SRM INSTITUTE OF SCIENCE AND TECHNOLOGY, RAMAPURAM CAMPUS, CHENNAI- 89

FACULTY OF ENGINEERING AND TECHNOLOGY

DEPARTMENT OF BIOMEDICAL ENGINEERING

VALUE ADDED COURSE

OVERVIEW

The medical devices and healthcare industry is witnessing transformation due to converging technologies, evolving regulatory compliances, and changing market demands. Medical devices are becoming more connected than ever and are shaping new solutions to offer value for healthcare such as improved quality of life for patients with chronic illness, reduced cost of treatment, and more. The changing technology makes it imperative for medical devices companies to adopt a strategic approach by leveraging technology advancements in multiple areas such as IoT, cloud, AI, and analytics to drive innovation that addresses market needs and challenges.

Capgemini's medical device engineering practice brings solutions and services that help our clients in designing customized devices with end-to-end product development and collaborate through the complete medical device valuechain. We also help clients retain their competitive edge by leveraging new technologies to optimize R&D costs and productivity, reduce time-to-market, improve supply chain efficiencies, strengthen partner ecosystem, and proactivelyseek new opportunities.

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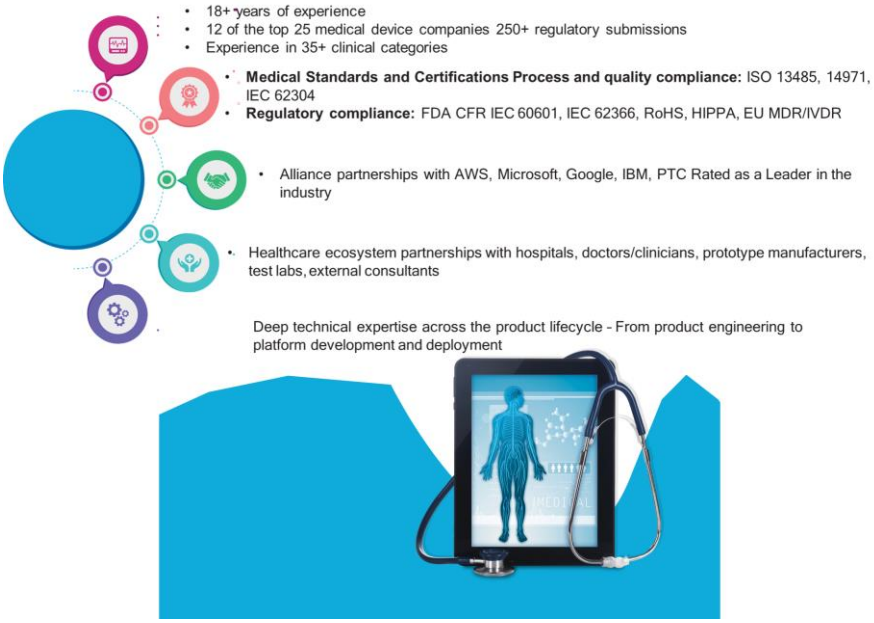

COURSES DETAILS

Department of biomedical engineering by collaborating with Capgemini offers the value-added course for the third year Biomedical Engineering students of SRMIST, Ramapuram campus for the current even Semester academic year (2022-2023 Even Semester). This offer is given for the students who have opted for Superset placement students.

The details are attached below:

The course details are as follows:

Course Code: 18BMV471T

Course Name: Requirement Engineering and Medical Devices

Total No of students opted: 20Nos

COURSE DESCRIPTION

This online course begins with an introduction to the fundamental concepts of requirements engineering and how they relate to medical device design. Participants will learn how to define user needs and translate them into design input requirements that meet the needs of patients, healthcare providers, regulators and other key stakeholders.

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The course is designed for medical device engineers who want to gain a deep understanding of the principles and practices of requirements engineering. It is based on requirements engineering best practices, ISO 13485 and QSR requirements and it covers the entire process of requirements engineering from user needs to design input requirements. The course also covers the importance of traceability.

LIST OF STUDENTS ENROLLED FOR THIS COURSE

S.NO	NAME OF THE STUDENT	REGISTER NUMBER
1	NITHIESH RAJAN N B	RA2011013020001
2	ARTHI T	RA2011013020004
3	KEERTHANA R	RA2011013020008
4	LOKESH KUMAR R	RA2011013020010
5	NEESANTHI M	RA2011013020013
6	IMMACULATE SUSAN A	RA2011013020014
7	ARSHWATHA NIVETHA R	RA2011013020020
8	ROSHINI M	RA2011013020022
9	MEENA SHRINIDHI A	RA2011013020024
10	CHANDRU R P	RA2011013020026
11	PAVITHRA K	RA2011013020029
12	YUTHIKA K	RA2011013020030
13	VARUNRAMANAN R	RA2011013020033
14	V SRIHAARUNI M VARADARAJAN	RA2011013020036
15	AARTHY V	RA2011013020038
16	KONDAPALLY SAI CHARAN	RA2011013020039
17	NANDHU SURESH	RA2011013020042
18	MUSKAN RATHI	RA2011013020045
19	ISHFA BALKEES FATHIMA M	RA2011013020047
20	ABARNISHA S	RA2011013020052

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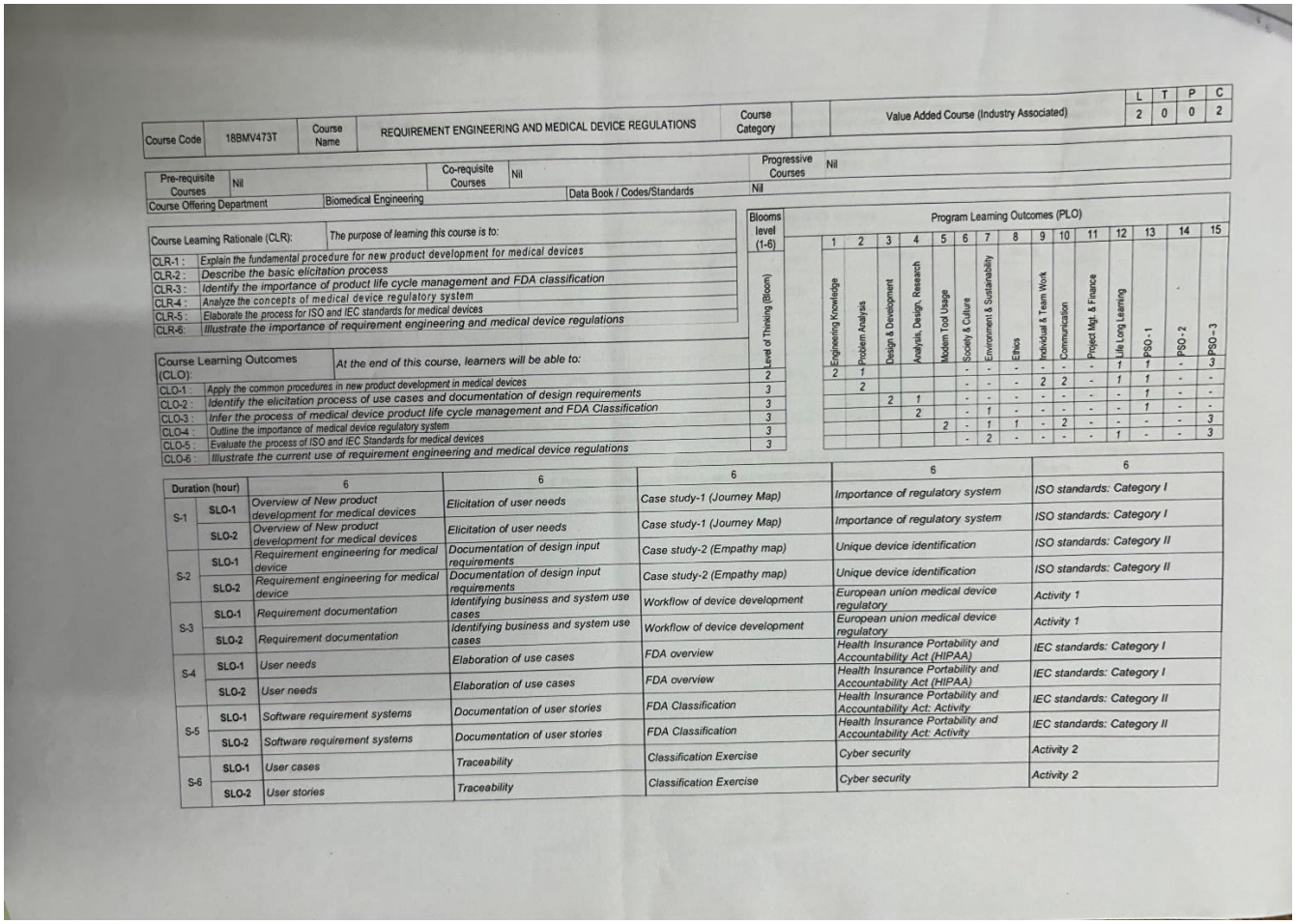
COURSE SYLLABUS



Course Code	18BMV473T	Course Name	REQUIREMENT ENGINEERING AND MEDICAL DEVICE REGULATIONS	Course Category	Value Added Course (Industry Associated)	L	T	P	C
						2	0	0	2

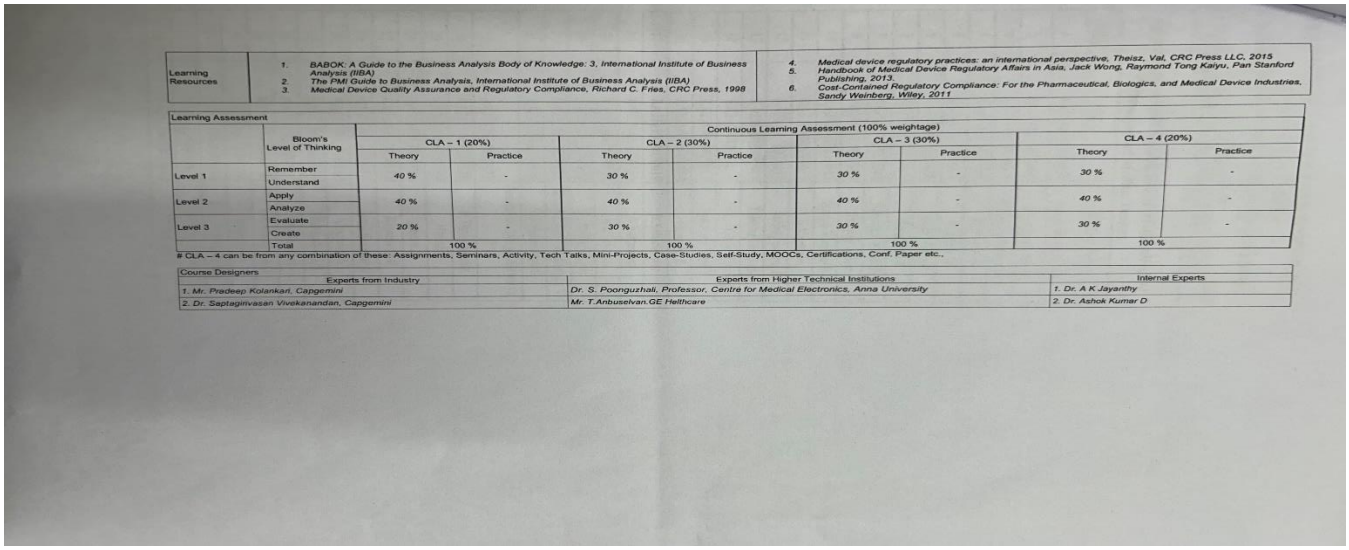
Pre-requisite Courses	Nil	Co-requisite Courses	Nil	Progressive Courses	Nil
Course Offering Department	Biomedical Engineering	Data Book / Codes/Standards		Nil	

Course Learning Rationale (CLR):	The purpose of learning this course is to:	Blooms level (1-6)
CLR-1 :	Explain the fundamental procedure for new product development for medical devices	
CLR-2 :	Describe the basic elicitation process	
CLR-3 :	Identify the importance of product life cycle management and FDA classification	
CLR-4 :	Analyze the concepts of medical device regulatory system	
CLR-5 :	Elaborate the process for ISO and IEC standards for medical devices	
CLR-6:	Illustrate the importance of requirement engineering and medical device regulations	

Course Learning Outcomes (CLO):	At the end of this course, learners will be able to:	Level of Thinking (Bloom)
CLO-1 :	Apply the common procedures in new product development in medical devices	2
CLO-2 :	Identify the elicitation process of use cases and documentation of design requirements	3
CLO-3 :	Infer the process of medical device product life cycle management and FDA Classification	3
CLO-4 :	Outline the importance of medical device regulatory system	3
CLO-5 :	Evaluate the process of ISO and IEC Standards for medical devices	3
CLO-6 :	Illustrate the current use of requirement engineering and medical device regulations	3

		1 Engineering Knowledge	2 Problem Analysis	3 Design & Development	4 Analysis, Design, Research	5 Modern Tool Usage	6 Society & Culture	7 Environment & Sustainability	8 Ethics	9 Individual & Team Work	10 Communication	11 Project Mgt. & Finance	12 Life Long Learning	13 PSO - 1	14 PSO - 2	15 PSO - 3
CLO-1		2	1				-	-	-	-	-	-	1	1	-	3
CLO-2			2				-	-	-	2	2	-	1	1	-	-
CLO-3				2	1		-	-	-	-	-	-	-	1	-	-
CLO-4					2		-	1	-	-	-	-	-	1	-	-
CLO-5						2	-	1	1	-	2	-	-	-	-	3
CLO-6							-	2	-	-	-	-	1	-	-	3

Duration (hour)		6	6	6	6	6
S-1	SLO-1	Overview of New product development for medical devices	Elicitation of user needs	Case study-1 (Journey Map)	Importance of regulatory system	ISO standards: Category I
	SLO-2	Overview of New product development for medical devices	Elicitation of user needs	Case study-1 (Journey Map)	Importance of regulatory system	ISO standards: Category I
S-2	SLO-1	Requirement engineering for medical device	Documentation of design input requirements	Case study-2 (Empathy map)	Unique device identification	ISO standards: Category II
	SLO-2	Requirement engineering for medical device	Documentation of design input requirements	Case study-2 (Empathy map)	Unique device identification	ISO standards: Category II
S-3	SLO-1	Requirement documentation	Identifying business and system use cases	Workflow of device development	European union medical device regulatory	Activity 1
	SLO-2	Requirement documentation	Identifying business and system use cases	Workflow of device development	European union medical device regulatory	Activity 1
S-4	SLO-1	User needs	Elaboration of use cases	FDA overview	Health Insurance Portability and Accountability Act (HIPAA)	IEC standards: Category I
	SLO-2	User needs	Elaboration of use cases	FDA overview	Health Insurance Portability and Accountability Act (HIPAA)	IEC standards: Category I
S-5	SLO-1	Software requirement systems	Documentation of user stories	FDA Classification	Health Insurance Portability and Accountability Act: Activity	IEC standards: Category II
	SLO-2	Software requirement systems	Documentation of user stories	FDA Classification	Health Insurance Portability and Accountability Act: Activity	IEC standards: Category II
S-6	SLO-1	User cases	Traceability	Classification Exercise	Cyber security	Activity 2
	SLO-2	User stories	Traceability	Classification Exercise	Cyber security	Activity 2



Learning Resources	1. BABOK: A Guide to the Business Analysis Body of Knowledge: 3, International Institute of Business Analysis (IIBA) 2. The PMI Guide to Business Analysis, International Institute of Business Analysis (IIBA) 3. Medical Device Quality Assurance and Regulatory Compliance, Richard C. Fries, CRC Press, 1998 4. Medical device regulatory practices: an international perspective, Theisz, Val, CRC Press LLC, 2015 5. Handbook of Medical Device Regulatory Affairs in Asia, Jack Wong, Raymond Tong Kaiyu, Pan Stanford Publishing, 2013. 6. Cost-Contained Regulatory Compliance: For the Pharmaceutical, Biologics, and Medical Device Industries, Sandy Weinberg, Wiley, 2011

Learning Assessment

	Bloom's Level of Thinking	Continuous Learning Assessment (100% weightage)							
		CLA – 1 (20%)		CLA – 2 (30%)		CLA – 3 (30%)		CLA – 4 (20%)	
		Theory	Practice	Theory	Practice	Theory	Practice	Theory	Practice
Level 1	Remember	40 %	-	30 %	-	30 %	-	30 %	-
	Understand								
Level 2	Apply	40 %	-	40 %	-	40 %	-	40 %	-
	Analyze								
Level 3	Evaluate	20 %	-	30 %	-	30 %	-	30 %	-
	Create								
	Total	100 %		100 %		100 %		100 %	

CLA – 4 can be from any combination of these: Assignments, Seminars, Activity, 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
1. Mr. Pradeep Kolankari, Capgemini	Dr. S. Poonguzhali, Professor, Centre for Medical Electronics, Anna University	1. Dr. A K Jayanthy
2. Dr. Saptagirivasan Vivekanandan, Capgemini	Mr. T.Anbuselvan.GE Helthcare	2. Dr. Ashok Kumar D