ACADEMIC CURRICULA

Minor Program in Computer Aided Diagnostics

(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 COMPUTER AIDED DIAGNOSTICS

S. No	Category	Subject Code	Subject Name	L	T	P	C
1	Core (9 Credits)	21MBM011F	Fundamentals of biomedical Engineering	3	0	0	3
2		21MBM012F	Bioelectric Signal Processing	2	1	0	3
3		21MBM013F	Multimodal Imaging Systems	3	0	0	3
4	Elective (9 Credits) Choice of any three	21MBM024E	Biomedical Measurement Systems	3	0	0	3
5		21MBM025E	Machine Learning and Pattern Recognition	3	0	0	3
6		21MBM026E	Biomedical Informatics	3	0	0	3
7		21MBM027E	Physiological Data Analytics	2	1	0	3
8		21MBM028E	Principles of Medical Imaging	3	0	0	3
9		21MBM029E	Regulatory Affairs in Medical Devices	3	0	0	3

Course Code	21MBM011F	Course Name	FUNDAMENTALS OF BIOMEDICAL ENGINEERING	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*		

		Program Outcomes (PO)												Program Specific Outcomes		
Course Learning Rationale (CLR):	*The purpose of learning this course is to:*	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*	*Environment & Sustainability*	*Ethics*	*Individual & Team Work*	*Communication*	*Project Mgt. & Finance*	*Life Long Learning*	*PSO – 1:*	*PSO – 2:*	*PSO – 3:*
CLR-1 :	*List the various physiological and anatomical systems of the body*															
CLR-2 :	*Understand the function and basic block diagram of bedside and central patient monitoring systems.*															
CLR-3 :	*Perceive the physics behind X-ray imaging and computed tomography (CT)*															
CLR-4 :	*Describe the properties and mechanics of bone*															
CLR-5 :	*Understand the fundamentals of biomaterials and their applications*															
Course Outcomes (CO):	*At the end of this course, learners will be able to:*															
CO-1 :	*Gain knowledge of Human Physiology and Anatomy*	*3*	*1*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*2*	*-*	*-*	*-*
CO-2 :	*Get familiarize with Biomedical Devices and Systems*	*3*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*1*	*-*	*-*	*-*
CO-3 :	*Explain the principle and construction of various imaging systems in medicine*	*2*	*-*	*3*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*		*-*	*-*	*-*
CO-4 :	*Understanding the basic concepts of bone biomechanics*	*3*	*-*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*1*	*-*	*-*	*-*
CO-5 :	*Comprehend the fundamental Knowledge in biomaterials*	*3*	*2*	*1*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*

Module-1: Introduction to the Physiological System:	***9 Hour***
Histology- Physiological system of the body- Cardiovascular system- biochemical system-Respiratory system- nervous system Excretory system- Cell, DNA, and atoms-The locomotor system- The digestive system-Cloning-Sources of Biomedical Signals-Basic Block diagram of medical instrumentation system	
Module-2: Patient Monitoring System:	***9 Hour***
Introduction to cardiac monitor-Basic Block diagram of Bedside patient monitoring systems-Basic block diagram of Central monitors- Measurement of heart rate-Average heart rate meters-Instantaneous heart rate measurements of pulse rate-Blood pressure measurement-Direct and indirect methods of monitoring blood pressure measuring apparatus using Korotkoff method- -Measurement of Respiration rate- Displacement method	
Module-3: Therapeutic Equipment:	***9 Hour***

Cardiac pacemaker-External and internal pacemaker- Surgical diathermy machine, short wave diathermy, and ultrasonic diathermy-Working of a hemodialysis machine, Peritoneal anesthesia machine-Ventilator and types of ventilators- Infusion pump and syringe pump.
Module-4: Biomechanics of bone ***9 Hour***
Introduction -Classification of bones, the composition of bones- Mechanical properties of boned-Bone fracture and traction-Biomechanics of soft tissue: tendons and ligaments-Skeletal muscle-Tissue between joints -types of synovial joints. -mechanics of upper Limp-mechanics of the elbow.
Module-5: Biomaterials ***9 Hour***
Introduction-Metallic biomaterials-: Stainless steel, CoCr alloy, Titanium alloy-dental material -gold -Corrosion of metallic implants. Polymeric biomaterials: Introduction-Selection of polymeric biomaterial-Polyvinyl chloride (PVC), Polyethylene (PE), Polypropylene (PP), Polystyrene (PS), Poly methyl methacrylate (PMMA, polyesters, Application of polymer. Bio ceramics: Nonabsorbable ceramics. Bioactive ceramics

Learning Resources	1. *G.S. Sawhney, Fundamental of Biomedical Engineering, 5th Edition, New Age International Pvt Ltd, 2015.* 2. *R. S Khandpur and Raghbir Khandpur, Biomedical Instrumentation, 3rd edition McGraw-Hill Education (India) Pvt Limited,2004*	3. *Joseph D. Bronzino, Donald R. Peterson. The Biomedical Engineering Handbook, CRC Press, 2018.* 4. *John G. Webster, Medical Instrumentation Application and Design Wiley India Private Limited; Third edition 2007*

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.S.Gnanavel*

Course Code	21MBM012F	Course Name	BIOELECTRIC SIGNAL PROCESSING	Course Category	C	*FOUNDATION COURSE*	L	T	P	C
							2	1	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 :	*Familiarize the origin of bioelectric potentials and study its characteristics*
CLR-2 :	*Analyze the various signal processing methods of ECG signals.*
CLR-3 :	*Implement various signal processing methods for analyzing EEG signals*
CLR-4 :	*Explore on EMG signal detection and classification*
CLR-5 :	*Demonstrate on Heart rate variability analysis and its applications*

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*	*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 :	*Explore the various bio signal origin and its characteristics*	*3*	*2*	*1*	-	-	-	-	-	-	-	-	-	-	-	-
CO-2 :	*Implement various signal processing methods for analyzing the ECG signals.*	*2*	*3*	*1*	-	-	-	-	-	-	-	-	-	-	-	-
CO-3 :	*Analyze the EEG signal with suitable signal processing methods*	-	-	*3*	-	*2*	-	-	-	-	-	-	-	-	-	-
CO-4 :	*Execute EMG signal processing and its classification*	*2*	*3*	-	-		-	-	-	-	-	-	-	-	-	-
CO-5 :	*Enumerate on analysis of Heart rate variability and its methods*	*2*	*3*	-	-	*1*	-	-	-	-	-	-	-	-	-	-

Module-1 – Origin of Bioelectric signals and its characteristics	***9 Hour***
Action potential, electroneurogram (ENG), electromyogram (EMG) , electrocardiogram (ECG) , electroencephalogram (EEG) , Event-related potentials (ERPs), electrogastrogram (EGG), phonocardiogrann (PCG), Carotid pulse wave signal	
Module-2 – Analysis of ECG signals	***9 Hour***
ECG data acquisition system, Lead configuration of ECG, Detection of the P Wave, Template matching techniques, Derivative-based methods for QRS detection, Pan-Tompkins algorithm for QRS detection, Normal and Ectopic ECG Beats, Analysis of Exercise ECG, case studies: The effect of myocardial ischemia and infarction on QRS waveshape	
Module-3 – Analysis of EEG signals	***9 Hour***
EEG signal acquisition, 10- 20 electrode placement arrangement, EEG Signal and Its Characteristics, EEG Analysis, Linear Prediction Theory, EEG rhythms, waves, and transients, Correlation Analysis of EEG channels, EEG analysis -time and frequency domain methods: Adaptive Segmentation of EEG Signal	
Module-4 – Analysis of EMG signals	***9 Hour***

EMG: anatomical and physiological background, Electrical noise and factors affecting EMG signal, EMG signal detection, EMG signal decomposition, EMG signal processing methods, EMG signal classification
Module-5 – Heart rate variability analysis ***9 Hour***
Heart rate variability –Physiological origin, Generation of HRV, Clinical significance of HRV, Factors Influences on HRV, Time domain methods of HRV, Frequency domain Methods, Non-linear analysis of HRV, Pit falls in understanding HRV, Applications of HRV analysis

Learning Resources	*1. R M Rangayyan "Biomedical Signal Analysis: A case Based Approach", IEEE Press, John Wiley & Sons. Inc, 2002* *2. Willis J. Tompkins "Biomedical Digital Signal Processing", EEE, PHI, 2004*	*3. D C Reddy "Biomedical Signal Processing: Principles and Techniques", Tata McGraw-Hill Publishing Co. Ltd, 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. U. Snekhalatha*

Course Code	21MBM013F	Course Name	MULTI MODAL IMAGING SYSTEMS	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 :	Demonstrate the working of X-ray and Computed Tomography
CLR-2 :	Narrate the working principle of SPECT and PET
CLR-3 :	Describe the working of different modes of Ultrasound Imaging
CLR-4 :	Explain the working principle and reconstruction of MRI
CLR-5 :	Understand the basics of thermal imaging and optical imaging systems

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	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 :	Illustrate the Instrumentation of X-ray and Computed Tomography	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CO-2 :	Differentiate SPECT, PET and multimodal imaging modalities of SPECT/CT and PET/CT	2	3	2	-	-	-	-	-	-	1	-	-	-	-	-
CO-3 :	Analyze the working of the Ultrasound Imaging Instrument and its different modes of operation	2	-	-	3	2	-	-	-	-	-	-	-	-	-	-
CO-4 :	Explain the basic NMR principle and MRI Instrumentation	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-
CO-5 :	Enumerate the applications of thermal imaging and optical imaging	2	2	2	-	-	-	-	-	-	-	-	-	-	-	-

Module-1: X-Ray Planar Radiography and Computed Tomography	***9 Hour***
Interactions of X-rays with the body, X-ray linear and mass attenuation coefficients, Instrumentation for planar radiography, X-ray detectors, Clinical applications of planar X-ray imaging, Computed tomography, Instrumentation for CT, Image reconstruction in CT, Clinical applications of CT.	
Module-2: Nuclear Medicine: Planar Scintigraphy, SPECT and PET/CT	***9 Hour***
Radioactivity and radiotracer half-life, The gamma camera, Clinical applications of planar scintigraphy, Single photon emission computed tomography (SPECT), Positron emission tomography (PET), Data processing in SPECT and PET, SPECT/CT, PET/CT- Clinical applications	
Module-3: Ultrasound Imaging	***9 Hour***
Absorption and total attenuation of ultrasound, Ultrasound Instrumentation, Transducer arrays, Clinical diagnostic scanning modes, Doppler ultrasound for blood flow measurements, Ultrasound contrast agents, Safety guidelines in ultrasound imaging, Clinical applications of ultrasound, Artifacts in ultrasound imaging.	
Module-4: Magnetic Resonance Imaging (MRI)	***9 Hour***
MRI Image acquisition, Tissue relaxation times, MRI instrumentation, Image Reconstruction, Functional MRI, MRI contrast agents, Safety considerations – specific absorption rate (SAR), Clinical applications.	

Module-5: Infrared Thermography and Optical Imaging	***9 Hour***
Principles of Infrared Thermography, Thermal Cameras, Recent Advances in 3D Infrared Thermography, Applications of Infrared Thermography, Optical hybrid Imaging Modalities, Microscopy, Optical Coherence Tomography, Fluorescence Resonance Energy Transfer (FRET) Imaging, Applications of Optical Imaging	

Learning Resources	1. *Nadine Barrie Smith, Andrew Webb, "Introduction to medical imaging: Physics, Engineering and clinical applications", Cambridge University Press, 1st edition, 2010.* 2. *Jerry L. Prince, Jonathan M. Links, Medical Imaging Signals and Systems, Pearson Education, Inc., 1st edition ,2015.* 3. *R.S.Khandpur., 'Handbook of Biomedical instrumentation', Tata McGraw Hill Publishing Co Ltd., 3rd edition, 2014.*	4. *M. A. Flower (Editor). "Webb's Physics of Medical Imaging, Second Edition", CRC Press, Taylor& Francis Group, ISBN: 978-0-7503-0573-0, 2nd edition, 2016.* 5. *K. Kirk Shung, Michael Smith, Benjamin M.W. Tsui., "Principles of medical imaging", Academic Press, 1st edition, 2012*

Learning Assessment

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

Course Code	21MBM024E	Course Name	BIOMEDICAL MEASUREMENT SYSTEMS	Course Category	E	ELECTIVE 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 :	*Provide an insight into the basics of measurement system*
CLR-2 :	*Gain understanding about sensing technologies*
CLR-3 :	*Explore the various transducers used for measurement of physical quantities*
CLR-4 :	*Acquire knowledge on biosensors*
CLR-5 :	*Learn the advances in sensing technologies*

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 various terminologies associated with measurement system*	*1*	*2*	*-*	*-*	*3*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-2 :	*Explain the fundamentals of sensing technologies*	*1*	*3*	*-*	*-*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-3 :	*Select an appropriate transducer for an application*	*1*	*-*	*3*	*3*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-4 :	*Explain the various principles of bio sensing techniques*	*1*	*2*	*2*	*-*	*3*	*3*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-5 :	*Detail the various modern sensors used for measurement of physical quantities*	*1*	*-*	*2*	*2*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*

Module-1 - Basics of Measurement	***9 Hour***
Measurement terminologies, building blocks of measurement systems, Types of instruments, Errors in measurements, Classification of errors, Sources and methods of minimizing errors, Error analysis, Standards- Need and Classification	
Module-2 – Transducers	***9 Hour***
System architecture, Classification, Static and dynamic characteristics of transducers, Instrument calibration: Need and types	
Module-3 – Systems for Measurement of Physical Quantities	***9 Hour***
Temperature transducers: RTD, Thermistor, Thermocouple, Stress and strain measurement: Strain gauge, Load cell, Displacement transducer, Piezoelectric sensors, Optical Sensors	
Module-4 – Biosensors	***9 Hour***
Functional block diagram, Genesis, Classification, Unique characteristics of biosensors, Applications of Biosensors: Glucose measurement, Biochips	
Module-5 – Modern Sensing Technologies	***9 Hour***

Smart sensors: Architecture, salient features, advantages, applications, e- Nose: System design, applications, Lab on a chip: System design and applications, Fiber optic sensors: Principles and applications

Learning Resources	1. *Electronic Instrumentation, Electronics engineering series, Kalsi H S, Tata McGraw-Hill, 2004,* 2. *A.K. Sawhney: "A Course in Electrical and Electronic Measurements and Instrumentation", 18th Edition, Dhanpat Rai Publications, 2001.* 3. *David A Bell, "Electronic Instrumentation and Measurements", Second Edition, PHI, 2003* 4. *Joseph J.Carr, Elements of Electronics Instrumentation and Measurement, Third Edition, PearsonEducation, 2003*	5. *Leslie Cromwell, Biomedical Instrumentation and Measurement, Prentice Hall of India, New Delhi,2007.* 6. *M.Arumugam, 'Bio-Medical Instrumentation', Anuradha Agencies, 2003.* 7. *Khandpur R.S, Handbook of Biomedical Instrumentation, , Tata McGraw-Hill, New Delhi, 2 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. Kathirvelu D, SRMIST*

Course Code	21MBM025E	Course Name	MACHINE LEARNING AND PATTERN RECOGNITION	Course Category	E	ELECTIVE 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 :	*Understanding the basics of machine learning*
CLR-2 :	*Gaining the depth knowledge of supervised learning*
CLR-3 :	*Describe the various types of unsupervised learning*
CLR-4 :	*Outline the basics of pattern recognition*
CLR-5 :	*Demonstrate sequencial data and combining models*

		Program Outcomes (PO)												Program Specific Outcomes		
Course Outcomes (CO):	*At the end of this course, learners will be able to:*	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*	*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 :	*Enumerate the basics of machine learning technique*	3	-	-	-	-	-	-	-	-	-	-	1	-	-	-
CO-2 :	*Illustrate various types of supervised learning techniques*	2	1	1	-	-	-	-	-	-	-	-	2	-	-	-
CO-3 :	*Discuss the various types of unsupervised learning*	2	1	1	-	-	-	-	-	-	-	-	2	-	-	-
CO-4 :	*Analyze the basics of pattern recognition techniques*	3	-	2	-	2	-	-	-	-	-	-	3	-	-	-
CO-5 :	*Interpret the various types of sequential data and combining models*	3	-	1	-	2	-	-	-	-	-	-	2	-	-	-

Module-1 – Introduction to Machine learning	***9 Hour***
Introduction to machine learning, Types of learning: Supervised learning - Unsupervised learning - Reinforcement learning – selecting a model – predictive or descriptive models – training a model – holdout method – K -fold cross validation – bootstrap learning – lazy vs easy learner - learning via uniform convergence- over fitting - under fitting – bias variance tradeoff	
Module-2 - Supervised Learning	***9 Hour***
Regression Models: linear regression - logistic regression – Support Vector Regression (SVR) – Gaussian Process Regression (GPR) - decision trees – random forest - ensemble methods – classification Models: Support Vector Machine – discriminant analysis - Naïve Bayes model - nearest neighbor	
Module-3 - Unsupervised Learning	***9 Hour***
Dimensionality reduction - principal component analysis (PCA) -Applications of PCA, Kernel PCA independent component analysis - connectivity based clustering – hierarchical - distribution based clustering - density based clustering –- centroid based clustering - K-Means - grid based clustering.	
Module-4 – Pattern Recognition	***9 Hour***
Introduction, basic concepts, paradigm for pattern recognition and regression, Representations of Patterns and Classes, Metric and non-metric proximity measures, Feature extraction, Different approaches to Feature Selection, Bayes Classifier, Multi-layer Perceptron, Reinforcement Learning with Human Interaction	

Module-5 – Sequential Data and Combining Models	***9 Hour***
Basic Sampling Algorithms., Gibbs Sampling, Monte Carlo Model, , Hidden Markov Models, Linear Dynamical Systems, Bayesian Model Averaging, Boosting, Tree-based Models, Conditional Mixture Models	

Learning Resources	*1. C. Bishop, Pattern Recognition and Machine Learning (Information Science and Statistics), Springer, 2006.* *2. Tony J. Cleophas and Aeilko H. Zwinderman, "Machine Learning in Medicine – a Complete Overview", Springer,2015* *3. R. O. Duda,P.E. Hart and D. G.Stork,Pattern Classification, Wiley, 2000.*	*4. S. Theodoridis and K. Koutroumbas, Pattern Recognition, Academic Press, 2009* *5. E. Alpaydin, Introduction to Machine Learning, Prentice-Hall of India, 2010*

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. P.Lakshmi Prabha, SRMIST*

Course Code	21MBM026E	Course Name	BIOMEDICAL INFORMATICS	Course Category	E	ELECTIVE 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 :	*Elaborate the need and overview of Medical Informatics*
CLR-2 :	*Explore the Elements of Hospital and clinical Information systems and Health information Security*
CLR-3 :	*Illustrate Consumer health Informatics and Telemedicine technology*
CLR-4 :	*Apply different Computer assisted decision-making algorithms to healthcare*
CLR-5 :	*Describe the applications of various computer aids for handicapped and for care of critically ill patients*

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 :	*Create electronic health records and retrieve data and apply data analytics*	-	-	*1*	-	*3*	-	-	-	-	-	*1*	-	-	-	-
CO-2 :	*Develop packages for Hospital Information system and Clinical Information system*	-	-	*1*	-	*2*	*1*	-	-	-	-	-	*1*	-	-	-
CO-3 :	*Generate personal health records and web portals for telemedicine*	-	-	*2*	-	*2*	*1*	-	-	*1*	-	*1*	-	-	-	-
CO-4 :	*Apply different decision-making algorithm for diagnosis*	-	-	*1*	*1*	*2*	-	-	-	*1*	-		-	-	-	-
CO-5 :	*Design and develop various computer aids for handicapped and for care of critically ill patients*	-	-	*2*	-	-	-	-	-	-	-	*2*	-	-	-	-

Module-1: Medical Informatics and Healthcare Data Analytics	***9 Hour***
Biomedical Informatics & perspective, Overview of health informatics, medical informatics standards, Converting Data to Information to knowledge, Clinical Data warehouses, Complexity of knowledge Model, Electronic Health record, medical information retrieval techniques, Data analytics terminology and pipeline	
Module-2: Hospital Information System and Clinical Information System	***9 Hour***
Functional capabilities of computerized Hospital Information system, need for computerization oh hospitals in India, Benefits of clinical information system, Sources of data for decision making, Modes of decision output to Physician, Clinical Information system Examples, Health information privacy and security, Authentication and Identity management	
Module-3: Consumer Health Informatics and Telemedicine	***9 Hour***
Current state of consumer health Informatics, Classification of Consumer Health Informatics Applications, Health Education & Information Applications, Patient Web Portals, Personal Health Records (PHRs), Electronic Patient Physician Communication, Home Telemedicine Devices and Sensors, Telemedicine Communication modes, Telemedicine applications – Radiology, Pharmacy, Mental health	
Module-4: Computer Assisted Medical Decision Making	***9 Hour***

General model of CMD, Various approaches in decision making, Computer assisted decision support systems, Algorithmic methods, Elements of a protocol, Probabilistic approaches to decision making, Sequential Bayes, Linear discriminant function, Database comparisons and case-based reasoning, Production rule systems, Decision analysis in clinical medicine, Computerized decision support for mechanical ventilation
Module-5: Computer Aids for the Handicapped & Computers in the Care of Critically Ill Patients ***9 Hour***
Mobility, EMG controlled limbs, Aids for Blind and visually handicapped, Braille system, Computer aids for the deaf, Computer speech generation and recognition, Robotics to assist the elderly infirm, Automated computer assisted Fluid and metabolic balance, Computer assisted surgery, Robotics in surgery

Learning Resources	1. *Ramchandra Lele., "Computers in Medicine Progress in Medical Informatics", Tata McGraw-Hill Publishing Company Limited, New Delhi First Edition, 2005* 2. *Mohan Bansal, M S., "Medical Informatics A Primer", Tata McGraw-Hill Publishing Company Limited, New Delhi, 2nd edition 2003.*	3. *Robert E Hoyt, Ann Yoshihashi, "HEALTH INFORMATICS Practical Guide for Healthcare and Information Technology Professionals Sixth Edition Practical Guide for Healthcare and Information Technology Professionals", Sixth Edition, 2014.* 4. *Edward H.Shortliffe, James J. Climino., "Biomedical informatics Computer Applications in Health Care and Biomedicine", Springer, Third Edition, 2006.*

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. S. P. Angeline Kirubha*

Course Code	21MBM027E	Course Name	PHYSIOLOGICAL DATA ANALYTICS	Course Category	E	ELECTIVE COURSE	L	T	P	C
							2	1	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 :	*Able to apply fundamental data processing algorithms*
CLR-2 :	*Learn to build suitable data analysis models*
CLR-3 :	*Understand techniques to evaluate the models*
CLR-4 :	*Learn to use python programming language for data analysis*
CLR-5 :	*Outline the various text analysis tools and get basic understanding of Big Data*

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*	*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 various tools for data processing and analysis*	*3*	*2*	*-*	*-*	*1*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-2 :	*Identify suitable models for data analysis*	*1*	*3*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-3 :	*Infer and summarize the results of the data analysis models*	*1*	*3*	*-*	*-*	*2*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-4 :	*Execute the data analysis models in python programming language*	*-*	*2*	*-*	*-*	*3*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
CO-5 :	*Summarize the tools for text analysis and exemplify big data analysis*	*3*	*2*	*1*	*1*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*

Module-1 – Exploratory Data Analytics	***9 Hour***
Descriptive Statistics – Mean, Standard Deviation, Skewness and Kurtosis – Box Plots – Pivot Table – Heat Map – Correlation Statistics, Probability Distributions, Inferential Statistics, Inferential Statistics through hypothesis tests, Regression & ANOV, Regression ANOVA (Analysis of Variance)	
Module-2 – Model Development	***9 Hour***
Simple and Multiple Regression – Model Evaluation using Visualization – Residual Plot – Distribution Plot – Polynomial Regression and Pipelines – Measures for In-sample Evaluation – Prediction and Decision Making	
Module-3 – Model Evaluation	***9 Hour***
Generalization Error – Out-of-Sample Evaluation Metrics – Cross Validation – Overfitting – Under Fitting and Model Selection – Prediction by using Ridge Regression – Testing Multiple Parameters by using Grid Search	
Module-4 - Data analytics and Visualization with Python	***9 Hour***
Essential Data Libraries for data analytics: Pandas, NumPy, SciPy. Plotting and visualization with python: Introduction to Matplotlib, Basic Plotting with Matplotlib, Create Histogram, Bar Chart, Pie chart, Box Plot, violin plot using Matplotlib. Introduction to seaborn Library, Multiple Plots, Regression plot, regplot.	
Module-5 – Text Analytics and Big Data	***9 Hour***
History of text mining, Roots of text mining overview of seven practices of text analytic, Application and use cases for Text mining: extracting meaning from unstructured text, Summarizing Text Text	

Analysis Steps, A Text Analysis Example , Collecting Raw Text ,Representing Text ,Term Frequency—Inverse Document Frequency (TFIDF),Categorizing Documents by Topics, Determining Sentiments, Gaining Insights .Big Data and its Importance, Four V's of Big Data, Drivers for Big Data, Introduction to Big Data Analytics, Big Data Analytics applications,

Learning Resources	1. *Data Science and Big Data Analytics: Discovering, Analyzing, Visualizing and Presenting Data, EMC Education services Wiley Publication.* 2. *Data Analytics using Python: Bharati Motwani, Wiley Publications.*	3. *Practical Text Mining and statistical Analysis for non-structured text data applications,1st edition, Grey Miner, Thomas Hill.* 4. *Python for Data Analysis: 3rd Edition, Wes McKinney, Publisher(s): O'Reilly Media, Inc.*

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. T. Jayanthi*

Course Code	21MBM028E	Course Name	PRINCIPLES OF MEDICAL IMAGING	Course Category	E	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 :	*Describe the principles of different image reconstruction algorithms*
CLR-2 :	*Examine the effectiveness of various preprocessing and segmentation techniques*
CLR-3 :	*Explain image registration techniques to align images from different modalities*
CLR-4 :	*Apply image Interpretation in Clinical Practice*
CLR-5 :	*Analyze emerging trends on future medical imaging practices*

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 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 :	*Analyze the principles of sampling and quantization in image acquisition*	*3*	-	-	-	-	-	-	-	-	-	-	*2*	-	-	-
CO-2 :	*Explain the importance of noise reduction, contrast enhancement, and normalization in medical images*	*2*	-	-	-	-	-	-	-	-	-	-	*1*	-	-	-
CO-3 :	*Examine the accuracy of different registration and fusion methods*	*2*	-	-	-	-	-	-	-	-	-	-	*1*	-	-	-
CO-4 :	*Describe the steps involved in adhering to image interpretation guidelines and protocols.*	*2*	-	-	-	-	-	-	-	-	-	-	*1*	-	-	-
CO-5 :	*Apply knowledge of clinical validation and integration processes to assess the effectiveness of new image processing technologies*	*3*	-	-	-	-	*1*	-	-	-	-	-	-	-	-	-

Module-1: Image Acquisition and Reconstruction	***9 Hour***
Overview of medical imaging - History and evolution - Importance and applications in medicine - Image Reconstruction Algorithms - Filtered back projection - Iterative reconstruction techniques - Fourier transforms in image reconstruction - Algebraic reconstruction techniques (ART)	
Module-2: Medical Image Processing Techniques	***9 Hour***
Preprocessing and Enhancement - Noise reduction techniques - Contrast enhancement methods - Image normalization and standardization - Segmentation Techniques - Thresholding methods - Region-based segmentation - Edge detection - Watershed algorithm - Feature Extraction and Representation - Texture analysis - Shape and size analysis - Feature space and dimensionality reduction - Principal Component Analysis (PCA)	
Module-3: Advanced Medical Image Analysis	***9 Hour***
Registration and Fusion - Image registration techniques - Rigid and non-rigid transformations - Multimodal image fusion - Pattern Recognition and Classification - Machine learning in medical imaging - Supervised and unsupervised learning - Deep learning applications - Quantitative Image Analysis – Radiomics - Image-based biomarkers - Statistical analysis of imaging data	

Module-4: Image Interpretation and Visualization in Medical Imaging	***9 Hour***
Image Interpretation in Clinical Practice - Diagnostic Criteria and Protocols - Standardized reporting systems - Image interpretation guidelines and best practices - Interactive and Automated Visualization Systems - Real-time image manipulation and analysis - Automated Visualization Systems - Automated detection and quantification tools	
Module-5: Applications and Emerging Trends in Medical Imaging	***9 Hour***
Clinical Applications of image processing technologies - Validation and clinical integration - Case studies and examples - Emerging Trends and Future Directions - AI and machine learning in imaging - 3D and 4D imaging - Portable and point-of-care imaging - Ethical and regulatory considerations in medical imaging	

Learning Resources	1. *David Sutton, Bharat Aggarwal, Textbook of Radiology and Imaging, 8th Edition, Elsevier, 2023.* 2. *Andreas Adam, Adrian K. Dixon, Jonathan H. Gillard, Cornelia M. Schaefer-Prokop, Grainger & Allison's Diagnostic Radiology: A Textbook of Medical Imaging, 7th Edition, Elsevier, 2021.* 3. *Jerrold T. Bushberg, J. Anthony Seibert, Edwin M. Leidholdt Jr., John M. Boone, The Essential Physics of Medical Imaging, 4th Edition, Lippincott Williams & Wilkins, 2020.*	4. *Paul Suetens, Fundamentals of Medical Imaging, 3rd Edition, Cambridge University Press, 2019* 5. *Penelope J. Allisy-Roberts, Jerry Williams, Farr's Physics for Medical Imaging, 3rd Edition, Elsevier, 2019.*

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. P.Muthu, SRMIST*

Course Code	21MBM029E	Course Name	REGULATORY AFFAIRS IN MEDICAL DEVICES	Course Category	E	ELECTIVE 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 regulations, risk management, and lifecycle of medical devices.*
CLR-2 :	*Learn ISO 13485 QMS for medical device quality assurance.*
CLR-3 :	*Develop awareness of risk principles and safety regulations.*
CLR-4 :	*Summarize design and development stages for medical devices.*
CLR-5 :	*Understand post-market surveillance and global regulatory requirements.*

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*	*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 :	*Understand and manage regulations, safety, and development of medical devices.*	*3*	-	*1*	-	-	*2*	-	*3*	*1*	*2*	-	*2*	-	-	-
CO-2 :	*Achieve QMS compliance, improve product quality, and maintain safety.*	*3*	-	*2*	*2*	-	-	*1*	*2*	*1*	-	*2*	-	-	-	-
CO-3 :	*Implement risk management for medical device safety.*	*3*	-	*2*	*2*	-	-	-	-	*1*	-	*2*	-	-	-	-
CO-4 :	*Plan effectively, comply with regulations, and develop successful products.*	*2*	-	*2*	-	*1*	-	*2*	-	*1*	*2*	-	-	-	-	-
CO-5 :	*Manage effective PMS implementation, compliance, and product safety enhancement.*	*3*	-	*2*	-	*1*	-	-	-	*1*	-	-	-	-	-	-

Module-1 –Regulatory Framework ***9 Hour***

Regulatory Framework- Conformity Assessment Bodies (CABs) – National and International Accreditation Bodies- Medical Devices - Country-based definition and classification– Medical Device Life cycle – Medical Devices, In-vitro devices, Biologics and Combination products – Risk Management of medical device.

Module-2 – Quality Management of Medical Devices ***9 Hour***

Quality Management System (QMS) - Scope of ISO 13485 - Clauses of ISO 13485 - Management Responsibility - Resource Management - Product Realization Planning - Customer-Related Processes. Design and Development Processes: Planning - Inputs - Outputs - Review -Verification - Validation - Transfer –Control of Monitoring and Measuring Equipment: Requirements for a calibration procedure - Calibration intervals and standards -Adjusting calibration equipment - Identifying calibration status - Safeguarding and protecting equipment - Documenting calibration procedures & CAPA

Module-3 – Risk Management of Medical Devices ***9 Hour***

Introduction to Risk (ISO 14971) – Importance of Risk in medical devices – Regulations and standards in Risk management - Principle of Risk – Risk Management process: Risk Management Planning- Risk Analysis - Risk Evaluation - Risk Controls - Overall Residual Risk Acceptability -Risk Management Review -Production & Post-Production Information. Design failure modes and effects analysis (DFMEA)- Process failure modes and effects analysis. Case study of risk management of medical devices.

Module-4 – Medical Device Management Process	***9 Hour***
Design & Development introduction and stages - Planning Stage: Purpose - Scope -Intended use – Principle of operation- comparison to predictive device – risk classification – clinical and regulatory Strategy – standards and guidelines. Process stage: Design Inputs - User needs - Common mistakes when defining user needs - Design input requirements - Multi-level requirements - Master V&V Plan - Design Outputs - Verification & Validation - Design Transfer. Product Identification and Traceability: Product Identifiers Software Identifiers - Product Grouping - Unique Device Identifier - Case Study of medical devices in pre-market phase.	
Module-5 –Post-Market Phase and Country Regulatory requirements	***9 Hour***
Product registration: FDA - 510(k), PMA approval - EU-MDR (CE Marking) - Health Canada License -CDCSO registration guidelines- Indian medical device rule 2017 - License renewals - Establishment registration - Introduction to Post-market surveillance (PMS) in medical devices – Importance of PMS- Key components of PMS – Reactive and proactive PMS – MDR requirements- Vigilance.	

Learning Resources	1. *Theisz, Val. Medical device regulatory practices: An international perspective, 2015, New York, Jenny Stanford Publishing, (1st Edition)* 2. *Jack Wong & Raymond Tong, Medical Regulatory Affairs: An International Handbook for Medical Devices and Healthcare Products, 3rd Edition, Jenny Stanford Publishing, 2022.*	3. *Handbook of Medical Device Regulatory Affairs in Asia, Second Edition, edited by Jack Wong, Raymond K. Y. Tong, 2018, Pan Stanford Publishing Pte. Ltd.*

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. N Ashwin Kumar, SRMIST*