5BIO1 MEDICAL DEVICE DESIGN

Lecturers: Professor Bruce Murphy and Professor David Taylor (bruce.murphy@tcd.ie)

Semester: 1

Course Organisation
The course runs for 24 weeks\(^1\) of the academic year and comprises two lectures per week, one workshop per week. Total contact time is 66 hours.

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<tr>
<th>Start Week</th>
<th>End Week</th>
<th>Laboratory/practical training</th>
<th>Lectures total</th>
<th>Total on student presentation time</th>
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<td>1</td>
<td>24</td>
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Course Description
This course aims to advance the student’s knowledge in the area of medical device design. Lectures are focused on what is required to bring a medical device from concept through to clinical use. Students will attend lectures on intellectual property, regulatory affairs, pre-clinical and clinical trial design, financing of medical device development, manufacturing techniques and requirements, reimbursement, and case studies of successful and unsuccessful medical device development. Placements and workshops will revolve around a core continuous assessment, whereby student teams will design a medical device that solves an *unmet* clinical need in conjunction with a clinical team or a medical device company.

Learning Outcomes
On successful completion of this course, students will be able to:

a) Conduct patent searches, analyse prior intellectual property

b) Determine regulatory classifications for a medical device, understand the CE and FDA regulatory process

c) Determine the potential finance required to develop a medical device.

d) Screen and identify clinical needs

e) Develop a project R&D plan, pre-clinical and clinical strategy.

f) Understand the importance of legal and ethical aspects of medical device design and development

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\(^1\) The course is run in tandem with the Bioengineering MSc. The MSc version includes an extended project with increased output expected at the project end date.
g) Describe the multifaceted approach that is required to successfully commercialise a medical device and will be able to apply this multifaceted approach to the design of new medical devices.

h) Conduct a medical device design concept evaluation both technically and commercially on a new medical device design.

**Course Content**

- Reimbursement
- Financing
- Regulation
- Intellectual property
- Pre-clinical assessment
- Clinical assessment
- Clinical needs identification
- Manufacturing methods
- Risk analysis
- Advanced anatomy and pathology
- Ethical and legal issues

**Course Notes**

**Teaching Strategies**

- Lectures
- Workshops
- Site placement
- Labs

**Assessment Modes**

Written Exam (50%), and team project (50%).

**Recommended Texts**

- BioDesign. Zenios, Yock, Makower. Cambridge