

<b>Module Code</b>	ME5BIO9- new code required
<b>Module Name</b>	Foundation Medical Device Design
<b>ECTS Weighting<sup>1</sup></b>	5 ECTS
<b>Semester taught</b>	Semester 1
<b>Module Coordinator/s</b>	Bruce Murphy
<b><a href="#">Module Learning Outcomes</a> with reference to the <a href="#">Graduate Attributes</a> and how they are developed in discipline</b>	<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 process of innovating in medical device design.</p> <p><b>Graduate Attributes: levels of attainment</b></p> <p>To act responsibly - Enhanced</p> <p>To think independently - Enhanced</p> <p>To develop continuously - Enhanced</p>
<b>Module Content</b>	<p>The course is designed to educate students in the area of the process of innovating medical technologies. This process starts with identifying clinical needs. 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 validating clinical needs, defining user requirements, 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>

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**Teaching and Learning Methods**

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

**Assessment Details<sup>2</sup>**

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
Exam	Medical device design exam -	LO1- LO5	100	Exam week S1

**Reassessment Requirements**

Examination

**Contact Hours and Indicative Student Workload<sup>2</sup>**

**Contact hours: (35) 30 Lectures,**

**Independent Study (50) (preparation for course and review of materials):**

**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**

**Module Co-requisite**

4BIO5 Biomechanics and 4BIO6 Biomaterials

**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**