Requirements of metallic biomaterials for use in implants and prostheses - Structural and chemical attributes: yield and tensile strength, ductility, stiffness, fatigue strength, fracture toughness, wear resistance, corrosion resistance - Elements of biocompatibility - Others: MRI compatibility, radiopacity Alloy systems used in metallic implants, their classification and properties	03	

Module 6	- Steels, titanium alloys, cobalt alloys and NITINOL - Materials selection for specific implant applications - Prevailing materials standards and databases		
	Tutorial: Discussion on material selection		1
	Manufacturing processes - Primary consolidation processes- shaped casting, forging, additive manufacturing, machining etc. and related trade-offs - Secondary processes- mechanical polishing heat treatments targeting improvement of specific properties - Finishing processes- Mechanical finishing, passivation, anodizing, electropolishing, shot and laser peening.	03	
	Tutorial: Create a prototype- plastic/metal/ foam board		2

Text Books:

1. Implants in Surgery, David Franklyn Williams, Robert Roaf, D. O. Maisels, W. B. Saunders, 1973
2. ASM Handbook, Volume 11: Failure Analysis and Prevention (ASM Handbooks), by R.J. Shipley, W.T. Becker
3. Product Design: Techniques in Reverse Engineering and New Product Development, Pearson by Kevin Otto , Kristin Wood
4. Product Design by Kevin Otto & Krisitn Wood, Pearson Education
5. The Mechanical Design Process by D.G. Ullman, McGraw- Hill, 2015
6. Engineering Design- A systematic Approach by G. Pahl and W. Beitz, Springer, 2007.
7. Fundamentals of medical implant materials, ASM Handbook, Materials for Medical Devices, Vol.23
8. Orthopaedic biomaterials in research and practice, Kevin L. Ong, Scott Lovald, Jonathan Black,
9. ‘Manufacturing Processes for Engineering Materials, S. Kalpakjian and S. R. Schmid
10. The Science and Design of Engineering Materials, J. P. Schaeffer, A. Saxena, S. D. Antolovich, T. H. Sanders Jr. and S. B. Warner, ‘.

Evaluation:

Assignment

1. Design project
2. Assignment
3. Seminar

- Total 100 marks. Written exam - 60 marks, Assignment and Seminar - 40 marks.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Er. Arvind Kumar Prajapati	Er. Subhash NN	Dr. Siva Kumar KGV
Module 2	Er. Arvind Kumar Prajapati	Er. Subhash NN	Dr. Siva Kumar KGV
Module 3	Er. Subhash NN	Er. Arvind Kumar Prajapati	Dr. Siva Kumar KGV
Module 4	Er. Subhash NN	Er. Arvind Kumar Prajapati	Dr. Siva Kumar KGV
Module 5	Dr. Siva Kumar KGV	Er. Muraleedharan C V	Er. Arvind Kumar Prajapati
Module 6	Dr. Siva Kumar KGV	Er. Muraleedharan C V	Er. Subhash NN

16.2.5 Advanced Polymer Technology

Course Title	Advanced Polymer Technology	Course Code		MDE 613		
Department	Medical Devices Engineering	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	0	2	3
		Description: L: Lecture, T: Tutorial, P: Practicals, C: credits				
Faculty	Dr. Roy Joseph, Dr. Ramesh P, Dr. Gijo Raj					
Course Objectives:	The course aims to provide comprehensive understanding and practical knowledge of polymeric materials, their properties, processing and applications in biomedical devices.					

Course Outcome:

The student is acquainted with comprehensive understanding of Polymers, their synthesis, characterization, processing, testing, rheology and applications in biomedical devices. Practical sessions would provide students with hands on experience in polymer compounding, processing, and Testing.

CO	Course Outcome	Bloom Knowledge Level (KL)
CO1	Gain understanding of different classifications of polymers, synthesis and physic-chemical characterization	K2, K3
CO2	Practical knowledge on polymer compounding and processing techniques	K2, K3, K 6
CO3	Practical knowledge on different mechanical testing of Polymeric materials	K2, K4, K5

CO4	Understand the basic concepts of Rheology, analyze and interpret experimental rheology curves on polymeric systems.	K2, K4
CO5	Understand the requirements for Polymers for Medical applications,	K2, K3

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Introduction to Polymers and Characterization techniques Classification of Polymers - Elastomers, plastics, thermoplastics, thermosets and fibres, Different mechanism of polymerisations such as addition, condensation, stereoregular polymerization, copolymerization, Important techniques of polymerization - bulk, emulsion, solution, suspension. Controlled polymerization techniques (ATRP, RAFT), Chemical Vapour Deposition and Polymerization. Polymer characterization, molecular weight concepts, molecular weight distribution, molecular weight determination by GPC, light scattering, viscosity, osmometry. Physical methods for polymer analysis such as Fourier transform infrared spectroscopy (FTIR), Confocal Raman spectroscopy, Nuclear Magnetic Resonance (NMR), Electron Spectroscopy for Chemical Analysis (ESCA), X-ray diffraction etc. Thermal analysis using Differential scanning calorimetry (DSC), Thermogravimetric Analysis (TGA), Differential thermal analysis (DTA), Dymanic mechanical analysis (DMA) etc. Morphological analysis by Scanning electron microscopy (SEM), Transmission electron microscopy (TEM), and Atomic Force Microscopy (AFM).	7	0	4
Module 2	Polymer Processing Additives for plastics and Elastomers, mixing and compounding of plastics and rubbers, mixing and compounding equipment, two-roll mill, internal mixers. Injection moulding, types of injection moulding machines, details of moulding process, Extrusion, single screw extruders, twin screw extruders, Filament extrusion, compression moulding. Transfer moulding, blow moulding, parison programming, calendaring, rotational moulding, thermoforming, casting, dip coating, machining of plastics, machining, Adhesion, joining and welding of plastics. Additive manufacturing techniques, 3D printing, 3D Bioprinting, electrospinning.	6	0	12
Module 3	Polymer Testing Important processability tests carried out on thermoplastics including melt flow index (MFI), specific gravity, bulk density, etc. Capillary rheometers, melting point, viscosity etc. Mechanical properties of polymers-tension, compression, flexural and shear, hardness, impact	6	0	8

	strength, resilience, abrasion resistance, creep and stress relaxation, compression set, dynamic fatigue, ageing properties. Nanomechanical property (adhesion elasticity) mapping using AFM			
Module 4	Applied Rheology Viscoelastic behaviour, Newtonian and non-Newtonian flow, pseudoplasticity, Bingham plastics and thixotropic behavior, Viscoelasticity of solid polymers, Maxwell and Kelvin models, creep phenomena, stress relaxation, Boltzmann principle, WLF equation Rotational and Oscillatory rheometers, Flow behavior, flow curve and viscosity curve, Oscillatory test, Limit of linear Viscoelastic region, Amplitude and Frequency sweeps. Time-dependent flow behavior (Rotational and Oscillation) Temperature-dependent behavior (Rotational and Oscillation),	6		6
Module 5	Polymers in Biomedical Applications Selection of polymers for Biomedical application, biocompatibility, implant design, polymeric implants and devices, leaching of additives, toxicity of additives, biological response to polymer implants. Clean room processing, Sterilisation methods, dry heat steam, ethylene oxide, electron beam sterilization, hydrogen peroxide gas plasma sterilization, gamma sterilization, packaging, shelf life.	5		

Text Books:

1. D.L.Wise et al. Eds., Encyclopedic handbook of Biomaterials and Bioengineering, Part A. Materials & part B. Applications, Volume 1 &2, Marcel Dekker Inc., New York, 1995.
2. Text book of Polymer Science by F.W.Billmeyer Jr. III Edn. Wiley Interscience Publishers, Canada 2002.
3. Polymer Chemistry by Seymour Carrahers Ed., C.E.Carraher VI Edn., Marcel Dekker, USA, 2003.
4. Plastics Materials 7th Ed, Brydson, John A. Butterworth-Heinemann, 1999.
5. Shalaby W. Shalaby, Biomedical Polymers, designed to degrade systems, Hanser Publishers, New York, 1994.
6. Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen and Jack E. Lemons, Biomaterials Science, An introduction to Materials Science, 3rd edition, Elsevier Academic Press, London, 2012.
7. Applied Rheology, Thomas G Mezger, Anton Paar GmbH, Austria, 4th Edition 2017
8. Maver U, Maver T, Persin Z, et al. (2013) Polymer Characterization with the Atomic Force Microscope. Polymer Science. InTech. DOI: 10.5772/51060.
9. Physicochemical Aspects of Polymer Surfaces, Volume 1, Editors K. L. Mittal, Springer New York, NY, https://doi.org/10.1007/978-1-4615-7584-9
10. POLYMER TESTING, Edition: 2nd Edition, Wolfgang Grellmann and Sabine Seidler
11. Pages: 712, eISBN: 978-1-56990-549-4, Print ISBN: 978-1-56990-548-7, © 2013 Carl Hanser Verlag GmbH & Co. KG
12. Jean-François Agassant, Pierre Avenas, Pierre J. Carreau, Bruno Vergnes, Michel Vincent, Polymer Processing, Editor(s): Jean-François Agassant, Pierre Avenas, Pierre J. Carreau, Bruno

Vergnes, Michel Vincent, Polymer Processing (Second Edition), Hanser, 2017, Pages I-XLI, ISBN 9781569906057.

Evaluation:

- Assignments: Two assignments
- Seminars – Two per group.
- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Gijo Raj	Dr. Renjith S	Dr. Manju S
Module 2	Dr. Gijo Raj	Dr. Shiny Velayudhan	Dr. Manju s
Module 3	Dr. Gijo Raj	Dr. Shiny Velayudhan	Dr. Manju S
Module 4	Dr. Roy Joseph	Dr. Gijo Raj	Dr. Shiny Velayudhan
Module 5	Dr. Ramesh P	Dr. Gijo Raj	Dr. Lynda V Thomas

16.2.6 Biomedical Signal and Image Processing

<table>
<tr><td>Course Title</td><td>Biomedical Signal and Image processing</td><td colspan="2">Course Code</td><td colspan="3">MDE 513</td></tr>
<tr><td>Department</td><td>Medical Devices Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td rowspan="2">Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>2</td><td>0</td><td>2</td><td>3</td></tr>
<tr><td colspan="5" rowspan="2">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Faculty</td><td>Sujesh S, Ranjth G., Saurabh S. Nair. Jithin Krishnan</td></tr>
<tr><td colspan="7">Course Objectives:</td></tr>
<tr><td colspan="7">To impart a comprehensive understanding of biomedical signals and images, and their processing. The students would be introduced to the mathematical concepts in signal and image processing, the importance of frequency domain analysis and transforms. The course aims to introduce the students to the acquisition, processing and analysis of different biomedical signals and images.
Prerequisites:
Should have done a course in Signal Processing or Image processing at the graduate level</td></tr>
<tr><td colspan="7">Course Outline:</td></tr>
</table>

- Signals and Systems, Image data, digital data.
- Classification of signals into different domains
- Time-frequency, Spatial frequency, Fourier analysis.
- Transforms – wavelet, PCA, ICA.
- Biomedical signal acquisition & analysis
- Biomedical image acquisition and analysis
- AI, Radiomics

Course Outcome:

MDE 513 - CO	Course Outcome	Bloom Knowledge Level (KL)
MDE 513 – CO1	Gain expertise in Biomedical Signal and image representation and their mathematical operations.	K2, & K3.
MDE 513 – CO2	Understand principles in Signal / image acquisition, storage and processing for different modalities.	K2 & K3
MDE 513 – CO3	Application of Filters, Transforms, Removal of Noise, and signal enhancement.	K2 & K3
MDE 513 – CO4	Understand techniques of Registration and segmentation of images.	K3, K4, & K5
MDE 513 – CO5	Awareness of the use of AI and the importance of signals and images in diagnosis, prognosis and disease prevention.	K3, K4, & K5

Syllabus:

Module	Topics (In detail)	No. of hours
Module 1	Mathematical representation of signal and images, operations, processing, noise removal, enhancement	6
Module 2	Modalities of biomedical images and signals	6
Module 3	Signal processing and Image processing techniques	6
Module 4	Registration and Segmentation	6
Module 5	Automated segmentation, classification, use of AI	6

Text Books:

1. Medical Image Analysis. Atam P Dhawan IEEE Press Series on Biomedical Engineering
2. Lim J S. Two-Dimensional Signal and Image Processing, Prentice Hall
3. Azuaje, Clifford, and McSharry (2006). Advanced Methods and Tools for ECG Data Analysis, Artech House

4. Bioelectrical Signal Processing in Cardiac and Neurological Applications by Leif Sörnmo and Pablo Laguna
5. Handbook of medical image processing and analysis by Isaac Bankman
6. Medical Image Processing, Reconstruction and Restoration: Concepts and Methods by Jiri Jan

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Sujesh S	Er. Ranjith G	Er. Saurabh S Nair
Module 2	Dr. Sujesh S	Er. Ranjith G	Er. Jithin Krishnan
Module 3	Er. Ranjith G	Dr. Sujesh S	Er. Saurabh S Nair
Module 4	Er. Saurabh S Nair	Er. Ranjith G	
Module 5	Er. Ranjith G	Dr. Sujesh S	

16.2.7 Medical Instrumentation and Sensors

<table>
<tr><td>Course Title</td><td>Medical Instrumentation and Sensors</td><td colspan="2">Course Code</td><td colspan="3">MDE 511</td></tr>
<tr><td>Department</td><td>Medical Devices Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td rowspan="2">Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>2</td><td>0</td><td>2</td><td>3</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td rowspan="2">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Faculty</td><td>Er. Vinod Kumar V, Er. Jithin Krishnan, Er. Muraleedharan C V, Er. Neethu S.</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">This course will provide the basics of bioelectricity, biosignals and instrumentation to capture the signals and the devices working based on these signals.</td></tr>
<tr><td colspan="7">The students will learn:</td></tr>
<tr><td colspan="7">Electrophysiology and Biosignals Concepts; Bio amplifiers and Electrical safety; Basic measurement Techniques; Basic sensors and Instrumentation; Fundamentals of Imaging and Sensing.</td></tr>
</table>

Course Outcome (CO):

CO	Course Outcome	Bloom Knowledge Level (KL)
MDE 511 – CO1	Electrophysiology and Bio signals Concepts	K1 & K2

MDE 511 – CO2	Bio amplifiers and Electrical safety	K1 & K2
MDE 511 – CO3	Basic measurement Techniques	K1, K2 & K3
MDE 511 – CO4	Basic sensors and Instrumentation	K1, K2 & K3
MDE 511 – CO5	Fundamentals of Imaging and Sensing	K1& K2

Syllabus:

Module	Topics (In detail)		No. of hours
Module 1	Electrophysiology and Bio-signals Concepts	Cell resting potential and action potentials – Hodgkin and Huxley model – Origin of bio potentials – characteristics - Frequency and amplitude ranges – ECG – Einthoven's triangle – 3 lead ECG system – EEG – 10-20 electrode system – Origin and characteristics of EMG – EOG – ERG electrodes and transducers. Electrode-electrolyte interface – Electrode–skin interface – Impedance – Polarization effects of electrode – Non-polarizable electrodes. Types of electrodes – Surface; needle and microelectrodes – ECG – EMG – EEG Electrodes.	4
Module 2	Bio-amplifiers and Electrical safety	Bio amplifier -Need for bio-amplifier - single-ended bio-amplifier, differential bio-amplifier – right leg driven ECG amplifier. Bandpass filtering, isolation amplifiers – transformer and optical isolation - isolated DC amplifier and AC carrier amplifier. Power line interference. Electrical safety: Physiological effects of electricity. Micro & macro shock hazards – Electrical Safety codes and standards – Protection of patients.	6
Module 3	Basic measurement Techniques	Temperature, respiration rate and pulse rate measurements. Blood Pressure: indirect methods - auscultatory method, oscillometric method, direct methods: electronic manometer. Blood flow and cardiac output measurement: Indicator dilution, thermal dilution and dye dilution method, Electromagnetic and ultrasound blood flow measurement	6
Module 4	Basic sensors and Instrumentation	Pulse Oximeter – pH meter – Auto analyser – Pacemakers – Defibrillator – Heart-lung machine – Nerve and muscle stimulators – Dialysis machines – Surgical diathermy equipment – Nebulizer; inhalator – Aspirator – Humidifier – Ventilator and spirometry. Biochemical sensors - pH, pO2 and pCo2, Ion selective Field-effect Transistor (ISFET), Immunologically sensitive FET (IMFET), Blood glucose sensors - Blood gas analysers, colourimeter, flame photometer,	7

		spectrophotometer, blood cell counter, auto analyser (simplified schematic description)	
Module 5	Fundamentals of Imaging and Sensing	Medical imaging techniques: Basics of diagnostic radiology – Production – Nature and properties of X-rays – X-ray machine – Block diagram – Digital radiography – CT – Basic Principle – Block diagram – Radioisotopes in medical diagnosis – Physics of radioactivity – Gamma Camera. Block diagram – SPECT Scanner – PET Scanner – Principles of NMR Imaging systems – Block diagram of NMR Imaging System – Ultrasonic Imaging Systems – Physics of Ultrasound waves – Doppler effect – Medical Ultrasound	7

Text Books:

1. Medical Instrumentation: Application and Design, John G Webster, TBS,
2. Introduction to Biomedical Equipment Technology, Joseph J.carr and John M. Brown, Pearson Education India.
3. Fundamentals of Medical Imaging, Paul Suetens, 2nd edition ,Cambridge University Press
4. Fundamental of Bio-Medical Instrumentation, O.N. Pandey & Rakesh Kr., S.K. Kataria & Sons

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Electrophysiology and Biosignals Concepts	Jithin Krishnan	Neethu S	Muraleedharan C V
Bio amplifiers and Electrical safety	Vinodkumar V	Muraleedharan C V	Neethu S
Basic measurement Techniques	Muraleedharan C V	Jithin Krishnan	Vinodkumar V
Basic sensors and Instrumentation	Jithin Krishnan	Neethu S	Vinodkumar V
Fundamentals of Imaging and Sensing	Vinodkumar V	Jithin Krishnan	Neethu S

16.2.8 Artificial Intelligence and Connected Health

Course Title	Artificial Intelligence and Connected Health	Course Code	MDE 515			
Department	Medical Devices Engineering	Credits	L	T	P	C

Offered for	MTech Biomedical Engineering		2	0	2	3
Faculty	Adjunct faculty/Professors of Practice /Faculty of BMT Wing	Description: L: Lecture, T: Tutorial, P: Lab, C: credits				

Course Objectives:

The student is imparted with a comprehensive understanding of the principles and applications of Machine Intelligence, Machine Learning, Deep Learning, Connected Health, and Telemedicine. The student is trained to develop and implement AI-based solutions for automated classification, diagnosis and other applications, as well as implement connected health technologies for real-time health data collection. A foundation is laid to develop advanced systems and technologies for providing health data-based AI solutions to healthcare problems.

Course Outline:

- Overview of Learning Systems – symbolic models and data-driven models.
- Machine Learning – features, various types and models.
- Deep Learning – CNN, RNN, Generative AI
- Connected Health and Telemedicine

Course Outcome:

MDE 515 - CO	Course Outcome	Bloom Knowledge Level (KL)
MDE 515 – CO1	Understand the mathematical models in AI	K1, K2, & K3.
MDE 515 – CO2	Gain expertise in data preprocessing, training and testing AI models.	K1, K2 & K3
MDE 515 – CO3	Build AI systems for classification including both algorithms and hardware.	K3, K4 & K5
MDE 515 – CO4	Understand telemedicine systems, and develop connected health systems including hardware	K3, K4, & K5
MDE 515 – CO5	Implement health monitoring and automated detection systems.	K3, K4, & K5

Syllabus:

Module	Topics (In detail)	No. of hours
Module 1	Machine Intelligence – Introduction, Learning Systems, Intelligence and Intelligent Machines	4
Module 2	Machine Learning – Data Pre-processing, Feature engineering, Data Analysis, Linear Regression Model, Supervised and unsupervised Learning, Classification and regression Models, Feature Selection / Reduction, Non-parametric Techniques, Density Estimation, Cross-validation, Regularisation,	8

	Support Vector Machine (SVM), Decision Trees, Random Forest, Ensemble Learning, Bagging, Boosting	
Module 3	Neural Networks - Perceptron, Multilayer Perceptron, Feedforward Operation, Backpropagation Algorithm, Activation Function	8
Module 4	Deep Learning Networks - CNN, RNN, GAN, Application and case studies using TensorFlow / PyTorch.	8
Module 5	Connected Health and Telemedicine – regulations, models, hardware and software architectures, health data analytics.	6

Text Books:

1. "Artificial Intelligence: A Modern Approach" by Stuart Russell and Peter Norvig.
2. "Hands-On Machine Learning with Scikit-Learn, Keras, and TensorFlow" by Aurelien Geron.
3. "Deep Learning" by Ian Goodfellow, Yoshua Bengio, and Aaron Courville.
4. "Machine Learning: A Probabilistic Perspective" by Kevin P. Murphy.
5. "Artificial Intelligence Engines: A Tutorial Introduction to the Mathematics of Deep Learning" by James V Stone.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Sujesh S	Er. Ranjith G	Er. Sarath S Nair
Module 2	Er. Ranjith G	Dr. Sujesh S	Er. Sarath S Nair
Module 3	Er. Ranjith G	Dr. Sujesh S	Er. Sarath S Nair
Module 4	Dr. Sujesh S	Er. Ranjith G	Er. Sarath S Nair
Module 5	Er. Sajith Lal M K	Er. Jithin Krishnan	Er. Neethu S

16.2.9 Laboratory Module & Internship 2

MDE 551 Laboratory Module	Practical sessions on various laboratory techniques used in various departments/divisions.	2 credits
MDE 552 Internship 2	Industry/Device Evaluation/ Development - Mini project	2 credits

16.3 Semester 2: Specialization – Applied Biosciences

16.3.1 Biological & Safety Evaluation

<table>
<tr><td>Course Title</td><td>Biological & Safety Evaluation</td><td>Course Code</td><td colspan="4">APB 611</td></tr>
<tr><td>Department</td><td>Applied Biosciences</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>2</td><td>0</td><td>2</td><td>3</td></tr>
<tr><td>Faculty</td><td>Dr Anil Kumar PR, Dr Mohanan PV, Dr Remya NS, Dr Mayanandkumar A, Dr Anugya Bhatt, Dr. P.R. Umashankar, Dr A. Sabareeswaran</td><td colspan="5">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">The objective of the course is to teach student about the invitro and invivo safety and efficacy evaluation of medical devices and biomaterials as per the ISO standard.</td></tr>
<tr><td colspan="7">The students will learn:
Series of ISO standard used for the medical device biological evaluation
How to analyse the blood compatibility of a medical device
Cytocompatibility analysis of Medical Devices
Methods of Testing
Use of calibrators and Controls
ILC and QC in medical Device testing
Students will understand about techniques used for animal cell culture, Cytotoxicity evaluation of biomaterials and Cytocompatibility evaluation of biomaterials
The module would provide students with a comprehensive understanding of biocompatibility assessment, toxicological risk evaluation, and compliance with regulatory standards, enabling them to ensure the safety and effectiveness of medical devices in clinical applications.
The objective of the course is to familiarize the students with the concepts of immunology with respect to biomaterials and medical devices and their evaluation.
The students will understand the importance of microbiology in medical device manufacturing and commercialization. Microbiological aspects for all medical device classes and composition, including biologics and tissue-based devices. Medical device-related infections and methods for combatting such infections. Bioburden analysis of devices and Sterility testing, Importance of packaging.</td></tr>
</table>

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)*
APB 611 – CO1	Acquire knowledge on in vitro cytotoxicity test methods and gain understanding on cytocompatibility evaluation	K1, K2

APB 611– CO2	Acquire knowledge on toxicological principles and methods, allowing them to evaluate safety and risks across diverse substances, including drugs, materials, medical devices, biologics, and combination products, and explore emerging trends in toxicological assessment.	K1, K2 & K3
APB 611– CO3	The students will learn • importance of microbiology in medical device manufacturing and commercialisation • Microbiological aspects for all classes and composition of medical device including biologics and tissue based devices • Medical device related infections and methods for combatting such infections • Bioburden analysis of devices • Sterility testing, • Importance of packaging.	K1, K2, K3
APB 611– CO4	The students will learn the basics of Hemocompatibility Evaluation	K1, K2, K3 K4
APB 611– CO5	The students will understand the basics of immune response to medical devices and its evaluation.	K2, K3, K4 & K5
APB 611– CO6	Quality Control	K2, K3, K5
APB 611– CO7	Inter Laboratory comparison/ Proficiency Testing	K2 & K3
*K1: Remember, K2: Understand, K3: Apply, K4: Analyze, K5: Evaluate, K6: Create		

Syllabus:

Module	Topics (In detail)	No. of hours
Module 1	Cytotoxicity and Cytocompatibility Evaluation: Introduction to animal cell culture: Type of cells, Primary cells, Cell lines, Immortalized cells, Stem cells, Growth curve, Aseptic techniques, Environment, Equipment, Cell cultureware, Safety in cell culture lab, Contamination in cell culture. Cytotoxicity evaluation of biomaterials: International Standards for cytotoxicity evaluation - ISO, ASTM, USP. ISO 10993-5, Direct Contact Method, Test on Extract Method, Indirect Contact Method, Cytotoxicity evaluation of nanoparticulate materials Cytocompatibility evaluation: Colony Counting, Cell adhesion, in vitro wound healing,	6

	Cell based assays: MTT Assay for cell proliferation/cytotoxicity, Neutral Red Assay, IC50 estimation	
Module 2	Toxicological Evaluation Introduction to Toxicology: History-evolution Toxicology of biomaterials/medical devices, drugs, chemicals and other compounds Selection of toxicity tests, standards/guidelines Dose range findings and dose-response relationship Mechanisms of drug/chemical action ADME and metabolism studies Toxicokinetics/pharmacokinetics actions Drug delivery systems, drug interaction and substance abuse Immunotoxicity, genotoxicity, carcinogenicity, reproductive toxicity including teratological studies, dominant lethal assays Risk assessment in toxicology Identification of leachants and the importance of physicochemical characterization Good Laboratory Practice in Toxicity Studies	8
Module 3	Microbiological Evaluation: Basic concepts, spectrum of microbes, detection of microbial contamination, Cellular response to stress, material microbes interactions, biofilms, microbial identification, sterility testing	8
Module 4	Hemocompatibility Evaluation: Classification of the devices, Methods of exposure of the devices to the blood, Blood parameters to be analyzed, Methods of analysis. Interpretation of the data.	8
Module 5	Evaluation of immune response to medical devices: This module deals with the basic concepts in immunology, immunogenicity of biomaterials and medical devices and their evaluation using in vitro and in vivo methods.	6
Module 6:	Histopathological Evaluation: Histology sample preparation for tissue material interface analysis, staining techniques, imaging and histomorphometry	6

Text Books:

1. ISO10993-23: 2021 Biological evaluation of medical devices-Part23: Tests for irritation, Accession No: 11412, Author(1): ISO, Publication Year: 2021, Edition, Collation : 60pp.
2. ISO 10993-10: 2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization, Accession No: 11437, , Author(1): ISO, Author(3) : ISO, Publication
3. Biological evaluation of medical devices-Part.I: Guidance on selection of tests Accession No: 6446, Author(1) :, Publication Year : 1992, Edition :, Collation: 11
4. Biological evaluation of medical devices: Part2- Animal welfare requirements (ISO 10993-2: 1992), Accession No: 6721, Author(1) : ISO, Publication Year :, Edition :, Collation : Call Number : ISO 10993-2.
5. Biological evaluation of medical devices: Part3- Tests for genotoxicity, carniogenicity and reproductive toxicity (ISO 10993-3: 1992), Accession No: 6722, Author(1): ISO, Publication Year :, Edition :, Collation: Call Number: ISO 10993-3 .
6. Biological evaluation of medical devices: Part4- Selection of tests for interactions with blood (ISO 10993-4: 1992), [REFERENCE] Accession No: 6723, Author(1), Publication Year :, Edition :, Collation: Call Number: ISO 10993-4
7. Biological evaluation of medical devices: Part5- Tests for toxicity: in vitro methods (ISO 10993-5:1999), [REFERENCE]
   Accession No. 6724, , Author(1) : ISO, Publication Year :, Edition :, Collation : Call Number : ISO 10993-5
8. ISO 10993-12: Biological evaluation of medical devices- Part 12: sample preparation and reference materials, Accession No. 9075, Author(1): International Organization for Standardization, Publication Year : 22, Edition: 2, Collation: 15pp. Call Number ISO 10993-12.
9. ISO 10993-6:2016 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation.
10. ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation
11. Biomedical Product and Materials Evaluation: Standards and Ethics, (2022), Ed P.V. Mohanan, Woodhead Publishing, Duxford, United Kingdom
12. Xian, W. (2009). A Laboratory Course in Biomaterials. United States: CRC Press.
13. Safety evaluation of pharmaceutical &Medical Devices, Shayne C Gad, Springer publication
14. Microbiology and sterility assurance in pharmaceuticals and medical devices edited Madhu Raju Saghee et al.
15. Handbook of microbiological quality control in Pharmaceutical and Medical devices. – Rosanmung Baird
16. Pharmaceutical microbiology manual – US FDA.

Faculty:

Module	Faculty 1	Faculty 2
Cytotoxicity and Cytocompatibility Evaluation	Dr AnilKumar PR	Dr. Naresh K
Toxicological Evaluation	Dr. Mohanan PV	Dr. Remya NS

Microbiological Evaluation	Dr. Maya Nandkumar A	Dr. Remya NS
Hemocompatibility Evaluation	Dr Anugya Bhatt	Dr. Ranjith P Nair
Evaluation of immune response to medical devices	Dr Umashankar PR	Dr. Sachin J Shenoy
Histopathological Evaluation	Dr Sabreeswaran A	Dr Umashankar PR

16.3.2 In-vivo Functional Safety Evaluation

Course Title	In-vivo Functional Safety Evaluation	Course Code	APB 615			
Department	Applied Biology	Credits	L	T	P	C
Offered for	MTech Medical Devices and Technology MTech Clinical Engineering		1.5	1	1	3
		Description: L: Lecture, T: Tutorial, P: Lab, C: credits				
Faculty	Dr. Umashankar PR, Dr Sachin J Shenoy, Dr. Harikrishnan VS.					
Course Objectives	The objective of this course is to provide an insight into the evaluation techniques, regulatory and ethics/welfare requirements for In-Vivo Functional Safety Evaluation of Medical Devices.					

Course Outcome:

At the end of this course, the students have a knowledge of, fundamental principles in pharmacology, drugs, drug delivery, pharmacokinetics, pharmacodynamics and various drug-device combination products. The students will also gain an overview of techniques for the safety and efficacy evaluation of drug-device combination products.

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 615 – CO1	Understand the legalities, statutory requirements, ethical issues involved and stepwise decision-making involved in animal experimentation in the way forward on the road of biomedical research.	K1, K2 & K3, K4
APB 615– CO2	The students will have knowledge of various animal models, techniques and methodologies to be followed while performing experiments using animal models.	K1, K2, K3
APB 615 – CO3	The students will have an understanding of the regulatory requirements for medical device testing, the standards and other guidance documents on In Vivo functional safety evaluation.	K1, K2, K3

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Laboratory Animal Science, Ethics and Welfare, Regulatory Aspects. Laws on Animal Experimentation, Statutory body roles and formalities, Requirements to initiate an experiment, Definition of Experiments, Animals covered by the rules, purposes of using animals for research and laws guiding them, and import of laboratory animals. Ethical Viewpoints in Biomedical Research, Basic concepts on animal welfare, theories of welfare, 3R's in Biomedical research, practical approaches. Animals Strains of different background and different types of breeding programmes. Various uses of genetically altered animals in scientific research. International rules of rodent Nomenclature. Genetically modified animals- various classes, basics of production. Potential disease risks to animals and humans in the animal facility, Methods available for maintaining appropriate health status (including use of barriers, different containment levels use of sentinels as relevant to the species). Health monitoring procedures. Signs of health in rodents and rabbits and deviations from good health. Routines and husbandry practices for the maintenance, care and welfare for a range of animals used in research; Suitable environmental and housing conditions; Types of diet, dietary requirements of the relevant animal species, advantages and disadvantages with each type of and husbandry practices for the maintenance, care and welfare for a range of animals used in research; Suitable environmental and housing conditions; Monitoring the conditions; adverse effects from inappropriate conditions. Recognise that changes to or disruption of circadian or photoperiod can affect animals. Acclimatisation, safe and humane handling, sexing and restraint of rodents and rabbits for common scientific procedures. Identification techniques for individual animals with advantages and disadvantages. Ensuring health and welfare in animal transport. Potential health hazards associated with contact with laboratory animals. Practical Sessions The course includes practical sessions, Hands-on handling training, basic techniques teaching and demonstrations of common procedures needed for researchers like sexing, feeding, environmental monitoring,	8	6	15

	traffic and operating procedures while working with lab animals, administration of experimental agents (enteral and parenteral) and collection of data (blood, urine samples etc).			
Module 2	Small and Large Animal Models, Experimental Design and techniques in animal experimentation (surgery, anaesthesia and instrumentation). Introduction to animal models, classification of animal models, refinement techniques in animal experimentation – analgesia, anaesthesia, perioperative care of experimental animals and euthanasia. Instrumentation, introduction to surgical techniques, Basic concepts in design, conduct and interpretation of animal studies for assessing the safety and performance of medical devices	6	3	0
Module 3	Preclinical Testing for Safety and Efficacy of Medical Devices Regulatory requirements for medical device testing, horizontal and vertical standards, identification and selection of suitable animal models for demonstrating device failure modes for different medical devices.	8	6	0

Text Books:

1. ISO standards: ISO 10993 and other relevant standards
2. CCSEA Guidelines for laboratory facilities -2015
3. Nagarajan P, Gudde R, Srinivasan R, Veterinary OT, editors. Essentials of laboratory animal science: Principles and practices. Springer; 2021 Jul 23.
4. Hau J, Schapiro SJ, Van Hoosier Jr GL. Handbook of laboratory animal science: Volume I, II & III. CRC press; 2011.
5. Hau, J., & Schapiro, S.J. (Eds.). (2021). Handbook of Laboratory Animal Science: Essential Principles and Practices (4th ed.). CRC Press. https://doi.org/10.1201/9780429439964
6. Guide for the care and use of laboratory animals (8th edn). National Research Council, 2010.
7. Flecknell, P., 2015. Laboratory animal anaesthesia. Academic press.
8. Hubrecht, R.C. and Kirkwood, J. eds., 2010. The UFAW handbook on the care and management of laboratory and other research animals. John Wiley & Sons.

Evaluation:

- Assignments: Two assignments
- Seminars – Two per group.
- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr Harikrishnan VS	Dr. Sachin J Shenoy,	Dr Umashankar PR

Module 2	Dr Sachin J Shenoy	Dr Harikrishnan VS	Dr Umashankar PR
Module 3	Dr Umashankar PR	Dr Sachin J Shenoy	Dr Harikrishnan VS

16.3.3 Applied Biochemistry and Physiology

<table>
<tr><td>Course Title</td><td>Applied Biochemistry and Physiology</td><td>Course Code</td><td colspan="4">APB 511</td></tr>
<tr><td>Department</td><td>Biochemistry, Applied Biology</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>1</td><td>1</td><td>2</td><td>3</td></tr>
<tr><td rowspan="2">Faculty</td><td rowspan="2"></td><td colspan="4">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="5">The course aims to provide students with a foundation in biochemistry, equipping them with the knowledge necessary to understand normal cellular and molecular processes, diagnose diseases, conduct biochemical experiments, and appreciate the biochemical basis of physiological functions and dysfunctions in the human body.</td></tr>
<tr><td colspan="6">The students will learn:</td></tr>
<tr><td colspan="6">Biochemical Basis of Life including Molecular Organization of Cell, structure and function of essential biomolecules, the composition and functions of the cell membrane, as well as the concept of cell signaling through receptors.
Metabolism Overview and Understand the concepts of Bioenergetics
The significance of organ function tests for assessing the health and functionality of various organ systems, and to recognize the use of biomarkers in diagnosing diseases and monitoring treatment responses and also understand the biochemical basis of metabolic diseases, such as diabetes mellitus, hyperlipidemia, atherosclerosis, molecular and biochemical aspects of cancer development and progression
The biochemical basis of hemostasis and thrombosis, also understand the principles of fluid and electrolyte balance, including their regulation in maintaining homeostasis and how hormones work at the biochemical level and understand signal transduction mechanisms. Also the biochemical basis of thermoregulation and the biochemical and physiological changes associated with aging and their implications for health
A range of biochemical laboratory techniques.</td></tr>
</table>

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 511 – CO1	Biochemical basis of life	K1, K2 & K3

APB 511 – CO2	Metabolism and Bioenergetics	K1, K2
APB 511 – CO3	Clinical Biochemistry	K1, K2 & K3
APB 511 – CO4	Systems physiology	K1, K2
APB 511 – CO5	Biochemical techniques	K1, K2, K3

Syllabus:

Module	Topics (In detail)	No. of hours		
		L	T	P
Module 1	Biochemical basis of life Molecular organisation of Cell, Cell membrane, subcellular organelles, chromosomes, Biomolecules proteins and amino acids, carbohydrates, lipids, nucleic acids and nucleotides, enzymes, vitamins, hormones, cell membrane receptors and cell signalling.	3	3	6
Module 2	Metabolism and Bioenergetics Overview, organ systems involved, major metabolic pathways of carbohydrate, fatty acids, proteins and amino acids, nucleic acids and nucleotides, Citric acid cycle, Biological oxidation and electron transport chain.	3	3	6
Module 3	Clinical Biochemistry Organ function tests, Biomarkers, Regulation of Blood glucose- Insulin and Diabetes Mellitus, Hyper lipedemia, atherosclerosis and cardiovascular diseases, Metabolic diseases, Biochemistry of cancer	3	3	6
Module 4	Systems Physiology Biochemical basis of Haemostasis and thrombosis, Fluid, electrolyte, acid-base balance, Hormone action and signal transduction, Thermoregulation and aging.	3	3	6
Module 5	Biochemical techniques Centrifugation, Microscopy, Protein purification techniques, macromolecular interactions: protein-protein, protein-DNA, protein-RNA and Protein-ligand, Immunoassays, Western blot, Electrophoretic techniques, Chromatography, Spectrophotometry, PCR, radio-immunoassays.	3	3	6

Text Books:

1. D. L. Nelson and M. M. Cox, Lehninger Principles of Biochemistry, 6th Ed., Macmillan Worth, 2012.
2. R. K. Murray, D. K. Granner, P.A. Mayes and V. W. Rodwell, Harper's Biochemistry, 30th Ed McGraw Hill, 2015.
3. Daniel D. Chiras, Human Biology, 7th Edition, Jones & Bartlett Pub, 2010.
4. Ross & Wilson, Anatomy & Physiology in Health and Illness, 13th Edition, Elsevier, 2018.
5. Keith Wislon and John Walker. Principles and Techniques of Biochemistry and Molecular Biology 8th Edition, Cambridge University Press 2018.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Madhusoodanan U.K.	Dr. Naresh Kasoju	Dr. Remya N.S.
Module 2	Dr. Cibin T.R.	Dr. Madhusoodanan U.K.	Dr. Remya N.S.
Module 3	Dr. Cibin T.R.	Dr. Madhusoodanan U.K.	Dr. Remya N.S.
Module 4	Dr. Remya N.S.	Dr. Naresh Kasoju	Dr. Remya N.S.
Module 5	Dr. Madhusoodanan U.K.	Dr. Cibin T.R.	Dr. Remya N.S.

16.3.4 General Pathology and Implant Biology

<table>
<tr><td>Course Title</td><td>General Pathology and Implant Biology</td><td colspan="2">Course Code</td><td colspan="3">APB 612</td></tr>
<tr><td>Department</td><td>Applied Biology</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td>Faculty</td><td>Dr. A. Sabareeswaran, Dr Deepthi AN,
Dr. Rajalakshmi</td><td colspan="5">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">The objective of this course is to familiarize the non-biology backgrounds students with the important terms used in pathology, introduce them to biocompatibility evaluation to enable them to apply in medical device development.</td></tr>
</table>

Course Outcome:

At the end of this course, the students will be able to remember the important terms used in pathology and understand the medical terminologies. Students will gain knowledge in basic pathology terminologies and

cellular pathology relevant to biomaterials and medical device biological evaluation and apply the knowledge for the purpose of developing medical devices.

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 612 – CO1	Gain a preliminary understanding of cells, tissues, homeostasis, and language of pathology	K1, K2, K3
APB 612 – CO2	Understand the tissue material interface and biocompatibility and apply the concepts in Medical Devices	K1, K2, K3
APB 612 – CO3	Understand the tissue processing, embedding and sectioning and staining.	K4, K5, K6

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	General pathology Basic understanding of the mechanism of cells and tissues, cell injury, necrosis, inflammation, wound healing, cellular adaptation, neoplasia, etc.	15	0	0
Module 2	Tissue material interface Tissue material interactions in metal, polymer, ceramic, composites and biological (includes Extracellular matrix, Tissue engineered scaffolds) biomaterials and medical devices, Histopathology in preclinical evaluation of medical devices.	15	0	0
Module 3	Histotechniques Histology preparation of tissues and organs with implant (Tutorial session)	0	15	0

Text Books:

1. Robbins and Cotran Pathologic basis of Disease
2. Biomaterials Science: An Introduction to Materials in Medicine Buddy D Ratner
3. Bancrofts theory and practice of histological techniques

Evaluation:

- Assignments: Two assignments
- Seminars – Two per group.

- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Deepthi AN	Dr. Rajalakshmi	Dr. A. Sabareeswaran
Module 2	Dr. A. Sabareeswaran	Adhoc faculty	
Module 3	Dr. A. Sabareeswaran/ Mr. Joseph Sebastian/ Ms. Sudha Chandran	Dr. Deepthi AN	Dr Rajalakshmi

16.3.5 OMICS (Genomics, Proteomics, Metabolomics)

<table>
<tr><td>Course Title</td><td>OMICS (Genomics, Proteomics, Metabolomics)</td><td>Course Code</td><td colspan="4">APB 512</td></tr>
<tr><td>Department</td><td>Department of Applied Biology</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>2</td><td>0</td><td>2</td><td>3</td></tr>
<tr><td rowspan="2">Faculty</td><td rowspan="2">Anugya Bhatt, Dr Anoop Kumar T, Dr. Anil Kumar P.R.</td><td colspan="5">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td>Course Objectives:</td><td colspan="5">To provide a broad overview of the goals, methods, and applications for OMICs in life sciences.
To familiarize the terminology, underlying principles and strategies, and the technical methodologies involved.</td></tr>
</table>

Course Outcome:

At the end of this course, the students will be able to remember the important terms used in omics and understand the basics of the technologies involved. They will also learn the basic practical skills to conduct experiments, collect data and interpret the results.

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 512 – CO1	Enhance knowledge in the scientific domains of Programming languages, Structural bioinformatics, genomics, transcriptomics, proteomics and metabolomics, Systems biology	K1, K2 & K3

APB 512 – CO2	Plan experiments with the knowledge gained, Illustrate key technologies involved in genomics, metabolomics, proteomics and transcriptomics	K1, K2, K3

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Genome & Genomics: Genome mapping: Physical and Genetic Map, Genome Sequencing, Next generation sequencing methods, Genome Annotation, Functional Genomics.	6	0	4
Module 2	Transcriptomics: Search for transcription factor binding sites, RNA-Seq, Microarrays, Regulatory RNAs: small or large, Computational prediction of miRNA target genes, RNA Darkmatter	6	0	4
Module 3	Proteomics: Basics of proteins and proteomics, Gel-based proteomics, tools of proteomics- SDS PAGE, Two-dimensional gel electrophoresis (2D PAGE), Difference in gel electrophoresis (DIGE), Liquid chromatography, Mass Spectrometry (ESI and MALDI), Protein identification by peptide mass fingerprinting, Applications of proteomics. Basics of mass spectrometry and sample preparation	6	0	4
Module 4	Metabolome and Metabolomics: Fundamental concept, Metabolic profiling and fingerprinting, Metabolic pathway analysis and metabolic networks, Single Cell Metabolomics, Metabolic Pathway as a target for Drug-screening, Metabolomics approach for hazard identification in human health assessment of environmental chemicals, Clinical implications of Metabolomics. Tools of metabolomics- Capillary electrophoresis, Gas chromatography, Electrochemical detectors.	6	0	4
Module 5	Computational Methods: Systems biology, Methods to Interpret and Integrate Data, Data processing, work flow, online database	4	0	14

Text Books:

1. Campbell, A.M. and Heyer, L. J. (2006) Discovering Genomics, Proteomic and Bioinformatics, 2nd Edition,
2. Cold Spring Laboratory Press.Wilson and Walker's (2018), Principles and Techniques of Biochemistry and Molecular Biology, 8th Ed. Hofmann and Clokie
3. Biomedical Perspectives and application edited by Debmalya Bath Kenner H
4. Fundamentals of Advanced Omics Technologies: From Genes to Metabolites 1st Edition - November 15, 2008, Editors: Carolina Simó, Alejandro Cifuentes, Virginia García-Cañas,

5. Transcriptomics: Expression pattern analysis. by Gomase, Virendra.
6. Metabolomics, by Ute Roessner, ISBN 978-953-51-0046-1, Hard cover, 364 pages, Publisher: InTech, Published
7. An introduction to bioinformatics algorithms by Neil C. Jones, Pavel Pevzner. MIT Press. 2004

Evaluation

- Assignments: Two assignments
- Seminars: Two per group.
- Total 100 marks. Written exam - 60 marks, Assignment and Seminar - 40 marks.

Faculty:

Module	Faculty 1	Faculty 2
Module 1	Dr. Anoopkumar T	Dr. Anugya Bhatt
Module 2	Dr. Anoopkumar T	Dr. Anugya Bhatt
Module 3	Dr. Anugya Bhatt	Dr. Anil Kumar PR
Module 4	Dr. Anil Kumar PR	Dr. Anugya Bhatt
Module 5	Dr. Anoopkumar T	Dr. Anil Kumar PR

16.3.6 Tissue Engineering & Regenerative Medicine

<table>
<tr><td>Course Title</td><td>Tissue Engineering & Regenerative Medicine</td><td>Course Code</td><td colspan="4">APB 613</td></tr>
<tr><td>Department</td><td>Applied Biology</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td>Faculty</td><td>Dr Lynda V Thomas, Dr. Anilkumar PR, Dr. Anugya Bhatt, Dr. Renjith P Nair, Dr. Naresh Kasoju.</td><td colspan="5">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">The objective of this course is to familiarize the non-biology backgrounds students with an introduction to Tissue Engineering, starting with the basic concepts, and discussing on the various approaches, cells, Biomaterial scaffolds, and factors constituting the microenvironment. The various fabrication techniques and the characterization of biomaterial scaffolds and constructs will also be taught with several case studies to enable them to be applied in medical device development.</td></tr>
</table>

Course Outcome:

At the end of this course, the students will be able to remember the important terms used in tissue engineering and understand the concepts required for planning and executing a tissue engineering program. They will also learn the basics of 3D cell culture and Biofabrication. Characterization of the Biomaterial scaffolds and the construct evaluation are topics that will help the students evaluate the developed construct in vitro.

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 613– CO1	Gain a preliminary understanding of the concept of tissue engineering, cells, scaffolds and microenvironment.	K1, K2 & K3
APB 613 – CO2	Understand the cell material interactions involved in the development of an ideal 3D matrix.	K1, K2, K3
APB 613 – CO3	Understand the 3D fabrication technologies	K1, K2, K3
APB 613 - CO4	Understand the different characterization techniques for evaluating the 3D scaffolds and the final evaluation of the constructs.	K1, K2, K3, K4

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Introduction to Regenerative Medicine Introduction, Definitions: Regenerative biology and Regenerative medicine, Types of regeneration, Strategies in regenerative medicine, Cell Therapy, Bioartificial tissues - Ethical concerns on regenerative medicine research Introduction to Tissue Engineering -Concepts • Introduction to tissue engineering, TE approaches, Biological hierarchy, cells-tissues-organs, Cell division, Cell cycle, Apoptosis, Stem Cells, Cell signaling - soluble and extracellular matrix signals, growth factor receptors, Growth factors and chemokines mediated cell signaling. • Tissue organization, Tissue types, Functional subunits. Tissue Dynamics and Homeostasis, Tissue Repair, Wound Healing, Regeneration, Angiogenesis. • Introduction to biomaterials to be used as scaffolds for tissue engineering: Requirements of an ideal scaffold material, Natural and synthetic polymers as scaffolds, Hydrogels as biomaterial,	10		

	physiochemical characterization of hydrogels, Decellularization of tissues and Organs. • Cell-free and Scaffold-free tissue engineering approaches • Case Studies-Discussions			
Module 2	Cell-Matrix Interaction • Introduction to matrix biology and extracellular composition, • Insights into extracellular matrix remodeling and tissue homeostasis • Basics on various materials in medicine and their characteristics • Effect of morpho-topological properties of materials on cell response • Effect of physicochemical properties of materials on cell response • Effect of mechano-properties of materials on cell response • Effect of bio-functional properties of materials on cell response	8		
Module 3	Biofabrication and 3D construct development • Fabrication technology of scaffolds: Traditional techniques, Nanotechnology, and Solid free-form fabrication techniques • 3D cell culture: Types of 3D culture, Cell aggregates and spheroids, • Bioassembly-based approaches, Additive manufacturing, CAD designing, 3D Models, G-Codes, Three dimensional (3D) Bioprinting - types of 3D Bioprinting, Classification of inks in 3D bioprinting.Bioinks, • Bioreactors: Definition, Types, Parts, Functioning • Case studies - Discussions	7	5	
Module 4	Characterization of biomaterial scaffolds for tissue engineering • Scaffold and construct evaluation- Physicochemical characterization: FTIR, NMR, XRD, DSC, TGA, Viscometry, HPLC/GPC: Principle, Analytical modes, Application areas, Case studies and application problems. • Mechanical Characterization UTM, DMA,Rheological Analysis: Principle, Analytical modes, Application areas, Case studies and application problems. • Surface Characterization: AFM, SEM, TEM, Liquid Extrusion Porosimetry, Mercury Intrusion Porosimetry, Contact angle, ESCA-SIMS: Principle, Analytical modes, Application areas. • Structural stability and Degradation: Types of degradation and their mechanism of action, Introduction to stability studies. • Biological characterization of cell biomaterial interaction: Introduction, imaging techniques, specialized cell-biomaterial interaction studies.	5	10	

	• Sterilization and Packaging characterization of TE products: Types of sterilization, packaging studies and standard testing of packaging materials. • Case Studies and application problems			

Text Books:

1. David L. Stocum, Regenerative Biology and Medicine, Elsevier Inc 2006, USA
2. Anthony Atala, Robert Lanza, James A. Thomson, Robert M. Nerem, Principles of Regenerative Medicine, 2008 Burlington, MA 01803, USA.
3. M. Kusano, S. Shioda (Eds.), New Frontiers in Regenerative Medicine, Springer 2007, Japan
4. Anthony Atala. Et al., Principles of regenerative medicine, Academic Press 2007
5. Tomlins, Paul, ed. Characterisation and design of tissue scaffolds. Elsevier, 2015
6. Atala, Anthony, and Robert Paul Lanza, eds. Methods of tissue engineering. Gulf professional publishing, 2001.
7. Reis, Rui L. Encyclopedia of tissue engineering and regenerative medicine. Academic Press, 2019.
8. Andrew D. Leavitt (auth.), Harold S. Bernstein (eds.), Tissue Engineering in Regenerative Medicine (2011) Humana Press, Springer New York Dordrecht Heidelberg London
9. Fundamentals of Tissue Engineering and Regenerative Medicine, Ulrich Meyer · Thomas Meyer, Jörg Handschel · Hans Peter Wiesmann (Eds.), 2009 Springer-Verlag Berlin Heidelberg
10. Regenerative Medicine, cellular therapies and tissue engineering 2nd Ed, Paramjit Dhot. IP publisher.

Evaluation

- Assignments: Two assignments
- Seminars – Two per group.
- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3	Faculty 4
Module 1	Dr. Lynda V Thomas	Dr. Anilkumar PR	Dr Anugya Bhatt	Dr Francis B
Module 2	Dr Naresh Kasoju	Dr Anugya Bhatt	Dr. Renjith P Nair	
Module 3	Dr. Anilkumar PR	Dr Anugya Bhatt	Dr. Renjith P Nair	
Module 4	Dr. Lynda V Thomas	Dr Naresh Kasoju	Dr. Renjith P Nair	

16.3.7 Tissue-based Medical Devices

Course Title	Tissue based Medical Devices	Course Code	APB 614			
Department	Applied Biology	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	1	0	3
		Description: L: Lecture, T: Tutorial, P: Lab, C: credits				
Faculty						
Course Objectives:	The objective of this course is to familiarize the students to the production of 'Tissue based medical devices and Tissue derived medical products, its qualification and safety evaluation					

Course Outcome:

At the end of this course, the students will be able to understand the production, qualification and safety evaluation of medical devices made from processed tissues and tissue derived medical products such as blood derived products. The students will be able to understand and analyse the safety and sterility evaluation reports of tissue based and tissue derived medical products.

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 614 – CO1	Gain a preliminary understanding of the different types of tissue based medical devices, their production and quality assurance.	K1, K2 & K3
APB 614 – CO2	Understand different aspects of Tissue derived medical products such as blood and blood products, their safety assurance and the regulations applicable.	K1, K2, K3
APB 614 – CO3	Gives an overview of tissue response especially immune response to Tissue based/ tissue derived medical devices and products.	K1, K2, K3
APB 614 - CO4	Gives an oversight about sterilization methods adopted for tissue based/ tissue derived products and concepts on sterility assurance.	K1, K2, K3

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P

Module 1	Introduction to Tissue based medical devices, Decellularised tissue based medical devices, chemically cross-linked tissue based medical devices: This module describes about the various forms of tissue derived medical products, their production and quality assurance.	6	3	
Module 2	Blood derived Products: Components of Blood, Collection of blood and its components, Preservation of blood components, Different types of Blood Derived Products: RBC concentrate, Fresh Frozen Plasma (FFP), Cryoprecipitate, Platelet Concentrate, Platelet rich plasma (PRP). Albumin Intravenous immunoglobulin (IVIG), Fibrinogen, Fibrin glue/ sealant, Factor VIII (FVIII), Factor IX (FIX), FXIII, Von Willebrand factor (VWF), etc. Viral Inactivation of Blood Derived Products, Regulation of Blood and Blood products	6	6	
Module 3	Host response to tissue based medical devices and products: Immunogenicity is a major concern of tissue based medical devices/ tissue derived medical products. This module deals with the immunogenicity evaluation of such products.	12	3	
Module 4	Sterilization of tissue based medical devices: Implant associated infection is another area of concern for tissue based/ tissue derived medical devices or products. This module addresses the methods adopted for sterilization as well as its assurance.	6	3	

Text Books:

1. P.R. Umashankar and Priyanka kumara (2020), Tissue Based Products: in C.P. Sharma (Eds) Biointegration of Medical Implant Materials, Second Edition- Biointegration of Medical Implant Materials, (Second Edition)Woodhead Publishing Series in Biomaterials, Pages 145-185.: ISBN: 978-0-08-102680-9
2. Buddy D Ratner, Allan Hoffman, Frederick J Shoen and Jack E Lemons (1996) ,An Introduction to Materials in Medicine, Academic Press, 1996. ISBN: 0-12-582460-2.
3. Production of Plasma Proteins for Therapeutic Use; Editor(s): Joseph Bertolini, Neil Goss, John Curling. Publisher: John Wiley & Sons
4. WHO guidelines on good manufacturing practices for blood establishments, Annex 4, TRS No 961
5. Modern Blood Banking & Transfusion Practices; Editor: Denise M Harmening. Publisher, F.A. Davis
6. AABB Technical Manual, 2023,
7. DGHS, Transfusion Medicine Technical Manual. 2022.

Evaluation

- Assignments: Two assignments
- Seminars – Two per group.
- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks

Faculty:

Module	Faculty 1	Faculty 2
Module 1	Dr. P.R. Umashankar	Dr. Renjith P Nair
Module 2	Dr. Renjith P. Nair	Dr. P.R. Umashankar
Module 3	Dr. P.R. Umashankar	Dr. Renjith P Nair
Module 4	Dr. Maya Nandakumar	Dr. Renjith P Nair

16.3.8 Fundamentals of Pharmacology

<table>
<tr><td>Course Title</td><td>Fundamentals of Pharmacology</td><td>Course Code</td><td colspan="4">APB 513</td></tr>
<tr><td>Department</td><td>Applied Biology</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td rowspan="2">Offered for</td><td rowspan="2">MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td colspan="5" rowspan="2">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Faculty</td><td>Dr Sachin J Shenoy, Dr Renjith S & Guest Faculty from the Pharmacology Department.</td></tr>
<tr><td>Course Objectives:</td><td colspan="5">This course is an introduction to fundamental pharmacology principles pertaining to medical device development and preclinical evaluation of drug-device combination products.</td></tr>
</table>

Course Outcome:

At the end of this course, the students have a knowledge of, fundamental principles in pharmacology, drugs, drug delivery, pharmacokinetics, pharmacodynamics and various drug-device combination products. The students will also gain an overview of techniques for the safety and efficacy evaluation of drug-device combination products.

CO	Course Outcome	Bloom Knowledge Level (KL)
APB 513 – CO1	Gain a preliminary understanding of pharmacological terms, drugs, classification, drug delivery, Pharmacokinetics, Pharmacodynamics, Drug metabolism and elimination.	K1, K2 & K3
APB 513 – CO2	Understand various drug-eluting devices and controlled drug delivery.	K1, K2, K3

APB 513 – CO3	Will be able to understand various invitro and in vivo techniques for evaluation of various drug-device combination products	K1, K2, K3, K4

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Introduction to fundamental pharmacology Drugs, the structure of drugs, classification of drugs, mechanism of action, pharmacokinetics, pharmacodynamics, drug metabolism, and elimination of drugs.	10	6	0
Module 2	Introduction to various drug-eluting devices and controlled drug delivery. Introduction to various drug-eluting devices and controlled drug delivery.	6	3	0
Module 3	Drug estimation/ evaluation techniques In vitro and In Vivo Techniques to evaluate the drug-device combination products. Chromatographic methods: HPLC, LC-MS, GC Validation requirements: Selectivity, sensitivity, precision, accuracy, linearity, LLoD, LLoQ Extraction methods: Liquid-liquid and solid-phase extraction Case studies of selected examples.	14	6	0

Text Books:

1. Tripathi KD. Essentials of medical pharmacology. JP Medical Ltd; 2013 Sep 30.
2. Riviere JE, Papich MG, editors. Veterinary pharmacology and therapeutics. John Wiley & Sons; 2018 Feb 28.
3. Hernandez MA, Rathinavelu A. Basic pharmacology: understanding drug actions and reactions. Routledge; 2017 Jul 12.
4. Pedersen-Bjergaard S, Gammelgaard B, Halvorsen TG. Introduction to pharmaceutical analytical chemistry. John Wiley & Sons; 2019 Apr 29.
5. Loralie J. Langman, Christine L. H. Snozek. LC-MS in Drug Analysis, Methods and Protocols. Springer link, 2012.

6. Wenkui Li, Jie Zhang, Francis L.S. Tse. Handbook of LC-MS Bioanalysis: Best Practices, Experimental Protocols, and Regulations. John Wiley & Sons, 2013.

Evaluation:

- Assignments: Two assignments
- Seminars – Two per group.
- Final Examination (3 Hours): 60 marks; Assignments and Seminars 40 marks.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr Sachin J Shenoy	Guest Faculty	Dr Renjith S
Module 2	Dr Sachin J Shenoy	Guest Faculty	Dr Renjith S
Module 3	Dr Renjith S	Dr Sachin J Shenoy	-

16.3.9 Laboratory Module & Internship 2

APB 551 Laboratory Module	Practical session on various laboratory techniques used in various departments/divisions	2 credits
APB 552 Internship 2	Industry/Device Evaluation/ Development - Mini project	2 credits

16.4 Semester 2: Specialization – Biomaterials

16.4.1 Polymeric Biomaterials

Course Title	Polymeric Biomaterials	Course Code	BST 611			
Department	Department of Biomaterial Science and Engineering	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	1	0	3
		Description:				
Faculty	Dr. Lizymol PP, Dr. Shiny Velayudhan and Dr. Manju S.	L: Lecture, T: Tutorial, P: Lab, C: credits				

Course Objectives:	The proposed course is intended to provide an in-depth understanding of polymers used in biomedical devices and implants. The various topics discussed are - Basics of polymers, different types of polymers, the types and techniques of polymerization and the properties and characterization of polymers and Applications of Polymers in Medicines.

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BST 611 – CO1	Gain understanding of general polymer characteristics, structure, classification	K1&K2
BST 611 – CO2	Gain understanding of various techniques for synthesis and fabrication of polymers	K2 & K3
BST 611 – CO3	The ability to relate/choose characterization data relevant to the process-structure-property-performance behaviour of a polymeric biomaterial. To gain knowledge of the various wet chemistry and spectroscopic techniques that are utilized to define the chemical composition of synthetic and biological biomaterials	K1, K2 & K3, K4
BST 611 – CO4	Gain understanding to choose suitable polymeric materials, or any combination thereof, for defined medical applications	K2 & K3

Syllabus:

Module	Topics (In detail)	No. of hours		
		L	T	P
Module 1	Polymers for Medical Applications: Introduction to Polymeric Biomaterials – Definition, Classification, General Characteristics, Properties and applications of Polymeric Biomaterials Natural polymers: Polysaccharides (cellulose, hyaluronic acid, chitosan, alginate, silk fibroin); Polypeptides (Collagen, Gelatin) Synthetic polymers(non-degradable): Polyethylene, Polypropylene, Polyamides, Polyacrylates, Fluorocarbon polymers, Silicon Rubber	8	4	

	Synthetic polymers(degradable): Polyesters (PLA, PGA, PCL, PHB), Mechanisms of Polymer Degradation, Degradation and structure-function relationship Hydrogels and Superabsorbent polymers, shape memory polymers (SMP) Concept of Sterilization: Various sterilization techniques employed for polymeric biomaterials			
Module 2	Synthesis and Fabrication of Polymers as Biomaterials: Introduction-homopolymerization and copolymerization, Types of Polymerization, Addition polymerization, Step-growth polymerization, Co-ordination polymerisation (stereoregular polymerization and metallocene polymerization), Ring opening polymerization, Techniques of polymerization- Bulk polymerisation, Emulsion polymerisation, Solution polymerisation and Suspension polymerisation; Controlled polymerisation techniques- Atom transfer radical polymerization (ATRP) and Reversible addition−fragmentation chain transfer polymerisation (RAFT) Surface modification of Polymers for Biomedical applications: non-biological modifications, biological modifications	6	3	
Module 3	Polymeric Biomaterials Characterization: Concept of molecular weight, Molecular weight distribution; Molecular weight determination (GPC, light scattering, viscosity, osmometry) Thermal Analysis: Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA); Thermomechanical Analysis (TMA), Dynamic Mechanical Thermal Analysis (DMTA) Elemental and Structural Characterization: Fourier Transform Infra-red (FTIR) spectroscopy, Ultraviolet- Visible spectroscopy, Raman Spectroscopy, Mass Spectrometry, Nuclear Magnetic Spectroscopy (NMR), X-ray photoelectron spectroscopy (XPS) Mechanical Characterization: Concept of Viscoelasticity, Stress-strain curves, Characterization techniques for Tensile, Compression, Flexural, Impact, Fatigue properties.	8	4	
Module 4	Applications of Polymers in Medicine: Polymeric biomaterials for orthopaedic, dental, and ophthalmological devices. Polymeric biomaterials for soft tissue applications	8	4	

	Polymeric biomaterials for cardiovascular and neurological applications Polymeric biomaterials in tissue engineering and regenerative medicine Composite polymeric materials and their use in medicine - (nano)fibers and (nano)particles filled polymers, a combination of natural and synthetic polymers, ceramics and metallic biomaterials			

Text Books:

1. Polymeric Biomaterials Structure and Function, Volume 1 Edited By Severian Dumitriu, Valentin Popa, ISBN 9780367617974, 920 Pages 404 B/W Illustrations, Published June 30, 2020 by CRC Press
2. Surface Modification of Polymeric Biomaterials, Editors: Buddy D. Ratner, David G. Castner, ISBN: 9781489919533, 1489919538, Page count: 206, Published: 29 June 2013, Publisher: Springer US
3. Biomaterials Surface Science, Editors: Andreas Taubert, Joao F. Mano, Jos¿ Carlos Rodr¿guez-Cabello, ISBN: 9783527649624, 352764962X, Page count: 616, Published: 23 July 2013, Publisher: Wiley.
4. Fundamentals of Biomaterials. AuthorsVasifHasirci, Nesrin Hasirci, ISBN978-1-4939-8854-9, Published: 27 November 2018, Springer New York, NY, DOIhttps://doi.org/10.1007/978-1-4939-8856-3
5. Rieger B, Künkel, Coates GW, Reichardt R, Dinjus E, Zevaco TA, volume editors. Synthetic biodegradable polymers. In: Advances in Polymer Science. Springer-Verlag Berlin Heidelberg. 2012; vol. 245, pp. 364. ISSN: 0065-3195
6. Guelcher SA, Hollinger JO, editors. An Introduction to Biomaterials. In: The biomedical engineering series, Neuman MR, series editor. Taylor & Francis Group, LLC. Boca Raton, Florida, USA. 2006, pp. 553. ISBN: 0-8493-2282-0.
7. Ratner BD, Hoffman AS, Schoen FJ, Lemons JE, editors. Biomaterials Science. An Introduction to Materials in Medicine. 2nd ed., Elsevier Academic press, California USA, London UK. 2004, pp. 851. ISBN: 0-12-582463-7.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Lizymol PP	Dr. Manju S	Dr. Shiny Velayudhan
Module 2	Dr. Manju S.	Dr. Shiny Velayudhan	Dr. Lizymol PP
Module 3	Dr. Shiny Velayudhan	Dr. Manju S.	Dr. Lizymol PP
Module 4	Dr. Shiny Velayudhan	Dr. Manju S.	Dr. Lizymol PP

16.4.2 Biomaterials Processing Techniques

Course Title	Biomaterials Processing Techniques	Course Code	BST 612			
Department	Department of Biomaterial Science & Technology	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	.5	1	
		Description:				
Faculty	Dr. H K Varma, Dr. Manoj Komath, Dr. Shiny Velayudhan, Dr. Manju S., Dr. Francis	L: Lecture, T: Tutorial, P: Lab, C: credits				
Course Objectives:	The objective of this course is to familiarize scholars with material processing in the biomaterial milieu. Course informs students of concepts & tools in bulk processing, surface processing and manufacturing techniques. Various aspects of material processing, impact on downstream applications and their application in device performance will be addressed. Additive manufacturing, 3D printing are dealt with in detail.					

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BST 612 – C01	Gain knowledge of biomaterial processing and preliminary processes.	K2 & K3
BST 612 – CO2	Understand effects & selection of processing techniques in biomaterial fabrication	K2 & K3
BST 612 – CO3	Gain in depth understanding of 3D processes for material processing and printing.	K1, K2 & K3
BST 612 – CO4	Fabrication of a 3D construct – plan, print, process	K5, K6

Syllabus:

Module	Topics (In detail)	Hours		
		L	T	P

Module 1	Processing of Plastics, Metals and Ceramics. Injection molding: Compression moulding, melt extrusion, solvent casting and melt spinning, Electrospinning. Creating porous structures foaming process, particle leaching technique. Polymeric microparticles crystallinity of the material. Influence of processing on the mechanical strength and degradation of materials. Molecular structure vis a vis material property; modifications via forming and processing.	6	4	
Module 2	(i) Metallurgical surface processing (Surface Hardening, Laser melting, Shot peening), Chemical surface processing (carburizing, nitriding, anodizing, chromizing, ion implantation), Coatings (electroplating, electroless plating, thermal spraying, chemical vapour deposition, physical vapour deposition). (ii) Casting (liquid metals and semisolids polymers), Powder Processing (metals and ceramics in powder form), Bulk Deformation Processing (metals in bulk or sheet form).	6	4	6
Module 3	Development of Additive Manufacturing (AM) Technology, Rapid Prototyping Stereolithography (SLA)- Digital Light Processing (DLP), Fused Deposition Modeling (FDM). Selective Laser Sintering (SLS), Selective Laser Melting (SLM), Electron Beam Melting (EBM). Ink-Based Direct Writing (DW), Nozzle Dispensing Processes, Inkjet Printing Processes. The status and scope of 3D printing in Healthcare. Advances in Bio-Printing. Selection of processes based on need, optimization strategies and application.	6	4	6

Text Books:

1. Ian Gibson, David Rosen, Brent Stucker, Mahyar Khorasani “Additive manufacturing technologies”. 3rd edition Springer Cham, Switzerland. (2021).
2. Andreas Gebhardt and Jan-Steffen Hötter “Additive Manufacturing: 3D Printing for Prototyping and Manufacturing”, Hanser publications, United States, (2015).
3. Milan Brandt, “Laser Additive Manufacturing: Materials, Design, Technologies, and Applications”, Woodhead Publishing., United Kingdom, 2016, ISBN:

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Manoj / Dr. H K Varma	Dr. Shiny Velayudhan/ Dr. Manju	Dr. Francis
Module 2	Dr. Shiny Velayudhan / Dr. Manju	Dr. Manoj Komath/ Dr. H K Varma	Dr. Manju/ Dr. Manoj Komath

Module 3	Dr. Shiny Velayudhan	Dr. Manju/ Dr. Francis	Dr. Francis / Dr. Manoj Komath

16.4.3 Nano Biomaterials

Course Title	Nano Biomaterials	Course Code	BST 511			
Department	Biomaterials Science and Technology	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	1	0	3
		Description: L: Lecture, T: Tutorial, P: Lab, C: credits				
Faculty	Adjunct Faculty/Professors of Practice/BMT Wing faculty					
Course Objectives:	Nanomaterials and nano-technology have made an immense impact in medicine, both in diagnostics and therapy. The objective of this course is to introduce the concepts of nanomedicines and theranostics. This course gives an overview of the essential features and biomedical applications of nano-biomaterials.					
The students will learn:	• The concepts of nanomaterials • Synthesis and characterisation of nanomaterials • Application of nanotechnology on detection, sensing and imaging • Nanomedicine and future directions					

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BST 511 – CO1	Understand the basics of developing nanomaterials for clinical applications and its characterization	K2, K3
BST 511 – CO2	Understand the concepts of theranostics, sensing and imaging	K2
BST 511 – CO3	Know about therapeutic applications of nanomaterials.	K2

Syllabus:

Module	Topics (In detail)	No. of hours
Module 1	**Nano-biomaterials: Introduction** Introduction to nanomaterials; Size dependant properties of nanomaterials; Types of nanomaterials; Nanoparticle synthesis – top-down and bottom up approaches - physical and chemical methods for the synthesis of nanomaterials-	10

	inorganic, polymeric, ceramic nanoparticles, semiconductor nanomaterials, carbon nanomaterials, metallic nanomaterials etc., Nanomaterial characterization.	
Module 2	**Nanobiomaterials in Imaging and Sensing** Introduction to biomedical imaging and sensor technology, role of different nanomaterials in imaging and sensing applications, nanomaterials as contrast agents: Optical imaging, MR imaging, CT imaging, PET and SPECT imaging, Nanosensors and sensor devices: lateral flow assay devices using nanotechnology, nanocolloids as biosensors.	10
Module 3	**Nanobiomaterials: therapeutic applications and biocompatibility** Nanomedicine, nanomaterials for cancer therapy, nanotheranostics, nanomaterials for neurodegenerative diseases, nanomaterials for cardiovascular diseases, nanomaterials in dental and orthopaedic applications, nanomaterials in tissue engineering, biocompatibility and toxicity of nanoparticles.	10

Text Books:

1. Nanomaterials for medical diagnosis and therapy, By Challa S. S. R. Kumar, Wiley-VCH, 2007
2. Cabor Harsanyi, Sensors in biomedical applications. Fundamentals, Technology and Applications, CRC Press, New York, 2000.
3. Nanomaterials: introduction to synthesis, properties and applications, Vollath, Dieter, (BMT Wing library, Call No. 620.5 VOL)
4. Fluorescence sensors and Biosensors, R. B. Thompson (Ed), CRC Press, New York, 2006.

Evaluation:

- Assignments : Two assignments
- Seminars : Two Seminars.
- Total 100 marks; Written exam - 60 marks, Assignment and Seminar - 40 marks.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. R.S. Jayasree, Adjunct Faculty	Dr. Manju S., Adjunct Faculty	Dr. Rekha M.R. Adjunct Faculty
Module 2	Dr. R.S. Jayasree, Adjunct Faculty	Dr. Manju S, Adjunct Faculty	Adjunct Faculty
Module 3	Dr. R.S. Jayasree, Adjunct Faculty	Dr. Rekha M.R.	Dr. Manju S., Adjunct Faculty

16.4.4 Drug Delivery Systems

Course Title	Drug Delivery Systems	Course Code	BST 613			
Department	Biomaterial Science and Technology	Credits	L	T	P	C
Offered for	MTech Biomedical Engineering		2	1	0	3
		Description: L: Lecture, T: Tutorial, P: Lab, C: credits				
Faculty	Dr. Rekha M.R., Dr. Manju S., Dr. Renjith S.					
Course Objectives:	The objective of this course is to introduce the concepts of drug delivery and advanced drug delivery systems. The students will be made aware of the limitations of the conventional drug delivery and how the biomaterial based advanced drug delivery systems can enhance the therapeutic benefits. This course is planned to give a detailed description of the need and the state of-the-art in advanced drug delivery.					
The students will learn:						
• The concepts of drug delivery • The limitations of conventional drug delivery • About different drug delivery systems • About the biological barriers and how to design delivery systems based on the clinical needs • Characterisation techniques						

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BST 613 – CO1	Understand the basics of developing drug delivery systems	K2
BST 613 – CO2	Understand the various characterization methods adopted for evaluating the DDS.	K2, K3
BST 613 – CO3	Know about the various design considerations for developing drug delivery systems as per clinical need.	K2

Syllabus:

Module	Topics (In detail)	No. of hours
Module 1	Drug Delivery Systems: Synthesis	10

	Introduction to drug delivery, Controlled drug delivery, Drug delivery systems (DDS) - Polymeric, dendrimers, liposomes metallic and inorganic types, methods for preparing above drug delivery systems, biological barriers and design considerations of DDS, localized drug delivery.	
Module 2	Drug Delivery Systems: Characterisation Spectroscopy (UV-Vis, FTIR, NMR, Raman), Chromatography – GPC HPLC and LCMS, Differential Scanning Calorimetry, Particle size and surface charge – dynamic light scattering, Imaging techniques – SEM, TEM, AFM, Confocal Raman microscopy, Confocal laser scanning microscopy, Swelling characteristics, Degradation profile, Drug loading and Release kinetics.	6
Module 3	Advanced drug delivery systems Stimuli Responsive Drug Delivery Systems (Stimuli- pH, thermal, magnetic, photosensitive, redox, biomolecule), targeted delivery systems, oral peptide delivery and gene delivery systems, Combinatorial delivery system, Theranostics.	14

Text Books:

1. Encyclopedia of controlled drug delivery. Vol. 1& 2. Mathiowitz, Edith, Wiley-Blac, 1999.
2. Nanomaterials for medical diagnosis and therapy, By Challa S. S. R. Kumar, Wiley-VCH, 2007 Cabor Harsanyi, Sensors in biomedical applications. Fundamentals, Technology and Applications, CRC Press, New York, 2000.
3. Smart Materials for Drug Delivery, Volume 1 and 2, Carmen Alvarez-Lorenzo and Angel Concheiro, RSC Publishing, 2015.
4. Advanced and Modern Approaches for Drug Delivery, Amit Kumar Nayak, Md Saquib Hasnain, Bibek Laha, Sabyasachi Maiti, 2023, Elsevier
5. Advanced Drug Delivery, Ashim Mitra, Chi H. Lee, Kun Cheng, 2013, Wiley
6. Polymer therapeutics I & II- R. Satchi-Fainaro and R. Duncan, Springer, 2005.
7. Polymeric Gene delivery: Principles and Applications- Mansoor M. Amiji, CRC Press, 2004.

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Rekha M.R.	Dr. Manju S.	
Module 2	Dr. Rekha M.R.	Dr. Manju S.	Dr. Renjith S
Module 3	Dr. Rekha M.R.	Dr. Manju S.	

16.4.5 Orthopaedic and Dental Materials

<table>
<tr><td>Course Title</td><td>Orthopaedic and Dental Materials</td><td>Course Code</td><td colspan="4">BST 614</td></tr>
<tr><td>Department</td><td>Department of Biomaterial Science and Engineering</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td>Offered for</td><td>MTech Biomedical Engineering</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td>Faculty</td><td>Dr. Lizymol PP, Dr. Manju S, Dr. HK Varma, Dr. Manoj Komath, Dr. Francis B. Fernandez, Dr. Shiny Velayudhan</td><td colspan="5">Description:
L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Course Objectives:</td><td colspan="6">(i) To provide an insight into the various aspects of the development and application of biomaterials in the clinical areas of Orthopaedics and Dentistry.
(ii) To learn the details of the clinically accepted materials.
(iii) To develop insight to Bone tissue engineering and its clinical potential.
(iv) To develop insight into materials used for repair and regeneration in Dentistry and their clinical application.</td></tr>
</table>

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)
BST 614 – CO1	An understanding of the clinical use of biomaterials in the areas of Orthopaedics and Dentistry	K1, K2
BST 614 – CO2	Getting familiar with the development of clinically acceptable materials useful for Orthopaedics and Dentistry.	K1, K2
BST 614 – CO3	Develop an understanding of bone tissue engineering in the clinical areas of Orthopaedics	K1, K2, K3
BST 614 – CO4	Develop an understanding of the repair and regeneration of dental tissues and the role of materials in it.	K1, K2, K3

Syllabus:

Module	Topics (In detail)	No. of hours		
		L	T	P
Module 1	**Bone tissue engineering:** - Structure and development of bone, Biomechanics of bone and joints and Metabolic bone diseases - Drug delivery and signal delivery in bone - Development of bone graft substitutes - Osteoconductivity and in vivo resorption of synthetic grafts	8	4	
Module 2	**Biomaterials in orthopedic applications:** Metallic biomaterials (Stainless steel, Co-Cr Alloys, Ti-Alloys, Nitinol), Corrosion of Metallic implants, Manufacturing and processing of Metallic implants. Introduction to Bioceramics, Bio-inert ceramics (Alumina, Zirconia, Carbon), Bioresorbable ceramics (Calcium Phosphate), Bio-active ceramics (Bioglass, Glass ceramics), Applications of bioceramics. Total Hip Replacement, Total Knee Replacement.	8	4	
Module 3	**Biomaterials in dental applications:** Dental diseases and restoration of damaged teeth. Introduction to dental materials, classification of dental materials Preventive dental materials- Caries removal agents, pit and fissure sealants) Restorative dental materials- composites, compomers, silicate, siloranes, dental amalgam, glass ionomer cements, resin modified glass ionomer cements, ormocers, Auxiliary dental materials. Dental implants and maxillofacial graft materials. Properties of dental materials.	6	3	2

	Polymers in dentistry, curing characteristics (chemical cure, heat cure, light cure and dual/multi cure systems), Linear/ volumetric shrinkage and shrinkage stress.			
Module 4	**Advanced Dental materials:** Oral factors affecting dental materials, Tissue engineering and regenerative dentistry, Drug delivery systems for Dental applications. Significance of nanotechnology in dentistry, Antibacterial/antibiofilm coatings on dental implants.	6	3	

Text Books:

1. Bone tissue engineering, Hollinger, Jeffrey O, et al. London: CRC Press, 2000.
2. Biomaterials Science and Tissue Engineering: Principles and Methods; Basu, Bikramjit; Cambridge IISc Series 2002.
3. Principles of Bone Biology; Editors: John P. Bilezikian, T. John Martin, Thomas L. Clemens, Clifford Rosen
   4th Edition; Academic Press, 2019.
4. Dental Materials and their selection (III Edition) Ed., William J.O'Brien, Quitessence Publishing Co., Canada 2002.
5. Science of Dental Materials, Philips, XI edn by Anusavice K.J., Saunders Publishing Co., USA, 2004.
6. Dental Materials, Foundations and Applications, Editor: John M Powers and John C Wataha; Elsevier 2017
7. Dental Materials, properties and manipulation, Editor: Robert G Craig, John M Powers and John C Wataha; Elsevier 2017
8. Polymeric Dental Materials, Editor: Michael Braden, Richard L. Clarke, Sandra Parker and John Nicholson; Springer 1997
9. Nanotechnology in Dentistry, Editor: Ashuthosh Kumar Shukla; IOP publishing 2021
10. Oral Biofilms and Modern Dental Materials-Advances Toward Bioactivity,Editor: Andrei Cristian Ionescu, Sebastian Hahnel; Springer 2021
11. Advanced Dental materials; Editors: Zohaib Khurshid, Shariq Najeeb, Muhammad Sohail Zafar, Farshid Sefat; Woodhead publishing 2021

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Dr. Francis B. Fernandez	Dr. HK Varma	Dr. Manoj Komath
Module 2	Dr. HK Varma	Dr. Manoj Komath	Dr. Francis B. Fernandez
Module 3	Dr. Lizymol PP	Dr. Manju S.	Dr. Shiny Velayudhan
Module 4	Dr. Lizymol PP	Dr. Manju S.	Dr. Shiny Velayudhan

16.4.6 Laboratory Module & Internship 2

BST 551 Laboratory Module	Practical session on various laboratory techniques used various departments/divisions.	2 credits
BST 552 Internship 2	Industry/Device Evaluation/ Development - Mini project	2 credits

16.5 Semester 3: Credit Course and Thesis Research

16.5.1 Technology, Quality & Regulatory Management of Medical Devices

<table>
<tr><td>Course Title</td><td>Technology, Quality & Regulatory Management of Medical devices</td><td>Course Code</td><td colspan="4">TQM 501</td></tr>
<tr><td>Department</td><td>Technology & Quality Management</td><td rowspan="2">Credits</td><td>L</td><td>T</td><td>P</td><td>C</td></tr>
<tr><td rowspan="2">Offered for</td><td rowspan="2">MTech Medical Devices and Technology</td><td>2</td><td>1</td><td>0</td><td>3</td></tr>
<tr><td rowspan="2" colspan="4">Description:

L: Lecture, T: Tutorial, P: Lab, C: credits</td></tr>
<tr><td>Faculty</td><td>Er S Balram, Er Leena Joseph, Er Vinodkumar V., Er Sandhya C.G., Er Rajkrishna Rajan, Er Amrutha C.</td></tr>
<tr><td>Course Objectives:</td><td colspan="5">The objective of this course is to familiarize with the concept of Intellectual Property Rights, Technology Transfer, regulatory requirements for medical devices including risk management and quality system management which includes calibration of equipment, validation of systems.</td></tr>
</table>

Course Outcome:

CO	Course Outcome	Bloom Knowledge Level (KL)*
TQM 501 - CO1	Understand the concept. Process and relevance of Intellectual Property Rights	K1, K2 & K3
TQM 501 - CO2	Understand the models and process of translation and Technology transfer including valuation and negotiation	K1, K2, K3
TQM 501 - CO3	Understand the importance, standards and process of regulatory practices for medical devices In India in comparison with Europe & US.	K1, K2, K3

TQM 501 – CO4	Understanding ISO 13485 Quality Management System and ISO 14971 basic risk management process for medical devices. Understand and practice the need and concept of metrology and it's significance in medical device development & evaluation.	K1, K2, K3, K4
*K1: Remember, K2: Understand, K3: Apply, K4: Analyze, K5: Evaluate, K6: Create		

Syllabus:

Module	Topics (In detail)	Number of hours		
		L	T	P
Module 1	Introduction to Intellectual property and its types. Patents and its significance in medical device development, Patentable criteria and inventions non-patentable. System and procedure of Patenting in India. Patent Cooperation Treaty and its significance. Patent Drafting –Contents of specifications, Grand of patent and rights conferred there by Divisional Applications & Patent of Addition, Opposition proceedings: - Pre grant & Post Grand oppositions. Restoration, Surrender & Revocation of Patents	7	3	
Module 2	Technology Transfer – concept, policy and models Invention disclosure, technology brief, technology marketing, technology IP valuation, Negotiation, Licensing & Agreements Entrepreneurship – Fundamentals of entrepreneurship, Business environment & communication, Sources of finance, Business plan,	7	3	
Module 3	Overview of Medical Device Regulation Medical devices & IVDs – definition and classification, Regulatory compliance Standards for medical devices, Comparison of India, US, EU regulations, Medical device registrations & submissions Post-market surveillance, IMDR 2017.	7	3	
Module 4	Quality Management Systems (QMS): Evolution of QMS, Principles of Total Quality Management (TQM), Different QMS systems in medical device development- ISO 13485, ISO 17025, Risk Management of Medical Devices- ISO 14971	5	3	
Module 4	Metrology and Calibration: Historical origins of metrology concepts, Metrological hierarchy of measurements and international standards, Types of Measurement systems - Mechanical, Thermal and Electro Technical systems, Traceability requirements for biocompatibility	2	1	6

	evaluations and analytical measurements; validation of systems (IQ, PQ and OQ). Estimations and Analysis for Metrology- Statistical for metrology, Tools for Analysis- uncertainty estimation, internal and external quality control measures, accreditation of metrological system.			

Text Books:

1. How to write a patent application (Hardcover) Author: Jeffrey G. Sheldon, Publisher: Practising Law Institute (1992)
2. Patents procedures and practices: Author Shail Jain & R.K. Jain: Publisher: Universal Law Publishing Company.
3. Dictionary on Indian Patent Law (Paperback), Author: Nanita Kalia Bindu Sharma, Publisher: Asia Law House (2012)
4. Law Relating to Intellectual Property Rights (IPR) by MK Bhandari 2021 [Paperback]: Publisher: Central Law Publications
5. The Art and Science of Technology Transfer, Phyllis L. Speser (2006)
6. Entrepreneurship for everyone, Robert Mellor
7. Entrepreneurial development, SS Khanka
8. Total Quality Management (TQM). Principles, Methods, and Applications, By Sunil Luthra, Dixit Garg, Ashish Agarwal, Sachin K. Mangla,1st Edition,2020
9. Traceable Temperatures: An Introduction to Temperature Measurement and Calibration, Wiley ; 2 nd edition(December 15, 2001)
10. Handbook of Metrology and Applications, Springer Verlag, Singapore; 1st ed. 2023 edition
11. Indian Medical Devices Rule, 2017
12. ISO 14971:2019 Medical devices — Application of risk management to medical devices
13. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purpose

Evaluation:

- Assignments: One assignment per module
- One Seminar per module
- Total 100 marks; Written examination (3 Hours) - 60 marks; Assignments and Seminars - 40 marks

Faculty:

Module	Faculty 1	Faculty 2	Faculty 3
Module 1	Er. Rajkrishna Rajan	Er S. Balram	
Module 2	Er. Sandhya C.G.	Er S. Balram	
Module 3	Er. Amrutha C.	Er S. Balram	
Module 4	Er. Leena Joseph	Er Vinodkumar V.	Er S. Balram

Module 5	Er. Leena Joseph	Er Vinodkumar V.	

16.5.2 Thesis Research

The thesis research spreads over the third and fourth semesters. It is to be evaluated in both semesters. Based on these evaluations the grade is finalised in the fourth semester. The total marks for the thesis research would be 150. An assessment may be conducted towards the end of the 3rd semester on the progress made by the student in his/her research. The student may submit a status report before the evaluation. The assessment may be conducted by an internal committee nominated by the Head BMT Wing/Dean.

Evaluation of the thesis research may be as follows:

- Progress evaluation by the Project Supervisor : 20 Marks
- Assessment by the committee (student report/presentation/viva) : 30 Marks

16.6 Semester 4: Comprehensive Course Viva and Thesis Research

16.6.1 Comprehensive Course Viva

This viva would cover the theory part of the courses learned by the student during the first and second semesters and will be conducted in Semester IV along with the thesis viva. Viva would be conducted by an internal committee nominated by the Head BMT Wing/Dean. The committee would assess the level of understanding of the subjects the student learned in the first two semesters. Marks may be awarded out of 100.

16.6.2 Thesis Research

The thesis research is continuing from the third semester and the grade is finalized in the fourth semester. The assessment committee consists of the project supervisor, MTech program coordinator, an internal expert, an external expert, and a nominee of the director/dean. The total marks for the thesis research would be 150. Evaluation of the thesis research in the semester IV may be as follows:

Total marks for the Project (50 from the 3rd semester) : 150

Marks awarded in the 4th Semester : 100

Thesis evaluation by the supervisor/s : 30 Marks

Presentation & evaluation by the Committee : 40 Marks

Evaluation by the External expert : 30 Marks