

5BIO1 MEDICAL DEVICE DESIGN

Lecturers: Assistant Professor Bruce Murphy (bruce.murphy@tcd.ie)

Semester: 1

Module Organisation

The module runs for 24 weeks¹ of the academic year and comprises two lectures per week, one workshop per week, practical training (in the first semester), and on-site (hospital/industry) placement. Total contact time is 88 hours.

Start Week	End Week	Laboratory/practical training	Lectures total	Total on site time (hospital /industry)	Case study/workshop time
1	24	12	44	12	22

Module Description

This module aims to advance the student's knowledge in the area of medical device design. The module is taught in a three pronged approach: (i) practical training (labs/workshops/site placement), (ii) lectures, and (iii) continuous assessment. 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 module, students will be able to:

1. Conduct patent searches, analyse prior intellectual property
2. Determine regulatory classifications for a medical device, understand the CE and FDA regulatory process
3. Determine the potential finance required to develop a medical device.
4. Screen and identify clinical needs
5. Develop a project R&D plan, pre-clinical and clinical strategy.
6. Develop a market and sales/distribution strategy

¹ The module is run in tandem with the Bioengineering MSc. The MSc version includes an extended project with increased output expected at the project end date.

7. Understand the importance of legal and ethical aspects of medical device design and development
8. 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.
9. Conduct a medical device design concept evaluation both technically and commercially on a new medical device design.

Module Content

- Reimbursement
- Financing
- Regulation
- Intellectual property
- Pre-clinical assessment
- Clinical assessment
- Clinical needs identification
- Manufacturing methods
- Risk analysis
- Advanced anatomy and pathology
- Case 1: Successful medical device development (Ardian)
- Case 2: Unsuccessful medical device development (Conor Med)
- Case 3: Successful medical device development (distal occlusion)
- Case 4: DePuy ASR (implications of class III failures)
- 3D modelling Creo 2.0
- Ethical and legal issues

Module Notes

Teaching Strategies

Lectures
Workshops
Site placement
Labs

Assessment Modes

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

Recommended Texts

- BioDesign. Zenios, Yock, Makower. Cambridge

Laboratory/practical

Creo 2.0 Medical Device 3D modelling.