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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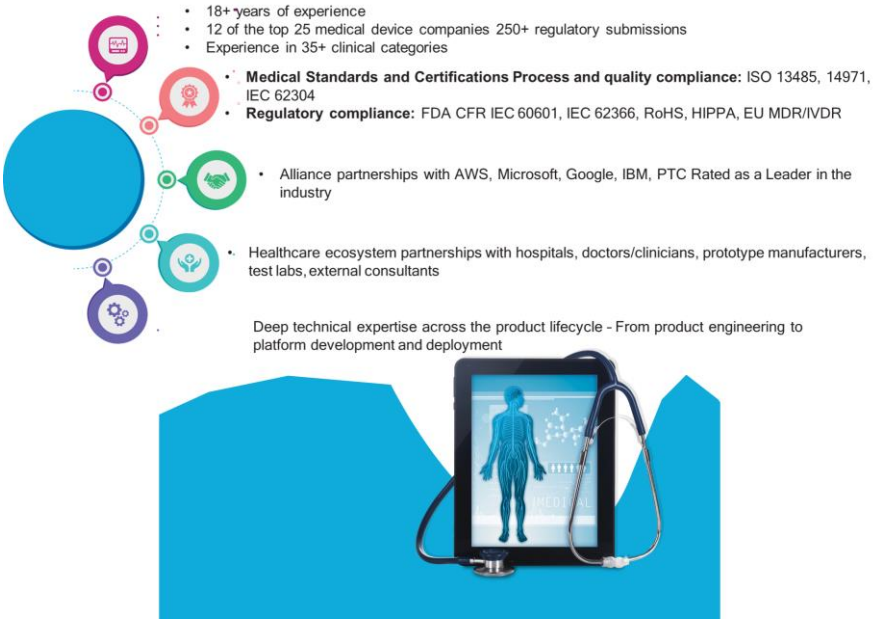

COURSES DETAILS

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 (2023-2024 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: 44Nos.

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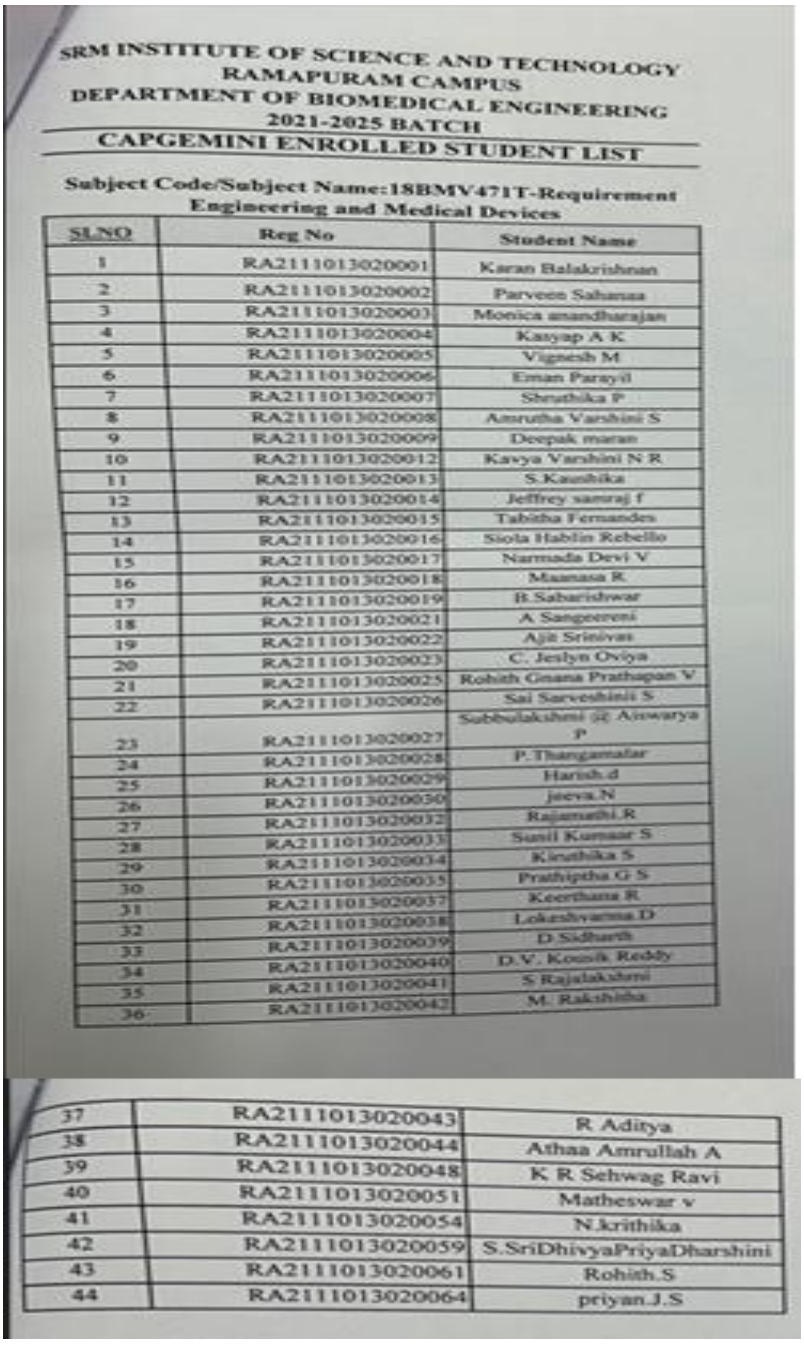
The course is designed for medical device engineers who want to gain a deep understanding of the principles and practices of requirements engineering. It is based on requirements engineering best practices, ISO 13485 and QSR requirements and it covers the entire process of requirements engineering from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

LIST OF STUDENTS ENROLLED FOR THIS COURSE



SRM INSTITUTE OF SCIENCE AND TECHNOLOGY
RAMAPURAM CAMPUS
DEPARTMENT OF BIOMEDICAL ENGINEERING
2021-2025 BATCH
CAPGEMINI ENROLLED STUDENT LIST

Subject Code/Subject Name:18BMV471T-Requirement Engineering and Medical Devices

SLNO	Reg No	Student Name
1	RA2111013020001	Karan Balakrishnan
2	RA2111013020002	Parveen Sahanaa
3	RA2111013020003	Monica anandharajan
4	RA2111013020004	Kavyap A K
5	RA2111013020005	Vignesh M
6	RA2111013020006	Eman Parayil
7	RA2111013020007	Shruthika P
8	RA2111013020008	Amrutha Varshini S
9	RA2111013020009	Deepak maran
10	RA2111013020012	Kavya Varshini N R
11	RA2111013020013	S.Kaushika
12	RA2111013020014	Jeffrey samraj f
13	RA2111013020015	Tabitha Fernandes
14	RA2111013020016	Siola Hablin Rebello
15	RA2111013020017	Narmada Devi V
16	RA2111013020018	Maanasa R
17	RA2111013020019	B.Sabarishwar
18	RA2111013020021	A Sangeeveni
19	RA2111013020022	Ajit Srinivas
20	RA2111013020023	C. Jeslyn Oviya
21	RA2111013020025	Rohith Gnana Prathapan V
22	RA2111013020026	Sai Sarveshinii S
23	RA2111013020027	Subbulakshmi @ Aiswarya P
24	RA2111013020028	P.Thangamalar
25	RA2111013020029	Harish.d
26	RA2111013020030	jaeva.N
27	RA2111013020032	Rajamathi.R
28	RA2111013020033	Sunil Kumaar S
29	RA2111013020034	Kiruthika S
30	RA2111013020035	Prathiptha G S
31	RA2111013020037	Keerthana R
32	RA2111013020038	Lokeshvarma.D
33	RA2111013020039	D.Sidharth
34	RA2111013020040	D.V. Kousik Reddy
35	RA2111013020041	S Rajalakshmi
36	RA2111013020042	M. Rakshitha
37	RA2111013020043	R Aditya
38	RA2111013020044	Athaa Amrullah A
39	RA2111013020048	K R Sehwag Ravi
40	RA2111013020051	Matheswar v
41	RA2111013020054	N.krithika
42	RA2111013020059	S.SriDhivyaPriyaDharshini
43	RA2111013020061	Rohith.S
44	RA2111013020064	priyan.J.S

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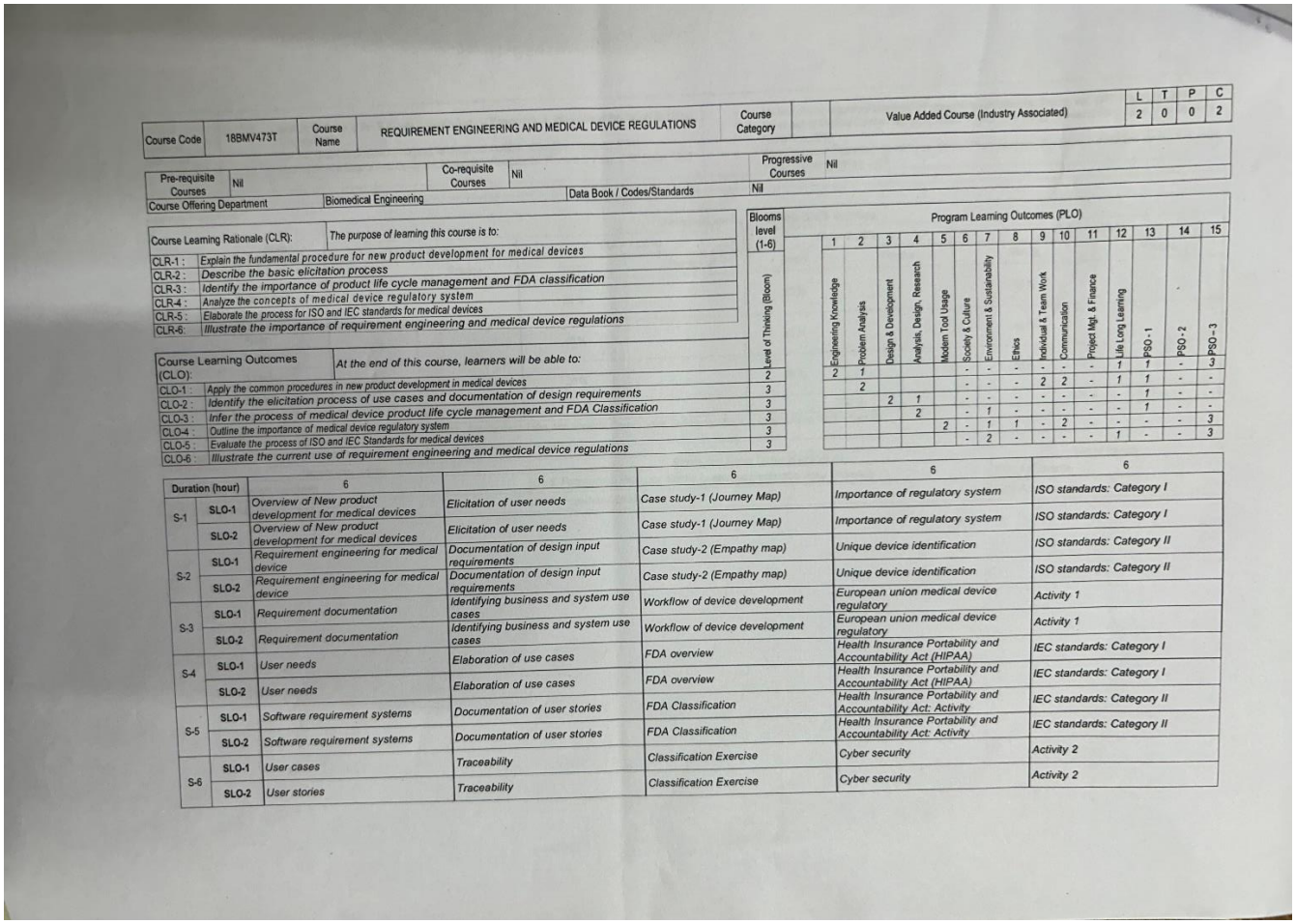
COURSE SYLLABUS



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

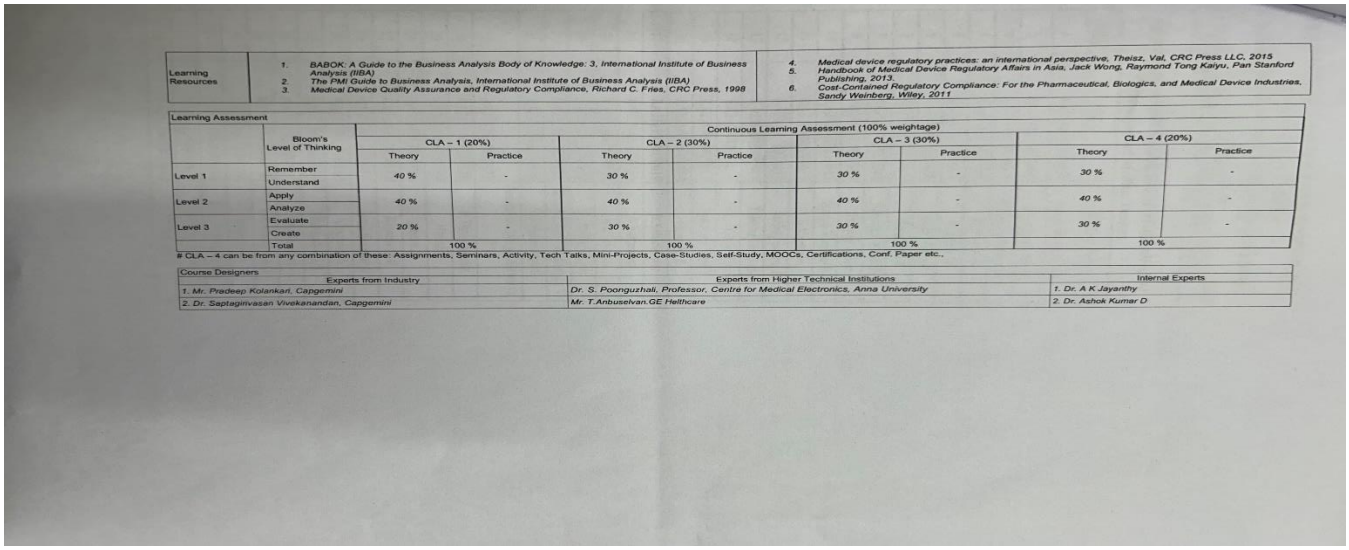
Pre-requisite Courses	Nil	Co-requisite Courses	Nil	Progressive Courses	Nil
Course Offering Department	Biomedical Engineering	Data Book / Codes/Standards		Nil	

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