GUJARAT TECHNOLOGICAL UNIVERSITY (GTU)

Competency-focused Outcome-based Green Curriculum-2021 (COGC-2021)

Semester - VI

Course Title: Medical Regulatory Affairs

(Course Code: 4360303)

Diploma programme in which this course is offered	Semester in which offered
Biomedical Engineering	6th Semester

1. RATIONALE

The field of medical device regulatory affairs plays a crucial role in ensuring the safety, efficacy, and quality of medical devices in the healthcare industry. As advancements in technology continue to drive innovation in medical devices, it is imperative for professionals in this field to possess a comprehensive understanding of the regulatory landscape. The purpose of this syllabus is to provide students with a solid foundation in medical device regulatory affairs, equipping them with the necessary knowledge and skills to navigate the complex regulatory environment. By studying this course, students will gain a deep understanding of the regulatory requirements and processes involved in bringing medical devices to market, ensuring compliance with relevant laws and regulations.

2. COMPETENCY

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

- **Apply regulatory knowledge to ensure compliance with relevant laws and regulations in medical devices.**

3. COURSE OUTCOMES (COs)

The theory should be taught and practical should be carried out in such a manner that students are able to acquire required learning outcomes in cognitive, psychomotor and affective domain to demonstrate following course outcomes:

(a) Identify medical devices in terms of medical regulations.
(b) Demonstrate the knowledge about significance of medical device safety and risk management.
(c) Describe national and international standard system of medical device.
(d) Illustrate regulations and standards of medical devices to EU -European Union medical device regulatory framework.
(e) Illustrate regulations and standards of medical devices to India United States regulatory framework.

4. TEACHING AND EXAMINATION SCHEME

Teaching Scheme (In Hours)			Total Credits (L+T+P)	Examination Scheme				
				Theory Marks		Practical Marks		Total Marks
L	T	P	C	CA	ESE	CA	ESE	
3	0	0	3	30	70	0	0	100

(*):Out of 30 marks under the theory CA, 10 marks are for assessment of the micro-project to facilitate integration of COs and the remaining 20 marks is the average of 2 tests to be taken during the semester for the assessing the attainment of the cognitive domain UOs required for the attainment of the COs.
***Legends: L**-Lecture; **T** – Tutorial/Teacher Guided Theory Practice; **P** -Practical; **C** – Credit, **CA** - Continuous Assessment; **ESE** -End Semester Examination.*

5. SUGGESTED PRACTICAL EXERCISES

The following practical outcomes (PrOs) that are the sub-components of the COs.*Some of the **PrOs** marked **'*'** are compulsory, as they are crucial for that particular CO at the 'Precision Level' of Dave's Taxonomy related to 'Psychomotor Domain'.*

Note

i. *More **Practical Exercises** can be designed and offered by the respective course teacher to develop the industry relevant skills/outcomes to match theCOs.The above table is only a suggestive list.*
ii. *The following are some **sample** 'Process' and 'Product' related skills(more may be added/deleted depending on the course) that occur in the above listed **Practical Exercises** of this course required which are embedded in the COs and ultimately the competency.*

S. No.	Sample Performance Indicators for the PrOs	Weightage in %
1	Case studies	30
2	Regulatory Document review	30
3	Regulatory Intelligence research	40
Total		**100**

6. AFFECTIVE DOMAIN OUTCOMES

The following ***sample*** Affective Domain Outcomes (ADOs) are embedded in many of the above mentioned COs and PrOs. More could be added to fulfill the development of this competency.

a) Develop effective communication and teamwork skills.
b) Cultivate a professional attitude towards staying updated with evolving regulations and guidelines.
c) Practice environmental friendly methods and processes in medical device regulations (Environment related)

The ADOs are best developed through the laboratory/field based exercises. Moreover, the level of achievement of the ADOs according to Krathwohl's 'Affective Domain Taxonomy' should gradually increase as planned below:

i. 'Valuing Level' in 1st year ii.

'Organization Level' in 2nd year.

iii. 'Characterization Level' in 3rd year.

7. UNDERPINNING THEORY

Only the major Underpinning Theory is formulated as higher level UOs of *Revised Bloom's taxonomy* in order development of the COs and competency is not missed out by the students and teachers. If required, more such higher level UOs could be included by the course teacher to focus on attainment of COs and competency

Unit	Unit Outcomes (UOs)	Topics and Sub-topic
Unit – I Introduction to medical Regulatory Affairs	1.a. Describe the Role and functions of regulatory agencies 1.b. Define FDA 1.c. Define EMA 1.d. Define CDSCO 1.e. Describe role and functions of CDSCO 1.f. Give classification of medical device based upon medical regulations 1.g. Enumerate Regulatory requirements for different device classes	1.1 Role of Regulatory Affairs in the Biomedical Industry 1.2 Regulatory Agencies and their Functions : FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), The Central Drugs Standard Control Organization(CDSCO), IPC, NPPA and Other global regulatory authorities 1.3 Classification of Medical device a per FDA 1.4 Classification of Medical device a per CDSCO 1.5 Regulatory requirements for different device classes
Unit– II Medical device safety and risk management	2.a. Describe the brief concept of medical device safety and risk management 2.b. Enumerate and Explain Phases in life span of medical device 2.c Describe Critical elements for regulatory attention 2.d Draw and explain Stages of regulatory control 2.e Describe Common framework of medical device regulations 2.f. Describe regulatory tools and general requirements of five members of GHTF 2.g Define GHTF(Global Harmonization Task Force)	2.1 Medical device safety and risk management 2.2 Phases in life span of medical device 2.3Critical elements for regulatory attention 2.3.1 product and use 2.3.2 product representation 2.4 Stages of regulatory control 2.5 Common framework of medical device 2.6 Regulatory tools and general requirements 2.6.1 Product control 2.7 GHTF(Global Harmonization Task Force)

Unit	Unit Outcomes (UOs)	Topics and Sub-topic

Unit– III Standards	3.a. Describe the need of standards 3.b. Explain the Voluntary and mandatory standards 3.c. Enlist typical process for Standard development 3.d. Give brief note on National and International Standard system 3.e. Explain the identification of standards (ISO,ANSI) 3.d. Explain the Current trends in use of standards in medical device regulations 3.e Define BIS 3.f. Describe Environmental Considerations in Medical Device Regulations:	3.1 Standards 3.1.1 Need of standards 3.1.2 Voluntary and mandatory standards 3.1.3 Standard Development process 3.1.4 National and International Standard system 3.1.5 Identifications of standards 3.1.6 Current trends in use of standards in medical device regulations 3.1.7 BIS- Bureau of Indian Standards 3.2 Environmental Considerations in medical device regulations
Unit – IV Regulation and standards in medical devices for EU European Union medical device regulatory framework	4.a. Explain Harmonized standards and various bodies in EU 4.b. Classify medical devices based upon risk 4.c. Define CE mark 4.d. Enumerate process to obtain CE mark 4.e. Explain technical documentation 4.f. Describe pre market and post market scenario of CE marked medical device	4.1 Harmonized standards and various bodies in EU 4.2 risk based classification of medical device in EU 4.3 CE mark and requirement of medical device for CE mark 4.4 procedure to obtain CE mark 4.5 labelling process 4.6 technical documentation and risk management system 4.7 pre market and post market scenario of CE marked medical device
Unit – IV Regulation and standards in medical devices for India United states medical device regulatory framework	5.a. Describe laws governing medical device and governing bodies 5.b. Describe role of distributors and subsidiary bodies 5.c. Describe product registration process and quality system regulations 5.d. Explain labelling and technical requirements in India Unites states regulations	5.1 laws governing medical device and governing bodies 5.2 risk based classification of medical device 5.3 role of distributors and subsidiary bodies 5.4 product registration process and quality system regulations 5.5 labelling and technical requirements 5.6 clinical trails 5.7 commercial aspects and regulations on price 5.8 Upcoming medical regulations in India
Unit	**Unit Outcomes (UOs)**	**Topics and Sub-topic**

		5.8.1 Regulatory updates and innovative platforms launched by Government if any- (ex.Medtech Mitra)

***Note**: The UOs need to be formulated at the 'Application Level' and above of Revised Bloom's Taxonomy' to accelerate the attainment of the COs and the competency.*

9. SUGGESTED SPECIFICATION TABLE FOR QUESTIONPAPER DESIGN

Unit No.	Unit Title	Teaching Hours	Distribution of Theory Marks			
			R Level	U Level	A	Total Marks
1	Introduction to medical Regulatory Affairs	4	4	6	0	10
2	Medical device safety and risk management	8	6	6	2	14
3	Standards	6	6	4	4	14
4	Regulation and standards in medical devices for EU European Union medical device regulatory framework	12	6	6	4	16
5	Regulation and standards in medical devices for India United states medical device regulatory framework	12	6	4	4	16
Total		**42**	28	28	14	**70**

***Legends:** R=Remember, U=Understand, A=Apply and above (Revised Bloom's taxonomy)*
***Note**: This specification table provides general guidelines to assist student for their learning and to teachers to teach and question paper designers/setters to formulate test items/questions assess the attainment of the UOs. The actual distribution of marks at different taxonomy levels (of R, U and A) in the question paper may vary slightly from the above table.*

10. SUGGESTED STUDENT ACTIVITIES

Other than the classroom and laboratory learning, following are the suggested student-related cocurricular activities which can be undertaken to accelerate the attainment of the various outcomes in this course: Students should perform following activities in group and prepare reports of about 5 pages for each activity. They should also collect/record physical evidences for their (student's) portfolio which may be useful for their placement interviews:

a) Assign case studies that simulate real-world regulatory challenges. Students can analyze the scenario, identify regulatory issues, and propose appropriate solutions based on their understanding of regulations and guidelines. Survey the market and collect the specifications of different critical care instruments supplied by reputed companies and compare them with respect to their strengths and shortcomings.
b) Regulatory Submission Exercise: Divide students into groups and assign them a hypothetical medical product or device. Ask them to prepare a regulatory submission package, including relevant documentation, labeling requirements, and compliance with regulatory standards.
c) Regulatory Compliance Audit: Have students conduct a mock regulatory compliance audit of a healthcare facility or medical device manufacturer. They can assess the organization's adherence to regulatory requirements, identify gaps, and propose corrective actions
d) Regulatory Writing Assignments: Assign writing tasks that require students to draft regulatory documents, such as product labeling, clinical trial protocols, or regulatory impact assessments. Provide feedback on their writing style, clarity, and adherence to regulatory guidelines.
e) Regulatory Research Project: Ask students to choose a specific regulatory topic or issue and conduct in-depth research. They can prepare a research paper or presentation summarizing their findings, analyzing the impact on the industry, and proposing recommendations.
f) Organize group discussions or debates on current regulatory issues or controversies in the medical field. Encourage students to critically analyze different perspectives and develop their argumentation skills.
g) Facilitate opportunities for students to gain practical experience through internships or practicum placements in regulatory affairs departments of healthcare organizations, regulatory agencies, or medical device companies.

11. SUGGESTED SPECIAL INSTRUCTIONAL STRATEGIES (if any)

These are sample strategies, which the teacher can use to accelerate the attainment of the various outcomes in this course:

a) Massive open online courses (MOOCs) may be used to teach various topics/ subtopics.
b) Guide student(s) in undertaking micro-projects.
c) Organize visits to regulatory agencies, pharmaceutical companies, or medical device manufacturers to give students a firsthand experience of regulatory processes and compliance requirements. This helps bridge the gap between theory and practice.
d) Conduct interactive workshops where students actively participate in regulatory affairs-related activities.
e) Integrate case-based learning into the syllabus, where students analyze and solve regulatory challenges through real or hypothetical scenarios.
f) Invite regulatory affairs professionals or representatives from regulatory agencies to speak to the class or organize visits to regulatory bodies or healthcare facilities. This provides students with insights into real-world regulatory practices and allows for networking opportunities.
g) Utilize online simulation tools or software that simulate regulatory affairs scenarios. Students can navigate through different regulatory challenges, make decisions, and experience the consequences of their actions

12. SUGGESTED MICRO-PROJECTS

Only one micro-project is planned to be undertaken by a student that needs to be assigned to him/her in the beginning of the semester. In the first four semesters, the micro-projects are group-based (group of 3 to 5). However, in the fifth and sixth semesters, the number of students in the group should not exceed three.

The micro-project could be industry application based, internet-based, workshop-based, laboratory-based or field-based. Each micro-project should encompass two or more COs which are in fact, an integration of PrOs, UOs and ADOs. Each student will have to maintain a dated work diary consisting of individual contributions in the project work and give a seminar presentation of it before submission. The duration of the micro project should be about 14-16 (fourteen to sixteen) student engagement hours during the course. The students ought to submit micro-project by the end of the semester to develop the industry oriented COs. A suggestive list of micro-projects is given here. This has to match the competency and the COs. Similar micro-projects could be added by the concerned course teacher. (It can be a Seminar with bound /hand written notes/ ppts of individual students OR a report on one of the medical device regulatory process)

Following micro projects can be implemented:

1. Regulatory Compliance Case Study: Assign students a case study where they analyze a real-life scenario involving regulatory compliance issues in the medical field. Students can research and present their findings on the regulatory challenges faced, the impact on the organization, and potential solutions.

2. Regulatory Submission Simulation: Divide students into groups and assign them different medical products or devices. Each group can then simulate the process of preparing and submitting a regulatory application for their assigned product. This project will help students understand the intricacies of regulatory submissions and the importance of compliance.

3. Regulatory Gap Analysis: Provide students with a set of regulations or guidelines related to medical devices or pharmaceuticals. Ask them to conduct a gap analysis by comparing the given regulations with a hypothetical or existing product. Students can identify areas where the product may not meet the regulatory requirements and propose strategies for compliance.

4. Regulatory Intelligence Report: Assign students the task of researching and preparing a regulatory intelligence report on a specific topic or region of interest. They can analyze recent regulatory changes, guidelines, or trends and present their findings, highlighting the potential impact on the medical industry.

5. Labeling and Packaging Compliance Exercise: Provide students with examples of medical product labels and packaging. Ask them to review and assess the compliance of these materials with relevant regulations. Students can identify any discrepancies or areas for improvement and propose modifications to ensure compliance.

6. Clinical Trial Protocol Review: Assign students a clinical trial protocol and ask them to critically review it from a regulatory perspective. They can identify any potential regulatory issues, such as ethical considerations, informed consent requirements, or data collection methods, and suggest improvements to align with regulatory standards.

13. SUGGESTED LEARNING RESOURCES

S. No.	Title of Book	Author	Publication with place, year and ISBN
1	Handbook of Medical Device Regulatory Affairs in Asia	Jack Wong , Raymond Tong	Pan Staford Publishing
S. No.	**Title of Book**	**Author**	**Publication with place, year and ISBN**
2	Medical Devices Regulations, Standards and Practices	Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo	Woodhead Publishing House
3	Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices	John J. Tobin , Gary Walsh	Wiley-VCH

14. SOFTWARE/LEARNING WEBSITES

[A] List of software/learning websites:

Sr No	Topic key word	Link
1.	Medical device overview and guiding principle World Health Organization Geneva	https://iupesm.org/wpcontent/uploads/2014/06/WHOMedical_Device_Regulatns.pdf
2.	Central Drugs Standard Control Organization (CDSCO)	https://cdsco.gov.in/opencms/opencms/en/Ho me/ https://cdscomdonline.gov.in/NewMedDev/Ho mepage
3.	FDA Learning Portal	https://www.fda.gov/training-and-continuingeducation/fda-learning-portal-studentsacademia-and-industry

4.	Med Device Online:	https://www.meddeviceonline.com/
5.	Regulatory Focus	https://www.raps.org/News-and-Articles
6.	Medscape	https://www.medscape.com/
7.	Regulatory Affairs Professionals Society (RAPS) Regulatory Exchange	https://www.raps.org/
8.	U.S. food and drug administration	https://www.fda.gov/drugs
9.	Ministry of Health and Family Welfare	https://www.mohfw.gov.in/
10.	Indian Council of Medical Research (ICMR)	https://main.icmr.nic.in/
11	Swayam Mooc	https://swayam.gov.in/
12	Nptel	https://nptel.ac.in/
13	FDA overview of medical device	https://www.fda.gov/medical-devices/deviceadvice-comprehensive-regulatoryassistance/overview-device-regulation
14	Medtech Mitra	https://medtechmitra.icmr.org.in/
15	National Medical Device Policy 2023	https://pharmaceuticals.gov.in/sites/default/files/Strategy%20Document%20on%20NMDP%20 2023_0.pdf

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15. PO-COMPETENCY-CO MAPPING

Semester III	Pos						
Competency & Course Outcomes	**PO 1 Basic & Discipline specific knowledge**	**PO 2 Problem Analysis**	**PO 3 Design/ development of solutions**	**PO 4 Engineering Tools, Experimentation & Testing**	**PO 5 Engineering practices for society, sustainability & environment**	**PO 6 Project Management**	**PO 7 Life-long learning**
Competency	**Apply regulatory knowledge to ensure compliance with relevant laws and regulations in medical devices**						
CO-1. Identify medical devices in terms of medical regulations	3	3	1	1	1	1	3
CO-2Apply the knowledge about significance of medical device safety and risk management.	3	3	3	2	2	1	3
CO-3 Describe national and international standard system of medical device.	3	3	3	2	2	2	3
CO-4 Illustrate regulations and standards of medical devices to EU -European Union medical device regulatory framework	3	3	2	2	2	3	2
CO-5 Illustrate regulations and standards of medical devices to India United States regulatory framework.	3	3	2	2	2	3	2

Legend: '**3**' for high, '**2**' for medium, '**1**' for low or '**-**' for the relevant correlation of each competency, CO, with PO/ PSO2

16. COURSE CURRICULUM DEVELOPMENT COMMITTEE

GTU Resource Persons

S. No.	Name and Designation	Institute	Contact No.	Email
1	Ms. M.H.Dave	G.P.Gandhinagar	9099757202	maitrihdave@gmail.com

2	Ms. N.B.Modi	G.G.P.Ahmedabad	9265538994	neelambm21@gmail.com