ACADEMIC CURRICULA

Minor Program in Medical Device Technology

(Choice Based Flexible Credit System)

SRM INSTITUTE OF SCIENCE AND TECHNOLOGY

(Deemed to be University u/s 3 of UGC Act, 1956)

Kattankulathur, Kancheepuram District 603203, Tamil Nadu, India

MINOR IN MEDICAL DEVICE TECHNOLOGY

Category	Course Code	Course title	Hours/week				Pre-requisite	Credits to be earned
			L	T	P	C		
Professional Core	21MBM111F	Biosensors: Fabrication and Application	3	0	0	3	NIL	11
	21MBM112F	Bioinstrumentation	3	1	0	4	NIL	
	21MBM113F	Design and development of Medical Devices	3	1	0	4	NIL	
Professional Electives (Any 3 electives)	21MBM211E	Therapeutics and Diagnostics	3	0	0	3	NIL	9
	21MBM212E	Medical Imaging Technology	3	0	0	3	NIL	
	21MBM213E	Human Movement Mechanics	3	0	0	3	NIL	
	21MBM214E	Principles and Practice of Assistive Technology	3	0	0	3	NIL	
	21MBM215E	Artificial Intelligence in Medical Devices	3	0	0	3	NIL	
	21MBM216E	Regulatory, Design and Quality Requirements	3	0	0	3	NIL	
							Total Credits	**20**

Course Code	21MBM111F	Course Name	BIOSENSORS: FABRICATION AND APPLICATION	Course Category	C	FOUNDATION COURSE	L	T	P	C
							3	0	0	3

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	**Data Book / Codes / Standards**		*Nil*	

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*Understand biosensor principles, types, and signal transduction.*
CLR-2 :	*Learn materials, fabrication techniques, and integration with medical devices.*
CLR-3 :	*Explore biosensor applications in diagnostics and disease monitoring.*
CLR-4 :	*Grasp biosensor performance metrics, calibration, and testing methods.*
CLR-5 :	*Examine emerging trends, challenges, and ethical issues in biosensors*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	**Program Outcomes (PO)**												**Program Specific Outcomes**		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design/development of solutions*	*Conduct investigations of complex problems*	*Modern Tool Usage*	*The engineer and society*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO – 1:*	*PSO – 2:*	*PSO – 3:*
CO-1 :	*Describe biosensor principles, components, and signal mechanisms.*	*3*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*1*	*-*	*-*	*-*
CO-2 :	*Understand materials, fabrication, and integration techniques for biosensors.*	*3*	*2*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*2*	*-*	*-*	*-*
CO-3 :	*Explain biosensor applications in medical diagnostics and monitoring.*	*2*	*2*	*1*	*-*	*2*	*2*	*-*	*-*	*-*	*-*	*-*	*2*	*-*	*-*	*-*
CO-4 :	*Evaluate biosensor performance using key metrics and calibration methods.*	*3*	*2*	*2*	*-*			*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-5 :	*Analyze future trends and challenges in biosensor technology.*	*3*	*2*	*2*	*-*	*2*	*2*	*-*	*-*	*-*	*-*	*-*	*3*	*-*	*-*	*-*

Module-1: Principles of Biosensors:	***9 Hour***
Introduction to biosensors: Definition, types, and components; Signal transduction: Electrochemical, optical, and piezoelectric mechanisms; Performance metrics: Sensitivity, selectivity, calibration, detection limit, response time, and reproducibility.	
Module-2: Fabrication of Biosensors:	***9 Hour***
Materials for biosensor fabrication: metals, conductive polymers, and biocompatible materials, nanomaterials; Microfabrication techniques: Photolithography, screen printing, inkjet printing, microfluidics, MEMS; Integration with medical devices: Electrode materials and selection criteria, micro- and nano-scale integration techniques, commercialization challenges.	
Module-3: Biosensor Applications in Medical Diagnostics:	***9 Hour***
Diagnostic devices: Blood glucose meters, pregnancy tests, Point-of-care testing (POCT) devices, wearable biosensors; Disease monitoring: Cancer biomarkers, infectious diseases, chronic conditions (diabetes, cardiovascular); Emerging applications: Bioelectronic sensors, personalized medicine, non-invasive diagnostics.	
Module-4: Performance Evaluation and Calibration of Biosensors:	***9 Hour***
Performance metrics: Sensitivity, accuracy, specificity, and detection limits; Calibration: Electrochemical, optical, and acoustic sensors, standard solutions; Testing: Clinical performance, quality assurance, regulatory compliance.	
Module-5: Emerging Trends and Challenges in Biosensors	***9 Hour***
Integration with medical devices: Data communication, power supply, wearable devices; Future trends: Nanotechnology, smart sensors, lab-on-a-chip, AI in biosensors; Regulatory and ethical issues: Medical device approval, data privacy, and security concerns.	

Learning Resources	1. *B.D. Malhotra, Biosensors and Bioelectronics: Fundamentals and Applications, Wiley-Blackwell, 2021.* 2. *S. A. M. T. Ghosh, Biomedical Sensors: Design, Principles, and Applications, CRC Press, 2021.* 3. *A. Chatterjee, Nanomaterials for Biosensors: Fundamentals and Applications, Elsevier, 2021.*	4. *J.G. Manjunatha, Electrochemical Sensors Based on Carbon Composite Materials: Fabrication, Properties and Applications, IOP Publishing, 2022.* 5. *A Nag, SC Mukhopadhyay, J Kosel, Printed Flexible Sensors: Fabrication, Characterization and Implementation, Springer, 2019.* 6. *PF Dunn. Fundamentals of Sensors for Engineering and Science, CRC Press, 2011.*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of module test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

Course Designers

Experts from Industry	***Experts from Higher Technical Institutions***	***Internal Experts***
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*.Dr. Sruthi Ann Alex*

Course Code	21MBM112F	Course Name	BIOINSTRUMENTATION	Course Category	C	PROFESSIONAL CORE	L	T	P	C
							3	1	0	4

Pre-requisite Courses	Nil	Co-requisite Courses	Nil	Progressive Courses	Nil
Course Offering Department	Biomedical Engineering	Data Book / Codes/Standards	Nil		

Course Learning Rationale (CLR):	The purpose of learning this course is to:
CLR-1 :	Measure and interpret various physiological parameters
CLR-2 :	Utilize the working of different recording equipment
CLR-3 :	Utilize the principle and working of blood pressure and respiratory rate measurement equipment
CLR-4 :	Utilize the principle and working of pulmonary function analyzers
CLR-5 :	To understand the working principles of various bioanalytical equipment and gain knowledge on the various aspects of patient safety

Course Outcomes (CO):	At the end of this course, learners will be able to:	Program Outcomes (PO)												Program Specific Outcomes		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	Problem Analysis	Design & Development	Analysis, Design, Research	Modern Tool Usage	Society & Culture	Environment & Sustainability	Ethics	Individual & Team Work	Communication	Project Mgt. & Finance	Life Long Learning	PSO - 1	PSO - 2	PSO - 3
CO-1 :	Describe the components of a man instrument system and the different type of bioelectrodes	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO-2 :	Describe the origin of biopotentials and its measurements using different type of electrodes	2	-	2	-	-	-	-	-	-	-	-	-	-	-	-
CO-3 :	Interpret the working principle of the blood pressure and respiratory rate measurement equipment	2	2	-	-	-	2	-	-	-	-	-	-	-	-	-
CO-4 :	Interpret the working principle of the pulmonary function measuring equipment	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
CO-5 :	Interpret the working principle of the bioanalytical equipment and P\predict various electrical hazards and implement safety methods while using biomedical equipment	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Module-1: Introduction to Bioinstrumentation System ***9 Hours***

Physiological systems of the human body -Components of Man-Instrument system -General constrains in design of Medical Instrumentation systems-- Electrode theory – Electrodes for ECG, EEG and EMG - Resting and action potential- Propagation of Action potential - Nernst equation, Goldman equation - Sources of bioelectric potentials

Module-2: Measurement of Bio Potentials ***9 Hours***

Basic anatomy and physiology of heart - Electrophysiology of the Heart - Electrocardiography(ECG) waveform and its characteristics - ECG lead configurations - Introduction to basic anatomy and function of brain -Electroencephalography(EEG), Brain waves - 10-20 system of placement of electrodes for EEG recording - EEG Machine -block diagram description - Electromyography(EMG):Basics of EMG - Recording of EMG - EMG machine - Measurement of nerve conduction velocity – Electroretinography(ERG)

Module-3: Blood Pressure and Respiratory Rate Measurements ***9 Hours***

Measurement of blood pressure - Direct methods - Indirect methods - Automatic blood pressure measuring apparatus - Rheographic method - Differential Auscultatory method - Oscillometric measurement method, Ultrasonic Doppler shift method - Measurement of respiration rate - Displacement method - Thermistor method - Co2 method of respiration rate - Apnoea detectors - Bedside patient monitoring system - Central monitoring system.

Module-4: Pulmonary Function Analyzers ***9 Hours***

Mechanism of respiration - Pulmonary function measurements - Respiratory volumes and capacities - Spirometry: Basic spirometer - edge spirometer - Ultrasonic spirometer - Pneumotachometers: turbine type Pneumotachometer - Fleisch-type & Venturi type Pneumotachometers -- Pulmonary function analyzers -- Respiratory gas analyzer - Infrared gas analyzer.

Module-5: Bioanalytical Equipments and Patient Safety	***9 Hours***
Types of blood cells - Calculation of cell size - Coulter counters - Automatic recognition and differential counting of cells - Patient Safety-Electric shock hazards - Leakage currents - Safety codes for electromedical equipment - Electrical safety analyzer - Testing of Biomedical equipment	

Learning Resources	*1. R.S.Khandpur, 'Handbook of Biomedical Instrumentation', Tata McGraw Hill Publishing Co Ltd., 3rd edition, 2014.* *2. Leslie Cromwell, Fred J.Weibell, Erich A. Pfeiffer, "Bio-Medical Instrumentation and Measurements", Pearson Education, PHI Learning Private limited, India, 2nd edition, 2007.*	*3. John G.Webster, "Specifications of Medical Instrumentation Application and Design",Wiley India Pvt Ltd, India, 4th edition, 2015.*

Learning Assessment							
	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of module test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

Course Designers		
Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr. Remya Raj, SRMIST*

Course Code	21MBM113F	Course Name	DESIGN AND DEVELOPMENT OF MEDICAL DEVICES	Course Category	C	FOUNDATION COURSE	L	T	P	C
							3	1	0	4

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	**Data Book / Codes / Standards**	*Nil*		

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*To provide a foundational understanding of medical devices, their classification, regulatory frameworks, and ethical considerations*
CLR-2 :	*Equips students with systematic design methodologies and risk management*
CLR-3 :	*To equip students with the knowledge and skills to apply design thinking, prototyping techniques*
CLR-4 :	*To familiarize students with regulatory compliance required to ensure the safety and efficacy of medical devices.*
CLR-5 :	*To explore innovative trends in medical device technology and analyse real-world case studies*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	**Program Outcomes (PO)**												**Program Specific Outcomes**		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design/development of solutions*	*Conduct investigations of complex problems*	*Modern Tool Usage*	*The engineer and society*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO – 1:*	*PSO – 2:*	*PSO – 3:*
CO-1 :	*Gain knowledge of basics of biomedical devices and its classifications*	*3*	-	-	-	-	-	-	-	-	-	-	*2*	-	-	-
CO-2 :	*Get familiarize with various design principles and processes*	*3*	*2*	-	-	-	-	-	-	-	-	-	*1*	-	-	-
CO-3 :	*Get familiarized with various prototyping and testing techniques*	*2*	-	*3*	-	-	-	-	-	-	-	-	-		-	-
CO-4 :	*Students will understand processes of regulatory compliance to ensure the safety and efficacy of medical devices.*	*3*	-	*2*	-	-	-	-	-	-	-	*1*	*2*	-	-	-
CO-5 :	*Get updated with the latest trends and advancements and opportunities in biomedical device technologies*	*3*	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Module-1: Introduction to Medical Devices	***9 Hour***
Biomedical devices-definitions, history and scope, Medical devices Type and Classification -Application based classification-Diagnostic-Therapeutic-Assistive-Regulatory Type of application-non-implantable - implantable-body contacting and non-contacting active and passive-Functional physiological and anatomical devices-examples.,–Based on risk and regulatory requirement-Class I, II and III -Regulatory Framework and Compliance (FDA, CE Marking, etc.)	
Module-2: Design Principles & Processes	***9 Hour***
Design Methodology, User-centred design, Concept Development and Feasibility Analysis, Risk Management-Proactive management-ISO 14971 standards & Failure Mode Effect Analysis (FMEA), Biocompatibility & material selection, QMS- overview and benefits	
Module-3: Prototyping & Testing	***9 Hour***
Development Lifecycle- Iterative design process, Human Factors Engineering and Ergonomics in Device Design, Design for Manufacturability and Scalability, 3D printing & rapid prototyping techniques –Additive manufacturing-examples- Subtractive manufacturing –examples, Validation Protocols-Bench testing & preclinical trials - Usability testing, Case study- TTK chitra heart valve	
Module-4: Regulatory Landscape for Biomedical Devices	***9 Hour***
Need for regulation and guidelines. Overview of regulatory bodies: FDA (USA) - EMA (Europe) - CDSCO (India), etc. Medical device regulations and standards- ISO 13485-IEC 60601-. Steps for regulatory approval: Pre-market approval (PMA) and 510(k) clearance (US). Ethical considerations-: Patient safety- informed consent-and data privacy-Case study- The Tuskegee Syphilis Study. Intellectual property (IP) and patents in medical devices.	
Module-5: Emerging trends in Biomedical Device Development	***9 Hour***

Emerging Trends and Technologies Topics: Wearable and Portable Medical Devices-Smart health devices-continuous monitoring systems.-Power management and miniaturization, Imaging and Diagnostics: CT-MRI- ultrasound, and AI-enhanced diagnostic tools, Internet of Medical Things (IoMT): Real-time monitoring- cloud-based data management. Challenges in data privacy and cybersecurity.

Learning Resources	1. *Medical Device Development, Edited by Jonathan S. Kahan, Barnett International, 2009, ISBN: 1-882615-92-* 2. *Current Trends in Biomedical Engineering –, by Christiane Bertachini Lombello*	3. *Biodesign The Process of Innovating Medical Technologies 2nd Edition by Paul G. Yock* 4. *Regulatory Affairs for Biomaterials and Medical Devices, by Stephen F. Amato*

Learning Assessment

	Bloom's Level of Thinking	Continuous Learning Assessment (CLA)				Summative Final Examination (40% weightage)	
		Formative CLA-1 Average of module test (50%)		Life-Long Learning CLA-2 (10%)			
		Theory	Practice	Theory	Practice	Theory	Practice
Level 1	Remember	20%	-	20%	-	20%	-
Level 2	Understand	20%	-	20%	-	20%	-
Level 3	Apply	30%	-	30%	-	30%	-
Level 4	Analyze	30%	-	30%	-	30%	-
Level 5	Evaluate	-	-	-	-	-	-
Level 6	Create	-	-	-	-	-	-
	Total	100 %		100 %		100 %	

Course Designers

Experts from Industry	Experts from Higher Technical Institutions	Internal Experts
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr.Shabeeb Ahamed KP*

Course Code	21MBM211E	Course Name	THERAPEUTICS AND DIAGNOSTICS	Course Category	E	PROFESSIONAL ELECTIVE	L	T	P	C
							3	0	0	3

Pre-requisite Courses	Nil	Co-requisite Courses	Nil	Progressive Courses	Nil
Course Offering Department	Biomedical Engineering	Data Book / Codes/Standards		Nil	

Course Learning Rationale (CLR):	The purpose of learning this course is to:
CLR-1 :	Understand the fundamentals of diagnostic and therapeutic equipment
CLR-2 :	Get an idea about functioning of different types of physiotherapy and electrotherapy equipment
CLR-3 :	Get an idea about the surgical diathermy units
CLR-4 :	Gain knowledge about respiratory care equipment
CLR-5 :	Familiarize about diagnosis procedure of hearing problems and hearing aids

Course Outcomes (CO):	At the end of this course, learners will be able to:	Program Outcomes (PO)												Program Specific Outcomes		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	Problem Analysis	Design & Development	Analysis, Design, Research	Modern Tool Usage	Society & Culture	Environment & Sustainability	Ethics	Individual & Team Work	Communication	Project Mgt. & Finance	Life Long Learning	PSO - 1	PSO - 2	PSO – 3
CO-1 :	Outline the importance of coronary care equipment	3	-	-	-	-	-	-	-	-	-	-	1	-	-	-
CO-2 :	Analyze the physiotherapy and electrotherapy equipment	3	-	2	-	-	-	-	-	-	-	-	-	-	-	-
CO-3 :	Understand the importance of surgical and therapeutic equipment	2		-	-	-	-	1	-	-	-	-	-	-	-	-
CO-4 :	Understand the importance of respiratory care equipment	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
CO-5 :	Understand the importance and design procedure of audiometers and hearing aids	1	-	-	2	-	-	-	2	-	-	-	-	-	-	-

Module-1: Coronary Care Equipment ***9 Hours***

Cardiac pacemakers: different modes of operation - External pacemaker - Implantable pacemakers - Pacemaker standard codes - Defibrillator: AC defibrillator - DC defibrillator - Implantable defibrillator - Automated external defibrillator (AED) - Pacer- cardioverter defibrillator - Heart lung machine (HLM) - Oxygenators - Functional details of oxygenators - Types of oxygenators

Module-2: Physiotherapy and Electrotherapy Equipment ***9 Hours***

Principle of surgical diathermy - Surgical diathermy unit - Safety aspects of electrosurgical units - Endoscopy -basic components - Endoscopy- different types - Laparoscope - Gastroscope - Bronchoscope - Cryogenic techniques - Modern lithotriptor system - Laser lithotripsy

Module-3: Surgical and Therapeutic Equipment ***9 Hours***

Short wave diathermy - Microwave diathermy - Ultrasonic therapy unit - Electro diagnostic apparatus - Electro therapeutic apparatus - Interferential current therapy - Transcutaneous electrical nerve stimulation (TENS) - Functional electrical stimulation (FES) Bladder stimulator - Spinal cord stimulator - Deep brain stimulation

Module-4: Respiratory Care Equipment ***9 Hours***

Mechanics of respiration - Introduction to Respiratory care equipment - Artificial ventilation - Ventilator terms - Working of Ventilators - Types of ventilators - Pressure volume flow diagram - Modern ventilator - High frequency ventilators - Humidifier - Nebulizer - Aspirator - Need for Anesthesia - Anesthesia machine - Capnography

Module-5: Audiometers and Hearing Aids ***9 Hours***

Mechanism of hearing - Sound conduction system - Basic audiometer - Pure tone audiometer - Speech audiometer - Bekesy audiometer system - Evoked response audiometry system - Calibration of audiometers - Hearing aids

Learning Resources	*1. R.S.Khandpur, 'Handbook of Bio-Medical instrumentation', Tata McGraw Hill Publishing Co Ltd., 3rd edition, 2014.* *2. Albert M.Cook and Webster.J.G, "Therapeutic Medical Devices", Prentice Hall Inc., New Jersey, 1st edition, 1982.*	*3. Leslie Cromwell, Fred J.Weibell, Erich A.Pfeiffer, "Bio-Medical Instrumentation and Measurements", Pearson Education, PHI Learning Private limited, India, 2nd edition, 2007.* *4. John G.Webster, "Specifications of Medical Instrumentation Application and Design", Wiley India Pvt Ltd, India, 4th edition, 2015.*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of unit test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

CLA – 4 can be from any combination of these: Assignments, Seminars, Tech Talks, Mini-Projects, Case-Studies, Self-Study, MOOCs, Certifications, Conf. Paper etc.,

Course Designers

Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr. Prasanna Venkatesh*

Course Code	21MBM212E	Course Name	MEDICAL IMAGING TECHNOLOGY	Course Category	E	PROFESSIONAL ELECTIVE	L	T	P	C
							3	0	0	3

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	Data Book / Codes / Standards		*Nil*	

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*Introduce the fundamental principles, instrumentation, and applications of X-ray radiography and fluoroscopy in medical imaging technology.*
CLR-2 :	*Provide an in-depth understanding of the principles, technology, image reconstruction, and clinical applications of computed tomography in medical imaging.*
CLR-3 :	*Explore the principles, instrumentation, techniques, and clinical applications of ultrasound imaging in medical diagnostics.*
CLR-4 :	*Gain the foundational knowledge of nuclear imaging techniques, instrumentation, radiopharmaceuticals, and clinical applications in medical diagnostics.*
CLR-5 :	*Acquire an in-depth understanding of the principles, technology, safety considerations, and clinical applications of Magnetic Resonance Imaging (MRI) in medical diagnostics.*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	Program Outcomes (PO)												Program Specific Outcomes		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design/development of solutions*	*Conduct investigations of complex problems*	*Modern Tool Usage*	*The engineer and society*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO – 1:*	*PSO – 2:*	*PSO – 3:*
CO-1 :	*Describe the principles, technology, safety, and clinical applications of X-ray radiography and fluoroscopy in medical imaging*	2	-	2	-	-	-	-	-	-	-	-	1	-	-	-
CO-2 :	*Explain the principles, technology, image reconstruction, and clinical applications of Computed Tomography in medical imaging.*	2	-	2	-	-	-	-	-	-	-	-	1	-	-	-
CO-3 :	*Comprehend the principles, instrumentation, and clinical applications of Ultrasound imaging in medical diagnostics.*	2	-	2	1	-	-	-	-	-	-	-	1	-	-	-
CO-4 :	*Realize the principles, instrumentation and clinical applications of nuclear imaging techniques.*	2	-	-	-	-	-	1	-	-	-	-	-	-	-	-
CO-5 :	*Discern the basic physics, instrumentation and clinical applications of MRI*	2	-	1	-	-	-	-	-	-	-	-	1	-	-	-

Module-1: X-Ray Radiography and Fluoroscopy	***9 Hours***
Introduction to X-Ray Imaging - X-Ray Tube and Generators - X-ray machine – Radiographic Image Formation - Fluoroscopy Systems – Mammography - Radiation Protection and Safety - Clinical Applications of X-Ray Radiography and Fluoroscopy	
Module-2: Computed Tomography	***9 Hours***
Introduction to Computed Tomography - Physics of CT Imaging – Generations of CT– CT Scanner Components – Image Reconstruction in CT: filtered back-projection (FBP) and iterative reconstruction (IR) - CT Image Quality and Dose Optimization - Clinical Applications of CT	
Module-3: Ultrasound Imaging	***9 Hours***
Introduction to Ultrasound Imaging - Physics of ultrasonic waves - Generation of ultrasound - Ultrasound Transducers and Beam Formation - Modes of Ultrasound Imaging: A-mode, B-mode, M-mode and Doppler - Clinical Applications of Ultrasound	

Module-4: Nuclear Imaging	***9 Hours***
Introduction to Nuclear Imaging - Radioisotopes in medical diagnosis – Radiation detector – Nuclear Imaging Systems: Gamma camera, PET, SPECT, Hybrid imaging systems – Radiation Safety in Nuclear Imaging – Clinical Applications of Nuclear Imaging	
Module-5: Magnetic Resonance Imaging	***9 Hours***
Introduction to MRI: Principles of MRI imaging system — MRI System Components and Operation – MRI Image Formation: T1 weighed and T2 weighed images – MRI Image Quality and Artifacts – MRI Safety and Bioeffects – Clinical Applications of MRI: functional MRI (fMRI) and magnetic resonance spectroscopy (MRS)	

Learning Resources	1. *R.S.Khandpur, "Handbook of Biomedical instrumentation", Tata McGraw Hill Publishing Co. Ltd., 3rd edition, 2014.* 2. *Jerrold T. Bushberg and John M. Boone, "The essential physics of medical imaging", Lippincott Williams & Wilkins, 3rd edition, 2011.* 3. *Nadine Barrie Smith, Andrew Webb, "Introduction to medical imaging: Physics, Engineering and clinical applications", Cambridge University Press, 1st edition, 2010.*	4. *Mostafa Analoui, Joseph D. Bronzino, and Donald R. Peterson. "Medical imaging: principles and practices", CRC Press, 2012.* 5. *Paul Sueten, "Fundamentals of medical imaging", Cambridge university press, 2017.* 6. *Stewart C. Bushong, "Radiologic Science for Technologists: Physics, Biology, and Protection", Elsevier, 2016.*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of unit test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

Course Designers		
Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr.Nijisha Shajil, Assistant Professor, SRMIST*

Course Code	21MBM213E	Course Name	HUMAN MOVEMENT MECHANICS	Course Category	E	PROFESSIONAL ELECTIVE	L	T	P	C
							3	0	0	3

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	Data Book / Codes / Standards		*Nil*	

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*Understand the fundamental principles of biomechanics and the role of mechanical forces in human movement*
CLR-2 :	*Explore the kinematic parameters and their significance in analyzing linear and angular human motion.*
CLR-3 :	*Gain insights into the kinetic principles of human movement, emphasizing energy, momentum, and force applications.*
CLR-4 :	*Study the structure and function of bones and muscles to comprehend their response to mechanical stresses.*
CLR-5 :	*Analyze biomechanical factors influencing movement and injury prevention in the upper and lower extremities.*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	Program Outcomes (PO)												Program Specific Outcomes		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design & Development*	*Analysis, Design, Research*	*Modern Tool Usage*	*Society & Culture*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO - 1*	*PSO - 2*	*PSO – 3*
CO-1 :	*Apply fundamental biomechanical principles and analyze mechanical forces acting on the human body.*	2	2	1	1	-	-	-	-	-	-	-	1	-	-	-
CO-2 :	*Evaluate linear and angular kinematics of human movement for various physical activities.*	2	1	-	-	-	-	-	-	-	-	-	1	-	-	-
CO-3 :	*Analyze kinetic principles such as force, momentum, and energy to interpret human motion.*	-	1	-	2	-	-	-	-	-	-	-	1	-	-	-
CO-4 :	*Understand the bone and muscle mechanics, focusing on stress responses and injuries.*	2	1	1	2	-	-	-	-	-	-	-	-	-	-	-
CO-5 :	*Evaluate the various biomechanical movements and loading conditions in the upper and lower extremities.*	-	2	2	2	-	-	-	-	-	-	-	-	-	-	-

Module-1: Introduction to Biomechanics and Fundamentals of Mechanics	***9 Hours***
Introduction to biomechanics- Basic dimensions and units of measurement - Types of motion - Standard reference and Joint movement terminologies - Qualitative analysis of human movement - Tools for measuring kinematic quantities - Basic concepts of kinetics - Mechanical loads on human body - Effects of loading - Tools for measuring Kinetic Quantities	
Module-2: Kinematics of Human Movements	***9 Hours***
Linear kinematic quantities: Distance and displacement – Speed-velocity and Acceleration, Kinematics of projectile motion and its associated factors - Analyzing projectile motion - Measuring angles - Angular kinematic relationship: Angular displacement - Angular speed and velocity - Angular acceleration - Relationship between linear and angular motion	
Module-3: Kinetics of Human Movement	***9 Hours***
Mechanical behavior of bodies in contact- Friction - Momentum, impulse and impact - Work, Power and Energy relationship - Conservation of mechanical energy - Principle of work and energy - Resistance to angular acceleration: Moment of inertia - Human body moment of inertia - Angular Momentum-Conservation of angular momentum - Angular Momentum-Transfer of angular momentum - Change in angular momentum	
Module-4: Bone and Muscle Biomechanics	***9 Hours***
Composition and structure Of bone tissue - Bone growth and development - Bone response to stress - Osteoporosis - Common injuries of bone - Structural organization of skeletal muscle - Skeletal muscle function - Factors affecting muscular force generation - Muscular strength, power and endurance - Common bone injuries - Common muscle injuries	

Module-5: Upper and Lower Extremity Biomechanics	***9 Hours***
Structure of the Shoulder - Movements of the shoulder Complex - Loads on the shoulder and injuries - Structure and movements of the elbow - Loads on the elbow - Common injuries of the elbow - Structure of Spine - Movements of Spine - Loads on the spine and injuries of the spine - Structure and movements of the hip - Loads and common injuries on hip - Structure and Movements of the knee - Loads on the knee and common injuries of knee	

Learning Resources	*1. Susan J Hall, "Basic Biomechanics", Tata Mcgraw hill, 7th Edition, 2014.* *2. Joseph Hamill, Kathleen M. Knutzen, "Biomechanical basis of human movement", Lippincott Williams & Wilkins, 3rd Edition, 2009.* *3. Duane Knudson, "Fundamentals of Biomechanics", Springer, 2nd Edition, 2007*	*4.Peter M. McGinnis, "Biomechanics of sports and exercise", Human kinetics, 3rd Edition, 2013.* *5. Vladimir m. Zatsiorsky, "Biomechanics in sport", Blackwell Science Ltd, Ist Edition, 2000.*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of unit test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 4	*Analyze*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 5	*Evaluate*	*10%*	*-*	*10%*	*-*	*10%*	*-*
Level 6	*Create*	*10%*	*-*	*10%*	*-*	*10%*	*-*
	Total	*100 %*		*100 %*		*100 %*	

Course Designers

Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr. Rohit Gupta*

Course Code	21MBM214E	Course Name	PRINCIPLES AND PRACTICE OF ASSISTIVE TECHNOLOGY	Course Category	E	PROFESSIONAL ELECTIVES	L	T	P	C
							3	0	0	3

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	**Data Book / Codes/Standards**		*Nil*	

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*Understanding the key principles of assistive technology*
CLR-2 :	*Identify the factors that influence the design of assistive devices*
CLR-3 :	*Usage of Assistive Technology that enable mobility*
CLR-4 :	*Uncover the assist devices for vital organs and advancements*
CLR-5 :	*Identify the assistive technology for prosthetic and implant device*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	**Program Outcomes (PO)**												**Program Specific Outcomes**		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design & Development*	*Analysis, Design, Research*	*Modern Tool Usage*	*Society & Culture*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO - 1*	*PSO - 2*	*PSO - 3*
CO-1 :	*Identifying the key principles of assistive technology*	*2*	*-*	*2*	*-*	*-*	*-*	*-*	*3*	*-*	*1*	*-*	*-*	*-*	*-*	*-*
CO-2 :	*Describe the factors that influence design and development of the assistive devices*	*2*	*-*	*-*	*-*	*-*	*3*	*-*	*-*	*1*	*1*	*-*	*-*	*-*	*-*	*-*
CO-3 :	*Summarize the usage of Assistive Technology that enable mobility*	*-*	*1*	*2*	*1*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*2*	*-*	*-*	*-*
CO-4 :	*Understand the working of assist devices for vital organs and advancements*	*-*	*1*	*-*	*1*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*2*	*-*	*-*	*-*
CO-5 :	*Describe the assistive technology for prosthetic and implant device*	*2*	*1*	*-*	*1*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*

Module-1: Assistive Technology Basic Principles	***9 Hours***
Introduction to human activity assistive technology - Definition of assistive technology - Principles of assistive technology - Human assistive technology model - Assistive Technology in Healthcare and Rehabilitation- Human assistive technology interface - Technologies that Assist People Who Have Disabilities - Design based on human ability - Standards for assistive technology - Socioeconomic and Ethical Considerations in Assistive Technology, Policies, Laws, and Regulations	
Module-2: Design And Development of Assistive Devices	***9 Hours***
Human Factors in Assistive Device Design- Materials and Manufacturing Methods for Assistive Devices- Sensors and Actuators in Mobility and Prosthetics- User-Centered Design Methodology for Assistive Devices- Prototyping and Rapid Development Techniques-Usability Testing and Feedback in Assistive Device Development	
Module-3: Assistive Technology Used for Various Vital Organs	***9 Hours***
Understanding physiology of heart - Cardiac assist devices - Intra-Aortic Balloon Pump (IABP) - Dialysis for kidneys - Hemodialyzer unit, membrane dialysis, - Portable dialyzer - Intermittent positive pressure breathing (IPPB) type assistance for lungs - Ventilator - Nebulizer, Humidifier - Classification of amputation types - Components of upper limb prosthesis Components of lower limb prosthesis- Latest use of assistive technology for chronic heart diseases and healthcare	
Module-4: Assistive Technology For Prosthesis And Implant Devices	***9 Hours***
Orthoses: need and types - Limb Orthoses-Spinal orthoses- Principles of implant design -cardiac implants - Clinical problems requiring implants for solution - Tissue engineering - Scaffolds - local and systemic effects of implants - Biocompatibility, Implants for Bone – Introduction to devices for nerve regeneration, dental and otologic implants	
Module-5: Digital And Emerging Assistive Technologies	***9 Hours***

Wearable Technologies and Smart Assistive Devices-Augmentative and Alternative Communication (AAC) Systems-Brain-Computer Interfaces (BCI): Principles and Applications-Role of Robotics, Machine Learning and AI in Assistive Technology- IoT-Enabled Smart Homes and Assistive Environments-Assistive Technologies for Cognitive and Learning Disabilities-Case Studies: Assistive Technologies for Older Adults-Technology Integration Challenges and Future Directions

Learning Resources	1. *Albert M. Cook, Janice Miller Polga ,'Assistive Technologies- E-Book: Principles and Practice', Elsvier mosby publication 2025.* 2. *Yadin David, Wolf W. von Maltzahn, Michael R. Neuman, Joseph.D, Bronzino, "Clinical Engineering", CRC Press, 1st edition,2010.* 3. *Suzanne Robitaille, "The illustrated guide to Assistive technology and devices–Tools and gadgets for living independently", Demos Health Newyork, First edition, 2010*	4. *Rory A Cooper, Hisaichi Ohnabe, Douglas A Hodson, "An Introduction to Rehabilitation Engineering", CRC Press, First edition, 2006* 5. *Gerr . M. Craddock "Assistive Technology-Shaping the future", IOS Press, 1st edition, 2003.*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of module test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

Course Designers

Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr. Varshini Karthik*

Course Code	21MBM215E	Course Name	ARTFICIAL INTELLIGENCE IN MEDICAL DEVICES	Course Category	E	PROFESSIONAL ELECTIVES	L	T	P	C
							3	0	0	3

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	**Data Book / Codes/Standards**		*Nil*	

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*Provide foundational knowledge of AI and its role in enhancing medical devices and improving clinical workflows*
CLR-2 :	*Introduction to AI techniques and framework critical for healthcare solutions*
CLR-3 :	*Exploring real-world applications in health monitoring, diagnosis, treatment, and drug discovery*
CLR-4 :	*Familiarization with the AI, IoT, edge computing, and cloud technologies used in designing and optimizing medical devices*
CLR-5 :	*Develop awareness of ethical concerns, privacy protection, and regulatory requirements for deploying AI in healthcare*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	**Program Outcomes (PO)**												**Program Specific Outcomes**		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design/development of solutions*	*Conduct investigations of complex problems*	*Modern Tool Usage*	*The engineer and society*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO – 1:*	*PSO – 2:*	*PSO – 3:*
CO-1 :	*Comprehend the role of AI in clinical workflows*	2	1	1	-	-	-	-	-	-	-	-	-	-	-	-
CO-2 :	*Utilize AI techniques and learning paradigms to process and analyze clinical data effectively.*	-	1	1	-	1	-	-	-	-	-	-	-	-	-	-
CO-3 :	*Analyze AI applications in healthcare through case studies and practical frameworks*	1	2	1	1	1	-	-	-	-	-	-	-	-	-	-
CO-4 :	*Understand the integration of AI, IoT, and cloud computing in medical devices*	-	-	1	1	1	-	-	-	-	-	-	-	-	-	-
CO-5 :	*Recognize the ethical and regulatory implications of deploying AI in healthcare*	-	-	-	-	-	-	1	2	-	-	-	-	-	-	-

Module-1: Introduction to AI in Medical Devices	***9 Hours***
The Role and significance of AI in medical devices and Clinical workflow, Healthcare advantages of using AI, Design considerations for AI-powered medical devices: Overview of medical devices, Clinical data	
Module-2: Basics of AI	***9 Hours***
Introduction to AI: Definition and Applications, Learning Paradigms: Supervised Learning (Classification & regression); Unsupervised Learning (Clustering); Reinforcement Learning, Deep learning, The Machine Learning Pipeline: Feature extraction, selection, and dimensionality reduction; Model building, validation, and evaluation metrics	
Module-3: Applications of AI in Healthcare	***9 Hours***
Framework and Case studies for use of AI in Healthcare, AI in Health Monitoring: Remote patient monitoring using artificial intelligence, AI in Disease Diagnosis: Cardiac Diagnosis using ECG signals, AI in clinical treatment: Cancer diagnostics and treatment decisions using AI, Use of AI in drug discovery	
Module-4: Integration of AI in Medical Devices	***9 Hours***
AI integration with medical devices: IoT and Wearable Technologies, Edge AI and Cloud Integration for Medical Devices: Trade-offs and applications, Case Studies: smart prosthetics, AI assisted surgery, Intelligent drug delivery systems	
Module-5: Ethics and Governance for Use of AI in Medical Devices	***9 Hours***
Ethical issues of using AI in clinical workflow: data protection, privacy, anonymity, biases, Regulations and governance frameworks for software as medical device: Understanding GDPR, HIPAA, and FDA regulations for AI-powered devices	

Learning Resources	*1. Artificial Intelligence in Healthcare, by Adam Bohr and Kaveh Memarzadeh, Academic Press, 2020* *2. Biomedical Signal Processing and Artificial Intelligence in Healthcare, Editor: Walid A. Zgallai, Academic press, 1st Edition - July 29, 2020* *3. Handbook of AI-Based Models in Healthcare and Medicine: Approaches, Theories, and Applications, Edited by Bhanu Chander, Koppala Guravaiah, B. Anoop, G. Kumaravelan, CRC press, 1st Edition, 2024*	*4. Artificial Intelligence in Biomedical and Modern Healthcare Informatics, by M. A. Ansari (Editor), R. S. Anand (Editor), Pragati Tripathi (Editor), Rajat Mehrotra (Editor), Belal Bin Heyat (Editor), Academic Press, 1 September 2024.* *5. Moreira, R. S., Soares, C., Torres, J. M., & Sobral, P. (2021). Combining IoT architectures in next generation healthcare computing systems. In Intelligent IoT Systems in Personalized Health Care (pp. 1-29). Academic Press.,* *6. Regulatory Documentation: FDA's "Artificial Intelligence and Machine Learning in Software as a Medical Device (SaMD)" white paper*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of module test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

CLA – 4 can be from any combination of these: Assignments, Seminars, Tech Talks, Mini-Projects, Case-Studies, Self-Study, MOOCs, Certifications, Conf. Paper etc.,

Course Designers

Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr. Deboleena Sadhukhan, SRMIST*

Course Code	21MBM216E	Course Name	REGULATORY, DESIGN AND QUALITY REQUIREMENTS	Course Category	E	PROFESSIONAL ELECTIVE	L	T	P	C
							3	0	0	3

Pre-requisite Courses	*Nil*	Co-requisite Courses	*Nil*	Progressive Courses	*Nil*
Course Offering Department	*Biomedical Engineering*	Data Book / Codes / Standards	*Nil*		

Course Learning Rationale (CLR):	*The purpose of learning this course is to:*
CLR-1 :	*Understand the fundamentals of regulatory strategy, including the legal frameworks*
CLR-2 :	*Gain insights into various design models and the classification systems used for medical devices.*
CLR-3 :	*Acquire a clear understanding of the design procedures, including verification, validation, and risk management processes.*
CLR-4 :	*Develop a deeper understanding of the design realization process, focusing on material selection, usability, and fundamental safety principles.*
CLR-5 :	*Gain knowledge of the Global medical device regulatory system, including its specific requirements and standards for compliance.*

Course Outcomes (CO):	*At the end of this course, learners will be able to:*	Program Outcomes (PO)												Program Specific Outcomes		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
		Engineering Knowledge	*Problem Analysis*	*Design/development of solutions*	*Conduct investigations of complex problems*	*Modern Tool Usage*	*The engineer and society*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO – 1:*	*PSO – 2:*	*PSO – 3:*
CO-1 :	*Gain a comprehensive understanding of national and international regulatory frameworks*	*2*	-	-	-	-	-	-	-	-	-	-	*1*	-	-	-
CO-2 :	*Apply various design models to medical device development process*	*2*	-	*2*	-	*2*	-	-	-	-	-	-	-	-	-	-
CO-3 :	*Implement quality assurance processes, including verification, validation, and risk assessment, to ensure safety and performance.*	*2*	*2*	*1*	-	*1*	-	-	-	-	-	-	*2*	-	-	-
CO-4 :	*Manage the design realization process, focusing on material selection, usability, and risk analysis to ensure the safety and effectiveness of medical devices.*	*1*	*2*	-	-	-	-	-	-	-	-	-	-	-	-	-
CO-5 :	*Understand global medical device regulations, ensuring compliance with FDA, EU, and international standards.*	-	-	-	*2*	-	-	*2*	-	-	-	-	*2*	-	-	-

***Module-1: Introduction to Regulatory Strategy*:**	**9 Hours**
Purpose of regulation - Principles of regulation - Legal frame work for regulation: National Legislative process - Legal frame work for regulation: EU Legislative process - Relationship between national and EU legal instruments - Basic legislation - Scope of legislation - Basic regulatory strategy - EU Vigilance communication systems - Quality assurance systems - Validation - Regulatory bodies - International Harmonization bodies - International conference on Harmonization - The World Health Organization	
Module-2: Design models	***9 Hours***
Overview of New product development for medical devices, Requirement engineering for medical device- Design life cycle - Design process versus design control - Design models-Pahl - Design models-Beitz - pugh model - Divergent-convergent model - Common design management models - Cross reference with regulatory requirements	
Module-3: Design procedure and its quality:	***9 Hours***
Product specification procedure - Design verification procedure - Validation/Evaluation procedure - Risk assessment procedure - Product design specification - Optimization - Overview of quality function deployment - QFD process - House of quality - Failure mode - Effect of Analysis - Six sigma	
Module-4: Design Realization	***9 Hours***
The process to design realization - Design Calculation - Material selection - Design for usability - Fundamental safety -Effectiveness principle - FDA'S interest in standards - Intellectual property - Risk analysis	

Module-5: Medical device regulations	***9 Hours***
Global Perspective on medical device regulations - FDA regulation - European union medical device regulatory- Medical device quality management systems requirements - Need for standards – ISO standards -IEC Standards-CDSCO	

Learning Resources		
	1.Richard Fries, "Reliable Design of Medical Devices", CRC Press, 2nd Edition, 2006 *2.Rose J E, "Total quality Management", Kogan Page Ltd., 1993* *3. John Bank, "The Essence of Total quality Management", Prentice Hall of India, 1993* *4. Basem S EL-Haik & Khalid S Mekki, "Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness", John Wiley & Sons, 1st Edition, 2008* *5. John J Tobin & Gary Walsh, "Medical Product Regulatory Affairs- Pharmaceutical, Diagnostics, Medical Devices", Wiley-Blackwell, 1st Edition, 2008*	*6. "Medical Device Regulations Global overview and guiding principles", World Health Organization Geneva, 2003* *7. Jack Wong and Raymond K Y Tong, "Handbook of Medical device regulatory affairs in Asia", Pan Stanford Publishing Pte. Ltd., 2nd Edition, 2018* *8.Peter Ogrodnik, "Medical Device Design Innovation from concept to Market", Elseiver, 2013* *9.Richard C.Fries, "Handbook of medical device design", Marcel Dekker AG, Second edition, 2005*

Learning Assessment

	Bloom's Level of Thinking	*Continuous Learning Assessment (CLA)*				*Summative Final Examination (40% weightage)*	
		Formative CLA-1 Average of module test (50%)		*Life-Long Learning CLA-2 (10%)*			
		Theory	*Practice*	*Theory*	*Practice*	*Theory*	*Practice*
Level 1	*Remember*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 2	*Understand*	*20%*	*-*	*20%*	*-*	*20%*	*-*
Level 3	*Apply*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 4	*Analyze*	*30%*	*-*	*30%*	*-*	*30%*	*-*
Level 5	*Evaluate*	*-*	*-*	*-*	*-*	*-*	*-*
Level 6	*Create*	*-*	*-*	*-*	*-*	*-*	*-*
	Total	*100 %*		*100 %*		*100 %*	

Course Designers

Experts from Industry	**Experts from Higher Technical Institutions**	**Internal Experts**
Mr. Anbuselvan T, Wipro GE Health care Pvt Ltd	*Dr.S.Poonguzhali, Professor, Anna University*	*Dr.D.Ashokkumar SRMIST*