

**INDIAN INSTITUTE OF INFORMATION TECHNOLOGY DESIGN AND MANUFACTURING
(IIITDM) KANCHEEPURAM**

Course Title	Design of Medical Devices	Course No				
Specialization	Integrated Product Design	Structure (LTPC)	2	1	0	3
Offered for	Master of Design (Semester 2)	Status	Core		Elective X	
Prepared by	Dr Raguraman Munusamy					
Prerequisite	None	To take effect from	2021 Batch			
Course Objectives	<ol style="list-style-type: none"> 1. Introduce the process of medical device design - the non-technical factors that impact a medical technology's clinical and market success, and to emerging themes that are shaping healthcare innovation 2. Challenge students to apply design thinking to the broader healthcare system. 					
Course Outcomes	<p>On successful completion of this course,</p> <ul style="list-style-type: none"> • Students gain exposure to clinical need identification, stakeholder interviews, ideation, and prototyping. • Students will become experts on intellectual property, FDA regulation, reimbursement, and startup financing introduce non-technical factors that help shape an innovation's path to impact. 					
Contents of the course (With approximate break up of hours)	<ul style="list-style-type: none"> • Introduction – Medical Device Development: Academia vs. Industry • Project Management – How corporations manage medical projects • Pre-clinical Device Development – Research projects • Regulatory considerations for medical device development • Manufacturing, Quality Control, and Quality Assurance • Business – What makes corporations tick and research labs tock • Marketing medical devices, and the basics of sales forces • Clinical trials, CRA's, and CRO's • Design Controls: DHF, Proposal, DDP, Inputs, Outputs, Specifications • Design Controls: Verification, Validation, Transfer • Risk Analysis: FMECA, Risk analysis document • Organization types, putting together project teams, Project Management: The Sequel • Consultants – Role in medical device development, Advamed, Anti-kickback statute, Confidentiality <p>Evaluation: 70% assignments/activities + 30% End Semester</p>					
Texts & References	<ol style="list-style-type: none"> 1. Paul H. King, Richard C. Fries (2009), Design of Biomedical Devices and Systems, CRC Press, ISBN:9781420061796 2. Richard C. Fries (2001), Handbook of Medical Device Design, Taylor & Francis, ISBN:9780429285141 3. Peter Ogrodnik (2019), Medical Device Design, Academic Press, ISBN:9780128149638 4. Paul Davim (2012), The Design and Manufacture of Medical Devices, Woodhead Publishing, ISBN:9781908818188 					