Module Code	MEP56BM1
Module Name	Medical Device Design Innovation Project
ECTS Weighting	10 ECTS
Semester taught	Semester 1 & 2
Module Coordinator/s	Bruce Murphy and Brooke Tornifoglio
Module Learning Outcomes with reference to the Graduate Attributes and how they are developed in discipline	On successful completion of this module, students should be able to: LO1. Understand the medical device regulatory systems in the US and European Union LO2. Apply engineering principles to determine how medical devices either have successfully treated patients or have failed. LO3. Understand the importance of the patenting system within the arena of medical device design LO4. Understand the importance of legal and ethical aspects of medical device design and development LO5. Understand the needs driven approach to developing new medical devices LO6 Understand how to work in a team environment LO7 Understand how to develop sophisticated test methods to understand the attributes of medical devices **Graduate Attributes: levels of attainment** To act responsibly - Enhanced To think independently - Enhanced To develop continuously - Enhanced To communicate effectively - Enhanced
Module Content	The module is designed to educate the course participants in the field of early stage, "needs lead," medical device design. The course firstly takes the format: whereby teams of students work together to discover the true nature of the clinical need and background information required to develop a new medical device in a particular area. The class then splits into a number of competing groups that can utilise this information to develop a solution to solve the clinical need. The teams must then advance the engineering solution, and in parallel advance the business case for their solution. A series of design iterations will occur over the course of the two semesters The solutions should meet the user requirements. The solution/business plan must satisfy, regulations, intellectual property constraints, manufacturing requirements, cost effective analysis and user needs. The final output is a business plan

and engineering plan that potentially will enable the solution to be developed in the future.
A secondary task that the students must complete in this module is the development of a novel test method for a medical device.
In some years students will interact closely with clinicians on either the innovation or testing or both parts of the module.
The need and the medical device change every year.

Teaching and Learning Methods

This module uses Blackboard, podium lectures, self-directed assignments, and workshops, and sometimes hospital visits to help students achieve the required learning outcomes.

Assessment Details
Please include the following:

- **Assessment Component**
- **Assessment description**
- **Learning Outcome(s) addressed**
- **% of total**
- **Assessment due date**

Assessment Component	Assessment Description	LO Addressed	% of total	Week due
Assignment	Presentations and reports related to the two projects in the module, the schedule and type of reports changes from year to year as the testing project can be quite different between years (a different medical device is chosen each year for this component and different clinical needs are addressed each year)	1-7	100	Over SEM 1 and SEM 2
			100	

Contact Hours and Indicative Student Workload[2]

Contact hours:	(44) 44 Lectures, 2 hour interactive workshop

	Supervised and independent lab testing: (40) lab based component
	Independent Study (80) (preparation for course and review of materials):
	Independent Study: (50) (preparation for assessment, incl. completion of assessment)
Recommended Reading List	Intellectual Property, Medicine and Health (Intellectual Property, Theory, Culture) 2nd Edition by Johanna Gibson (Author) **Biodesign: The Process of Innovating Medical Technologies 2nd Edition by Paul G. Yock (Author), Stefanos Zenios (Author), Josh Makower (Author), Todd J. Brinton (Author), Uday N. Kumar (Author), F. T. Jay Watkins (Author), Lyn Denend (Author), The Founder's Dilemmas: Anticipating and Avoiding the Pitfalls That Can Sink a Startup (The Kauffman Foundation Series on Innovation and Entrepreneurship) Paperback – April 1, 2013 by Noam Wasserman (Author) The Innovator's Dilemma: The Revolutionary Book That Will Change the Way You Do Business Paperback – October 4, 2011 by Clayton M. Christensen Venture Deals: Be Smarter Than Your Lawyer and Venture Capitalist Hardcover – December 26, 2012 by Brad Feld (Author), Jason Mendelson The Survival Guide to Eu Medical Device Regulations Paperback – June 20, 2017 by Petri Pommelin ** Highly recommended
Module Pre-requisite	4BM5 Biomechanics and 4BM6 Biomaterials
Module Co-requisite	4BM15 Medical Device Design Fundamentals
Module Approval Date	
Approved by	
Academic Start Year	2025
Academic Year of Date	2026