

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	Bruce Murphy Brooke Tornifoglio
Module learning outcomes (LO) with reference to the graduate attributes and how they are developed in discipline	<p>On successful completion of this module, students should have:</p> <p>LO1: understand the medical device regulatory systems in the US and European Union.</p> <p>LO2: apply engineering principles to determine how medical devices either have successfully treated patients or failed.</p> <p>LO3: understand the importance of the patenting system within the arena of medical device design.</p> <p>LO4: understand the importance of legal and ethical aspects of medical device design and development.</p> <p>LO5: understand the needs driven approach to developing new medical devices</p> <p>Graduate Attributes: levels of attainment</p> <p>To act responsibly - Enhanced</p> <p>To think independently - Enhanced</p> <p>To develop continuously - Enhanced</p> <p>To communicate effectively - Enhanced</p>
Module content	<p>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.</p>

Teaching and learning methods	This module uses Blackboard, podium lectures, and self-directed assignments to help students achieve the required learning outcomes.																															
Assessment details	<table><tr><th>Assesment component</th><th>LO</th><th>% of total</th><th>Week due</th></tr><tr><td>Background report</td><td>1-4</td><td>15</td><td>S1, week 8</td></tr><tr><td>IP landscape report</td><td>1-4</td><td>10</td><td>S1, week 13 S2, week 11</td></tr><tr><td>Brainstorming presentation</td><td>1-5</td><td>10</td><td>S2, week 1</td></tr><tr><td>Business case report</td><td>1-4</td><td>5</td><td>S2, week 6</td></tr><tr><td>Final report and presentation</td><td>1-5</td><td>40</td><td>S2, week 13</td></tr><tr><td>Individual report and interview</td><td>1-5</td><td>20</td><td>S2, week 13</td></tr></table> <p><u>Weeks due are subject to change and will be confirmed in class.</u></p> <p>Attendance is mandatory. Students may be deemed non-satisfactory and not eligible to sit the exam if they attend less than 80% of lectures (except for in case of valid medical note).</p>				Assesment component	LO	% of total	Week due	Background report	1-4	15	S1, week 8	IP landscape report	1-4	10	S1, week 13 S2, week 11	Brainstorming presentation	1-5	10	S2, week 1	Business case report	1-4	5	S2, week 6	Final report and presentation	1-5	40	S2, week 13	Individual report and interview	1-5	20	S2, week 13
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Indicative student workload	<p>Contact hours: 44 lecture hours via weekly 2 hour interactive workshops</p> <p>Independent study: 80 hours (preparation and review of materials)</p> <p>Independent study: 25 hours (preparation and completion of assessments)</p>																															
Recommended reading list	<p>Intellectual Property, Medicine and Health (Intellectual Property, Theory, Culture) 2nd Edition by Johanna Gibson (Author)</p> <p>**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),</p> <p>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)</p> <p>The Innovator's Dilemma: The Revolutionary Book That Will Change the Way You Do Business Paperback – October 4, 2011 by Clayton M. Christensen</p> <p>Zero to One: Notes on Startups, or How to Build the Future Hardcover – September 16, 2014 by Peter Thiel</p> <p>Venture Deals: Be Smarter Than Your Lawyer and Venture Capitalist Hardcover – December 26, 2012 by Brad Feld (Author), Jason</p>																															

	<p>Mendelson</p> <p>The Survival Guide to Eu Medical Device Regulations Paperback – June 20, 2017 by Petri Pommelin</p> <p>** Highly recommended</p>
Module pre-requisite	<p>4BIO5 Biomechanics</p> <p>4BIO6 Biomaterials</p>
Module co-requisite	None
Module website	
Other schools/departments involved in delivery of this module?	N/A
Module approval date	
Approved by	<p>Bruce Murphy</p> <p>Brooke Tornifoglio</p>
Academic start year	2025
Academic year of date	2025/2026