

Module Code	ME5BIO1
Module Name	Medical Device Design Innovation Project
ECTS Weighting¹	10 ECTS
Semester taught	Semester 1 & 2
Module Coordinator/s	Bruce Murphy
Module Learning Outcomes with reference to the Graduate Attributes and how they are developed in discipline	<p>On successful completion of this module, students should be able to:</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 have 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 firstly takes the format: whereby teams of students work together to discover the true nature of the clinical need and the background information required to develop a new medical device in a particular area. The class then splits into a number of competing groups that utilise the discovered 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 the first Semester 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>

Furthermore, the teams must develop a test method for the medical device that is chosen for that particular year. The test method will be validated by the lecturer prior to the students uncovering the particular characteristics of the device.

Teaching and Learning Methods

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

Assessment Details²

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	Background report, and individual interview	1-4	30	Week 6 S1
Assignment	User requirements, design inputs and design iterations completed	1-5	30	Week 12 S1/ 1-2/S2
Assignment	Final report (engineering + regulatory+ IP + Business)	1-5	40	Week 10 S2
Assignments	Multiple presentations that the lecturer will provide feedback on during the course of the module.	1-5	0	
			100	

Reassessment Requirements

Contact Hours and Indicative Student Workload²

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

Independent Study (80) (preparation for course and review of materials):

Independent Study (25) (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

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 and 4BIO6 Biomaterials

Module Co-requisite

4BM15/56BM9 Medical Device Design Fundamentals