**Module Template for New and Revised Modules**

<table>
<thead>
<tr>
<th>Module Code</th>
<th>ME5BIO9</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>
</table>

### 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.

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1. [An Introduction to Module Design](#) from AISHE provides a great deal of information on designing and re-designing modules.
2. [TEP Glossary](#)
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>Written examination</td>
<td>End of semester examination</td>
<td>1-4</td>
<td>100</td>
<td>Exam period</td>
</tr>
<tr>
<td>Assignment</td>
<td>Mid semester</td>
<td>LO2 or LO3</td>
<td>0</td>
<td>Week 8</td>
</tr>
</tbody>
</table>

Reassessment Requirements

Contact Hours and Indicative Student Workload

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


- **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)

3 TEP Guidelines on Workload and Assessment
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

<table>
<thead>
<tr>
<th>Module Pre-requisite</th>
<th>4BIOS Biomechanics and 4BIO6 Biomaterials</th>
</tr>
</thead>
</table>

**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**