GUJARAT TECHNOLOGICAL UNIVERSITY
BIOMEDICAL ENGINEERING (03)

Regulatory Standards for Medical Devices

SUBJECT CODE:2180307

B.E. 8th SEMESTER

Type of course: Core

Prerequisite: Anatomy and Physiology, Medical Electronics, Basic Principle of Medical Equipment

Rationale: This subject provides key foundational information related to the global regulation of medical devices with emphasis placed on US, EU and Asia-Pacific countries. 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 & Asia- Pacific with an emphasis on the product lifecycle and an extended examination of the submissions process.

COMPETENCY

The course content should be taught and curriculum should be implemented with the aim to develop required skills so that students are able to acquire following competency:

Development of Medical Device Regulatory, Certification, Quality Assurance & Risk Management for medical device manufacturing industry.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks				Total Marks
				Theory Marks		Practical Marks		
L	T	P	C	ESE (E)	PA (M)	Viva (V)	PA (I)	
4	0	2	6	70	30	30	20	150

Content:

Sr. No.	Content	Total Hrs	% Weightage
1	**Introduction of Medical Devices: Definition and Lifecycle** Definition of medical devices: global perspectives, Types of Medical Devices, Market Trends for Medical Devices, Safety issues, Development of regulation and standards, Life cycles of Medical devices from research and development until regulatory approval.	6	15
2	**Medical Device Regulation in the US** General Regulation of Medical Devices, Overview of US Medical Device Regulation, Device Development, Quality Systems and Agency Interactions, Marketing Submissions, Advertising, Labeling and Promotion, Post-market Considerations and Requirements.	12	25
3	**Quality and Compliance & Medical Device Regulation in the EU** Overview of Medical Devices Directives, Classification of Medical Device in EU, 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, Trends, Combination Products Regulated as Medicinal Products	14	25
4	**Medical Device Regulatory System in China** Definition of medical device, classification of medical devices, Registration	08	15

	Process, Medical devices registration certificate, Product testing, Clinical trials, Enforcing GMPs, China Compulsory Certification Mark (CCC)		
5	**Medical Device Regulatory System in India** Overview of Regulatory Environment, Functions Undertaken by DCGI and FDA, Indian Pharmacopoeial Commission, Detail of Key Regulator(s),Role of Distributors or Local Subsidiaries, Product Registration or Conformity Assessment Route and Time Required, Quality System Regulation, Product Registration and Quality System Regulation for Combined Device–Drug Product, Registration Fee, Technical Material Requirement , Labeling, Post-Marketing, Manufacturing-Related Regulation, Clinical Trial-Related Regulation, Commercial Aspect , Upcoming Regulation Changes, Related Agencies/Departments and Ministries	14	20
	Total -	54	100

Reference Books:

No.	Title of Books	Author	Publication
1	Handbook of medical Device Regulatory Affairs in Asia	Jack Wong , Raymond K.Y.Tong	Panstanford
2	Medical Devices: Regulations, Standards and Practices	Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo	Woodhead
3	Medical Device Design and Regulation	Carl T. DeMarco	ASQ Quality Press
4	Medical Device Regulations: Global Overview and Guiding Principles	World Health Organization	WHO
5	International Medical Device Regulation: Europe, USA, Canada, Japan	Daniel Shoukier	Bellingswood Group

Suggested Specification table with Marks (Theory):

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

Legends: R: Remembrance; U: Understanding; A: Application, N: Analyze and E: Evaluate 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.

Course Outcome:

After completion of the course the student will be able to:

1. The history and evolution of the regulatory profession and the role of the regulatory professional throughout the product lifecycle.
2. Foundational knowledge and the core competencies of regulatory professionals working in industry, regulatory agencies, research and other environments
3. Fundamentals of global medical device regulation, including identification of regulatory agencies and processes in major regulatory systems.
4. Device regulation in the US, EU, China, ASEAN and Asia-Pacific Countries Quality and compliance
5. Global regulatory pathways and submission processes.