

<b>Module Code</b>	ME5BIO9			
<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  LO2. Apply engineering principles to determine how medical devices either have successfully treated patients or have 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</p> <p><b>Graduate Attributes: levels of attainment</b>  To act responsibly - Enhanced  To think independently - Enhanced  To develop continuously - Enhanced  To communicate effectively - <b>Enhanced</b></p>			
<b>Module Content</b>	<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> <p>Below are a list of the some of the topics of early stage medical device innovation that are covered in the course (note these are examples and can change):</p> <table border="1"> <tr> <td>Medical Device Design Fundamentals Lectures</td> <td></td> <td></td> </tr> </table>	Medical Device Design Fundamentals Lectures		
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Lecture 1	Lecture 2	Lecture 3
<p><b>Part 1</b> Introductions (You, Me the course)</p> <p><b>Part 2</b> From Concept to Patient</p>	<p><b>Part 1</b> Strategic Focus</p> <p><b>Part 2</b> Identify a clinical Need</p>	<p><b>Part 1</b> The observation process</p> <p><b>Part 2</b> TAVR Learning from successes and understanding clinical data</p>

TAVR + Clinical Data analysis (example cont'd.)	<p>Review of observations and problems of a live case (interactive class) You tell me your observations and problem statements!</p> <p>Requires you to watch video prior to this class!</p>	TAVR+ Clinical Data analysis (example cont'd.)
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Designing a medical device with anatomical aspects and structure/function relationships in your mind. Part 1	Designing a medical device with anatomical aspects and structure/function relationships in your mind. Part 2.	Mechanical Design example - what you need to know if you are to change a design -implications on engineering considerations.
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Design of Experiments tools - implementing these tools in the design process

Intellectual Property basics	Intellectual property knowing a bit more about the process, timelines and strategies	(cont'd.) Intellectual property knowing a bit more about the process, timelines and strategies
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Guest Lectures and IP case study

READING WEEK

Learning from mechanical Failures 1	Learning From Failures 2	Learning from failures 3
The European Regulatory System	The US regulatory system	Risk Management
Quality Management Systems 1	Reimbursement Basics	Manufacturing Technology in med devices 1
Manufacturing Technology in Medical Devices 2	Needs Screening	Concept Generation/ Selection /Screening

**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	
Exam	Medical device design exam on coursework	LO2	100	

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**Reassessment Requirements**

Examination

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

**Contact hours: (35) 33 Lectures,**

**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**