Module descriptor for MEP56BM1: Medical Device Design Innovation Project

Module code	MEP56BM1
Module name	Medical Device Design Innovation Project
ECTS weighting	10 ECTS
Semester taught	Semester 1 & 2
Module coordinator/s	Professor Bruce Murphy Assistant Professor Brooke Tornifoglio
Module learning outcomes (LO) with reference to the graduate attributes and how they are developed in discipline	On successful completion of this module, students should have: 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 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 **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 takes the format whereby teams of students work together to discover the true nature of a 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 in the second half of Semester 1 and continue into Semester 2. 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.

	This module includes a second parallel project looking at a specific case of medical device testing. This project will have students speaking with clinicians, where appropriate, being in the lab, designing test rigs for a specific purpose, and testing various devices and variables/conditions which influence their performance.
Teaching and learning methods	This module uses Blackboard, podium lectures, and self-directed assignments to help students achieve the required learning outcomes. Students will give informal and formal updates on progress each week in class.
Assessment details	<table><tr><th>Assesment component</th><th>LO</th><th>% of total</th><th>Week due</th></tr><tr><td>Innovation Project</td><td rowspan="6">1-5</td><td rowspan="6">60</td><td></td></tr><tr><td>Background presentation (5%)</td><td>S1</td></tr><tr><td>Progress updates (30%)</td><td>S1+2</td></tr><tr><td>Final presentation (30%)</td><td>S2</td></tr><tr><td>Final report (20%)</td><td>S2</td></tr><tr><td>Individual component (15%)</td><td>S2</td></tr><tr><td>Medical Device Testing Project</td><td rowspan="4">1-4</td><td rowspan="4">40</td><td></td></tr><tr><td>Background presentation (10%)</td><td>S1</td></tr><tr><td>Final testing protocol report (45%)</td><td>S1</td></tr><tr><td>Final report + results (45%)</td><td>S2</td></tr></table> Due to the nature of engaging with clinicians and the iterative process in design, there is expected uncertainty on timelines. Changes will be communicated in class. A GANTT chart will be shared at the beginning of S1 and if/when updated communicated. Attendance is mandatory. Students may be deemed non-satisfactory and not eligible to submit if they attend less than 80% of lectures (except for in case of valid medical note).
Reassment requirements	See module coordinator.
Indicative student workload	**Contact hours**: 44 hours via weekly clinics **Independent study**: 80 hours (preparation and review of materials) **Independent study**: 100 hours (preparation and completion of assessments)
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 Zero to One: Notes on Startups, or How to Build the Future Hardcover – September 16, 2014 by Peter Thiel 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	4BIO5 Biomechanics 4BIO6 Biomaterials
Module co-requisite	MEP56BM9: Fundamentals of Medical Device Design
Module website	
Other schools/departments involved in delivery of this module?	N/A
Module approval date	2026
Approved by	Bruce Murphy Brooke Tornifoglio
Academic start year	2026
Academic year of date	2026/2027