<table>
<thead>
<tr>
<th>Module Code</th>
<th>MEP56BM9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module Name</td>
<td>Medical Device Design Fundamentals</td>
</tr>
<tr>
<td>ECTS Weighting</td>
<td>5 ECTS</td>
</tr>
<tr>
<td>Semester taught</td>
<td>Semester 1</td>
</tr>
<tr>
<td>Module Coordinator/s</td>
<td>Bruce Murphy</td>
</tr>
</tbody>
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**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

<table>
<thead>
<tr>
<th>Assessment Component</th>
<th>Assessment Description</th>
<th>LO Addressed</th>
<th>% of total</th>
<th>Week due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam</td>
<td>Medical device design exam</td>
<td>LO1-LO4</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Reassessment Requirements

Examination

Contact Hours and Indicative Student Workload

<table>
<thead>
<tr>
<th>Contact hours: (35) 33 Lectures, 2 hour interactive workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent Study (50) (preparation for course and review of materials):</td>
</tr>
<tr>
<td>Independent Study (35) (preparation for assessment, incl. completion of assessment):</td>
</tr>
</tbody>
</table>

Recommended Reading List

- 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
**Module Pre-requisite**

| Pre-requisite | 4BIO5 Biomechanics and 4BIO6 Biomaterials |

**Module Co-requisite**

| Co-requisite |

**Module Website**

| Website |

**Are other Schools/Departments involved in the delivery of this module?**

If yes, please provide details.

**Module Approval Date**

| Approval Date |

**Approved by**

| Signed by |

**Academic Start Year**

|  |

**Academic Year of Date**

|  |