

Module Code	ME5BIO9
Module Name	Foundation Medical Device Design
ECTS Weighting¹	5 ECTS
Semester taught	Semester 1
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>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 course is designed to educate students in the area of medical device design. This is a broad course and its focus does not solely revolve around the engineering challenges associated with designing a medical device, lectures focus on many aspects: understanding clinical trial data, understanding the anatomical fundamentals associated with the device area, developing intellectual property strategies, regulation of medical devices, risk analysis, manufacturing techniques and requirements, reimbursement, and case studies of successful and unsuccessful medical device development.</p>

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: <ul style="list-style-type: none"> • Assessment Component • Assessment description • Learning Outcome(s) addressed • % of total • Assessment due date 	Assessment Component	Assessment Description	LO Addressed	% of total	Week due
	Assignment	Medical device design assignment	LO2	50	Week 7 S1
	Assignment	Regulation and IP assignment /Initiative in medical device design	LO1 and LO3	50	Week 12 S1

Reassessment Requirements Examination

Contact Hours and Indicative Student Workload²	Contact hours: (35) 33 Lectures, 2 hour interactive workshop
	Independent Study (50) (preparation for course and review of materials):
	Independent Study (35) (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

Module Website

**Are other Schools/Departments involved in the delivery of this module?
If yes, please provide details.**

Module Approval Date

Approved by

Academic Start Year

Academic Year of Date