Module Code	MEP56BM9
Module Name	Medical Device Design Fundamentals
ECTS Weighting	5 ECTS
Semester taught	Semester 1
Module Coordinator/s	Assoc. Prof. Bruce Murphy
Module Learning Outcomes with reference to the Graduate Attributes and how they are developed in discipline	On successful completion of this module, students should be able to: 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 **Graduate Attributes: levels of attainment** To act responsibly - Enhanced To think independently - Enhanced To develop continuously - Enhanced To communicate effectively - Enhanced
Module Content	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.
Teaching and Learning Methods	This module uses Blackboard, podium lectures, self-directed assignments, to help students achieve the required learning outcomes.

Assessment Details
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
Written examination	End of semester examination	1-4	100	Exam period
Assignment	Mid semester	LO2 or LO3	0	Week 8

Reassessment Requirements

There is no reassessment for the MSc in Bioengineering

Contact Hours and Indicative Student Workload Error! Bookmark not defined.

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	XX/XX/2020
Approved by	Assoc. Prof. Bruce Murphy
Academic Start Year	2019
Academic Year of Date	2020