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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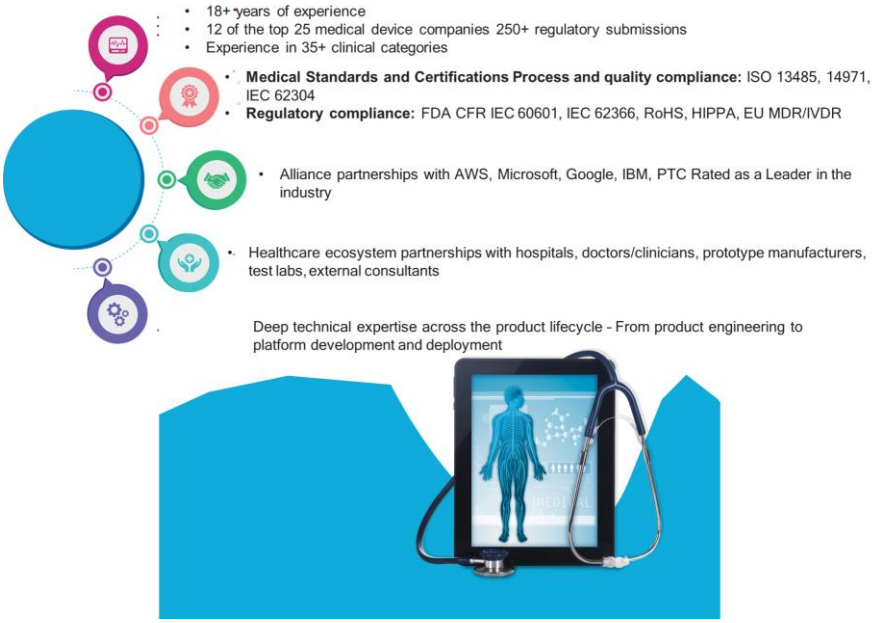

COURSES DETAILS

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 (2023-24 Odd 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: 18BMV0602T

Course Name: Verification and Validation of Medical Devices

Total No of students opted: 25Nos.

COURSE DESCRIPTION

This online & Self-Paced Training Course is focused on Medical Device Software Verification and Validation, according to the requirements of IEC 62304, IEC 82304-1 and EU MDR 2017/745. The aim of the course is to enable manufacturers to know what process validation evidence is necessary to demonstrate the manufacturing process is validated. This training

course has been designed to give manufacturers an awareness of EU regulatory and quality requirements regarding manufacturing process validation and the nature of 'special processes.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Appreciate concepts and rationale of manufacturing process validation • Recognize the importance of manufacturing process validation • Gain awareness of relevant ISO 13485:2016 expectations and IMDRF guidance (previously GHTF) • Recognize situations where a manufacturing process requires validation • Have the tools to create a Master Validation Plan and validation protocols • Define objectives of equipment and process validations • Recognize relevant and pertinent factors of manufacturing process validation studies • Plan for worst case conditions and challenges • Identify how process capability studies can be used to validate manufacturing processes • Complete installation, operational and performance qualification • Maintain a state of validation • Recognize when revalidation may be required	This course will help you to: • Understand manufacturing process validation • Improve your understanding of the Medical Device Regulation (MDR) and quality standards requirements relating to manufacturing process validation • Be able to apply your knowledge to your organization, to enable it to produce compliant devices • Ensure auditable technical documentation meets applicable EU regulatory requirements

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LIST OF STUDENTS ENROLLED FOR THIS COURSE

SRM Institute of Science & Technology

Faculty of Engineering & Technology

Department of Biomedical Engineering

ACADEMIC YEAR (2023-2024)

IV Year BME (2020-2024)BATCH

PLACEMENT STUDENTS(SUPERSET CATEGORY)

ENROLLED FOR CAPGEMINI COURSE

(BMV0602T-Verification and Validation of Medical Devices)

S.No	Register No	Name of the student
1	RA2011013020001	NITHIESH RAJAN N B
2	RA2011013020004	ARTHI T
3	RA2011013020007	RAKESH KUMAR K S
4	RA2011013020008	KEERTHANA R
5	RA2011013020010	LOKESH KUMAR R
6	RA2011013020013	NEESANTHI M
7	RA2011013020014	IMMACULATE SUSAN A
8	RA2011013020015	JASON ANTHONY J
9	RA2011013020017	SABRINA SAURIYATH A
10	RA2011013020019	MOHAMED SABIR HUSSAIN S
11	RA2011013020020	ARSHWATHA NIVETHA R
12	RA2011013020022	ROSHINI M
13	RA2011013020023	SHONELLE ANDREA MORAIS
14	RA2011013020026	CHANDRU R P
15	RA2011013020027	PRIYAMVADA J MENON
16	RA2011013020028	RITHIKA TAMIL
17	RA2011013020029	PAVITHRA K
18	RA2011013020030	YUTHIKA K
19	RA2011013020033	VARUNRAMANAN R
20	RA2011013020034	GIRIDHARAN K
21	RA2011013020036	V SRIHAARUNI M VARADARAJAN
22	RA2011013020038	AARTHY V
23	RA2011013020042	NANDHU SURESH
24	RA2011013020047	ISHFA BALKEES FATHIMA M
25	RA2011013020052	ABARNISHA S

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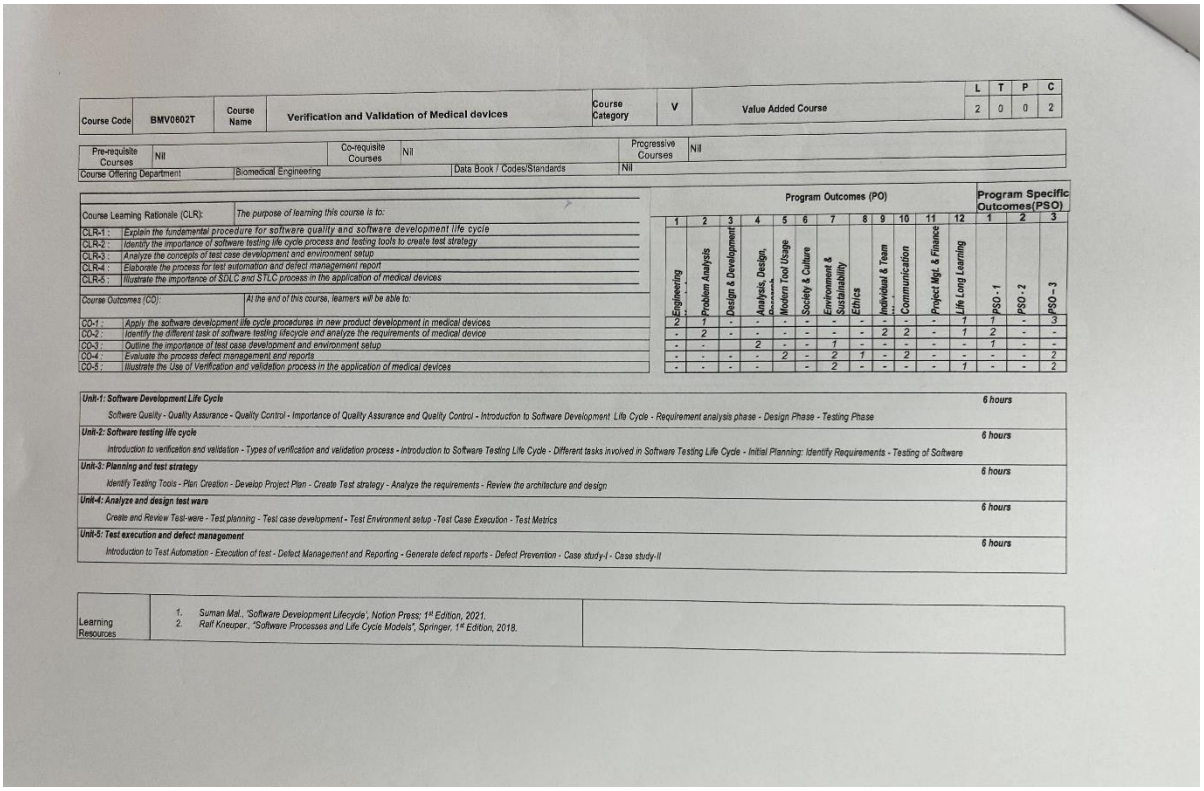
COURSE SYLLABUS



Course Code	BMV0602T	Course Name	Verification and Validation of Medical devices	Course Category	V	Value Added Course	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		

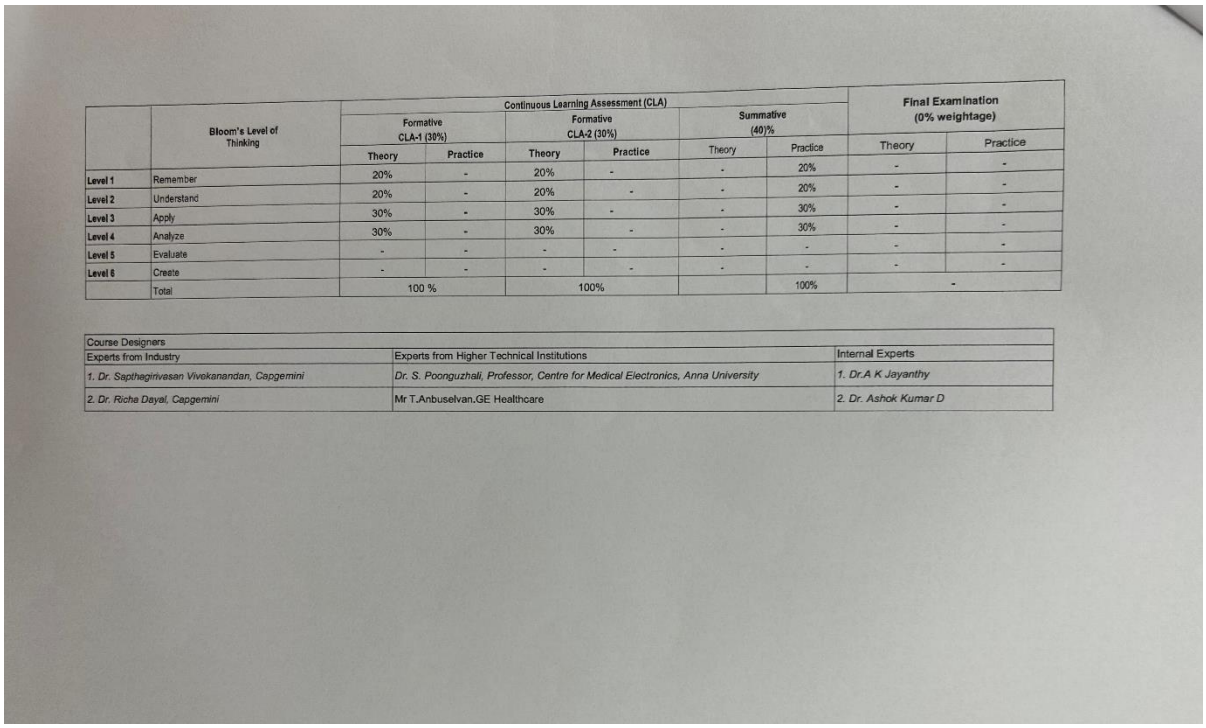
Course Learning Rationale (CLR):	The purpose of learning this course is to:
CLR-1 :	Explain the fundamental procedure for software quality and software development life cycle
CLR-2 :	Identify the importance of software testing life cycle process and testing tools to create test strategy
CLR-3 :	Analyze the concepts of test case development and environment setup
CLR-4 :	Elaborate the process for test automation and defect management report
CLR-5 :	Illustrate the importance of SDLC and STLC process in the application of medical devices

Course Outcomes (CO):	At the end of this course, learners will be able to:
CO-1 :	Apply the software development life cycle procedures in new product development in medical devices
CO-2 :	Identify the different task of software testing lifecycle and analyze the requirements of medical device
CO-3 :	Outline the importance of test case development and environment setup
CO-4 :	Evaluate the process defect management and reports
CO-5 :	Illustrate the Use of Verification and validation process in the application of medical devices

	Program Outcomes (PO)												Program Specific Outcomes(PSO)		
	1 Engineering	2 Problem Analysis	3 Design & Development	4 Analysis, Design,	5 Modern Tool Usage	6 Society & Culture	7 Environment & Sustainability	8 Ethics	9 Individual & Team	10 Communication	11 Project Mgt. & Finance	12 Life Long Learning	1 PSO - 1	2 PSO - 2	3 PSO - 3
CO-1 :	2	1	-	-	-	-	-	-	-	-	-	1	1	-	3
CO-2 :	-	2	-	-	-	-	-	-	2	2	-	1	2	-	-
CO-3 :	-	-		2	-	-	1	-	-	-	-	-	1	-	-
CO-4 :	-	-	-	-	2	-	2	1	-	2	-	-	-	-	2
CO-5 :	-	-	-	-		-	2	-	-	-	-	1	-	-	2

Unit-1: Software Development Life Cycle		***6 hours***
	Software Quality - Quality Assurance - Quality Control - Importance of Quality Assurance and Quality Control - Introduction to Software Development Life Cycle - Requirement analysis phase - Design Phase - Testing Phase	
Unit-2: Software testing life cycle		***6 hours***
	Introduction to verification and validation - Types of verification and validation process - Introduction to Software Testing Life Cycle - Different tasks involved in Software Testing Life Cycle - Initial Planning: Identify Requirements - Testing of Software	
Unit-3: Planning and test strategy		***6 hours***
	Identify Testing Tools - Plan Creation - Develop Project Plan - Create Test strategy - Analyze the requirements - Review the architecture and design	
Unit-4: Analyze and design test ware		***6 hours***
	Create and Review Test-ware - Test planning - Test case development - Test Environment setup - Test Case Execution - Test Metrics	
Unit-5: Test execution and defect management		***6 hours***
	Introduction to Test Automation - Execution of test - Defect Management and Reporting - Generate defect reports - Defect Prevention - Case study-I - Case study-II	

Learning Resources	1. Suman Mal., "Software Development Lifecycle", Notion Press; 1st Edition, 2021. 2. Ralf Kneuper., "Software Processes and Life Cycle Models", Springer, 1st Edition, 2018.



	Bloom's Level of Thinking	Continuous Learning Assessment (CLA)						Final Examination (0% weightage)	
		Formative CLA-1 (30%)		Formative CLA-2 (30%)		Summative (40)%			
		Theory	Practice	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
1. Dr. Sapthagirivasan Vivekanandan, Capgemini	*Dr. S. Poonguzhali, Professor, Centre for Medical Electronics, Anna University*	*1. Dr.A K Jayanthy*
2. Dr. Richa Dayal, Capgemini	Mr T.Anbuselvan,GE Healthcare	*2. Dr. Ashok Kumar D*