GUJARAT TECHNOLOGICAL UNIVERSITY

Program Name: Master of Engineering
Level: PG
Branch: Biomedical Engineering
Course / Subject Code : ME02031071
Course / Subject Name : Medical Device Design and Development

w. e. f. Academic Year:	2024-25
Semester:	2
Category of the Course:	Professional Elective Course

Prerequisite:	Basic Engineering Knowledge, Medical Device Regulatory Standards, Product Design Fundamentals, Business and Economics Basics, Problem-Solving and Analytical Skills
Rationale:	The Medical Device Design and Development course is designed to provide a comprehensive understanding of the multidisciplinary process involved in the creation of medical devices. As the healthcare industry continues to evolve, the demand for innovative and reliable medical devices that meet regulatory standards, improve patient outcomes, and are economically viable is growing exponentially.

Course Outcome:

After Completion of the Course, Student will able to:

No	Course Outcomes	RBT Level
01	Formulate and analyze a problem for the product design.	R, U, A
02	Analyze the various stages of product development and regulatory requirements.	U, A, E, N
03	Understand the process of manufacturing, testing and validation for scalable product Development. Design and develop medical devices for commercialization.	U, A, N, E, C
04	Understand the Innovation & Product Development process in the Business Context.	U, A, N, E
05	Analyze the economics in product development and business strategies for turnover from commercialization.	A, N, E

**Revised Bloom's Taxonomy (RBT)*

Teaching and Examination Scheme:

Teaching Scheme (in Hours)			Total Credits L+T+ (PR/2)	Assessment Pattern and Marks				Total Marks
				Theory		Tutorial / Practical		
L	T	PR	C	ESE (E)	PA / CA (M)	PA/CA (I)	ESE (V)	
3	0	2	4	70	30	20	30	150

Course Content:

Unit No.	Content	No. of Hours	% of Weightage
1.	**PRODUCT DESIGN** Definition, History and Modern Practice – Designs; Design and Product Life Cycle; Design Process; Medical device, Challenges in medical device, Understanding the innovation cycle, Good Design Practice. Understanding, analyzing and validating user needs, Screening Needs, Technical Requirements, Concept Generation – Innovation Survey Questionnaire, Morphological Matrix, QFD, Concept Analysis and validation, Concept Modelling, Concept Screening & Validation.	10	20
2.	**PRODUCT DEVELOPMENT AND REGULATORY** Breakthrough Products, Platform Products, Front End of Innovations / Fuzzy Front End, Generic Product Development Process (Concept Development, System Design, Detailed Design, Test & Refinement, Production Ramp-up), Variants of Development Processes (Market Pull, Technology Push, Platform, Process-Intensive, Customized, High-Risk, Quick Build, Complex Systems), Good Documentation Practice, Prototyping Specifications, Prototyping, Medical Device standards, Quality management systems, Medical Device Classification, Design of Clinical Trials, Design Control & Regulatory Requirements, Documentation in Medical Devices, Regulatory pathways. Case studies on design and development of medical devices.	10	25
3.	**SCALABLE PRODUCT DEVELOPMENT** Design for manufacturing, Design for assembly, Design for Serviceability, Design for usability, Medical Device Verification & Validation, Product Testing & Regulatory compliance, Clinical trial & validation, Device Certification.	7	15
4.	**MANUFACTURING AND BUSINESS STRATEGIES** Lean Manufacturing – Toyota Production System, Good Manufacturing Practices, Framework for Product Strategy – Core Strategic Vision (CSV), Characteristics of good CSV, Opportunity Identification Process & Generating Opportunities, Quality of Opportunities – Real-Win-Worth It (3M RWW), Product Planning Process, Technology S- Curve, Evaluating and Prioritizing Projects, Product-Process Change Matrix, Resource Planning, Total Available Market (Segmentation, Targeting & Positioning), ServedAvailable Market, Product Platform Strategy, Market Platform Plan (Product Platform Management, Product Line Strategy).	9	20

5.	**PRODUCT ECONOMICS AND MARKET INFUSIONS** Economics/Finance in Product Development (Sales Forecasting – ATAR Model/ Bases Model, Pricing the product, Cash flow in Product Development, Categorizing the costs, Structuring Manufacturing Costs, Prototyping Costs, Development Costs, Cost Volume Profit Analysis, Breakeven Analysis, Common Return Metrics – Payback/ NPV/ IRR, Common Comparison Metrics – WACC/ RRR/ MARR). Business Model Canvas, Marketing Channels, Sales Models, Post Commercialization Surveillance, End of Life support. Case Studies on product economics.	9	20
	Total	**45**	**100**

Suggested Specification Table with Marks (Theory):

Distribution of Theory Marks (in %)					
R Level	**U Level**	**A Level**	**N Level**	**E Level**	**C Level**
10	**20**	**20**	**15**	**15**	**20**

Where R: Remember; U: Understanding; A: Application, N: Analyze and E: Evaluate C: Create (as per Revised Bloom's Taxonomy)

References/Suggested Learning Resources:

(a) Books:

1. Jones, J.C. "Design Methods", John Wiley, 2nd Edition, 1992.
2. Cross N, "Engineering Design Methods", John Wiley, 4th Edition, 2008.
3. Michael E. McGrath, "Product Strategy for High-Technology Companies", 2nd Edition, McGraw Hill, 2000.
4. Ulrich, K.T., and Eppinger, S.D., "Product Design and Development", McGraw Hill, 7th Edition, 2020.
5. Paul H king, Richard C. Fries, Arthur T. Johnson, "Design of Biomedical Devices and Systems", 3rd Edition, CRC Press, 2014.
6. Peter J. Ogrodnik, "Medical Device Design: Innovation from Concept to Market", Academic Press Inc, 1st Edition, 2012.
7. Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel, "Bio design: The Process of Innovating Medical Technologies", Cambridge University press, 2 nd Edition, 2015.

(b) Open source software and website:

1. https://www.freecadweb.org/
2. https://www.blender.org/
3. https://grabcad.com/
4. https://www.opendocman.com/
5. https://www.iso.org/iso-13485-medical-devices.html
6. https://www.openfoam.com/
7. https://www.businessmodelnavigator.com/

Suggested Course Practical List:

1. User Needs Analysis and Concept Generation.
2. Concept Screening and Validation
3. Design Control and Documentation
4. Regulatory Pathway Simulation
5. Design for Manufacturing (DFM) and Assembly (DFA)
6. Prototyping Using 3D Printing
7. Lean Manufacturing and Process Optimization
8. Market Analysis and Segmentation
9. Product Economics and Market Infusions
10. Post-Market Surveillance Simulation
11. Collaborative Design Project (simulation)

List of Laboratory/Learning Resources Required:

1. Design software's (Autocad, Solid Works, Fusion 360, Blender)
2. ANSYS simulation software
3. 3D printers
4. Embedded system development kits

Suggested Project List:

- Development of a Wearable Health Monitoring Device
- Portable ECG Monitoring System
- Medical Device with User Interface for Elderly
- Medical Device with Augmented Reality (AR) for Surgical Assistance
- Prosthetic Limb Design and Development

Suggested Activities for Students:

Students should design projects using Solid works/ Autocad / Fusion 360 to address real-life design problems.

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