GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Engineering
Subject Code: 3170313
Semester – VII
Subject Name: Regulatory Standards for Medical Devices

Type of course: Professional Elective Course

Prerequisite: Anatomy and Physiology, Medical Instrumentation, Medical Electronics

Rationale: This subject provides foundational information related to the global regulation of medical devices with emphasis placed on US, EU and India. Additionally, the role of the global regulatory professional will be examined in the context of these regulatory frameworks to design medical devices. The course will prepare students for more in-depth examinations of submissions and the development of regulatory strategy. The module also delves into medical device regulation in the US, EU & India with an emphasis on the product lifecycle and an extended examination of the submissions process.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks				Total Marks
				Theory Marks		Practical Marks		
L	T	P	C	ESE (E)	PA (M)	ESE (V)	PA (I)	
3	0	2	4	70	30	30	20	150

Sr. No.	Content	Total Hrs
1	**Introduction of Medical Devices: Definition and Lifecycle** Definition of Medical Devices: global perspectives, Types of Medical Devices including Combination Devices, Categorization of Medical Devices according to ISO 10993, Market Trends for Medical Devices, Safety issues, Development of regulation and standards, Life cycles of Medical devices from research and development until regulatory approval.	7
2	**Medical Device Regulation in the US** Regulatory Framework and Organization of USFDA, Medical Device Classifications according to FDA, Overview of US Medical Device Regulations, Regulatory Controls on Medical Devices in US, Quality Systems Regulations (21 CFR Part 820) and Agency Interactions, Marketing Submissions, Advertising, Labeling and Promotion, Post-market Considerations and Requirements.	12
3	**Quality and Compliance & Medical Device Regulation in the EU** Overview of the Key Regulators of Medical Devices in EU, Classification of Medical Device in EU, Medical Device Directives, New Medical Device Regulations of 2017, Notified Body, Conformity Assessment Procedures, Essential Requirements, Labeling, Quality Management System (ISO 13485), Risk Management (ISO 14971), Clinical Evaluation, CE Mark Certificate and Declaration of Conformity, Post-Market Surveillance and vigilance.	12

4	**Medical Device Regulatory System in India** Overview of Regulatory framework/ organizations, Functions Undertaken by DCGI and CDSCO, Medical Device Classifications, Medical Device Regulation Acts & Rules with Upcoming Changes, Standards of Quality Assurance & Testing, Detail of Key Regulator(s), Product Registration or Conformity Assessment Route and Time Required, Quality System Regulation for Combined Device–Drug Product, Product Registration Fees, Technical Material Requirement, Labeling, Post-Marketing, Manufacturing-Related Regulation, Clinical Trial-Related Regulation, Commercial Aspect, Inspections of Medical Devices, Import and export of medical devices, Role of Distributors or Local Subsidiaries, Role of Related Agencies/Departments in Medical Device Regulations.	**14**
	Total Teaching Hours	**45**

Teaching and Examination Scheme:

Teaching Scheme			**Credits**	**Examination Marks**				**Total Marks**
L	**T**	**P**	**C**	**Theory Marks**		**Practical Marks**		
				ESE (E)	**PA (M)**	**ESE (V)**	**PA (I)**	
3	0	2	4	70	30	30	20	150

Content: Suggested Specification table with Marks (Theory):

Distribution of Theory Marks					
R Level	U Level	A Level	N Level	E Level	C Level
10	**35**	**30**	**15**	**10**	**0**

Legends: R: Remembrance; U: Understanding; A: Application, N: Analyze and E: Evaluate C: Create and above Levels (Revised Bloom's Taxonomy)

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Reference Books:

Sr. No.	**Title of Books**	**Author**	**Publication**
1	Medical Devices: Regulations, Standards and Practices	Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo	Woodhead Publishing
2	Medical Device Regulations: Global Overview and Guiding Principles	World Health Organization	WHO

3	Handbook of medical Device Regulatory Affairs in Asia	Jack Wong , Raymond K.Y.Tong	Panstanford
4	Medical Device Design and Regulation	Carl T. DeMarco	ASQ Quality Press

Course Outcomes: After completion of the course students will be able to,

Sr. No.	CO statement	Marks % weightage
CO-1	Understand the history and evolution of the regulatory standards for medical device, Classification and life cycle of medical device.	16%
CO-2	To know and apply medical device regulation of USFDA.	26%
CO-3	To know and apply medical device regulation of EU.	26%
CO-4	To know and apply medical device regulation of INDIA.	32%

List of Experiments:

Sr. No.	Name of the Practical
1	To Study about the Overview of Medical Devices: Definitions, Classification and life cycle.
2	To Study the Safety Issues related to Medical Devices with appropriate Case Study.
3	To Study the Categorization of Medical Devices according to ISO 10993.
4	To Study the General Regulations of Medical Devices in US.
5	To Study about the Quality Management Systems and agency interactions of Medical Devices in US.
6	To Study the Medical Devices Directives and New Medical Device Regulations in the EU.
7	To Study about the Quality and Compliance of Medical Device in the EU.
8	To Study about the Overview of regulatory environment of medical devices in India.

9	To Study about the Quality System Regulation for Medical Devices in India.
10	To Study the Manufacturing and Clinical Trial related Regulations in India.

List of Open Source Software/learning website:

1. www.nptel.ac.in/www.onlinecourses.nptel.ac.in,
2. www. cdsco.gov.in, www.ec.europa.eu, www.fda.gov