ME5BIO1 MEDICAL DEVICE DESIGN – [10 Credits]

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

Semester: 1 and 2

Module Organisation
The module runs for 2 semesters of the academic year and comprises three lectures every week for the first semester. During the second semester a series of workshops and student presentations take place that are designed to guide the student through the process of designing a medical device. Total contact time is approximately 60 hours. At the end of the first semester an examination takes place, which is worth 50% of the overall marks associated with this course. The other 50% of the marks associated with this course are assigned to a group project that runs over both semesters, students must self-select the groups for this group project – active participation in the group project is required, non-satisfactory participation in the group project will result in the student being removed from the course.

Module Description
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, manufacturing techniques and requirements, reimbursement, and case studies of successful and unsuccessful medical device development

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

1. Conduct patent searches, analyse novelty/infringement issues
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.

Updated: 03/09/2018
4. Screen and identify clinical needs

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

6. Understand the importance of legal and ethical aspects of medical device design and development

7. 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.

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

**Module Content**

- Medical device stress/failure analysis
- Financing
- Regulation
- Intellectual property
- Pre-clinical assessment
- Clinical assessment
- Clinical needs identification
- Manufacturing methods
- Risk analysis
- Advanced anatomy and pathology
- Ethical and legal issues

**Module Notes**
Provided via blackboard

**Teaching Strategies**
The module is taught using a combination of lectures and workshops.

**Assessment Modes**
Written Exam (50%), and team project (50%).

**Reassessment Mode**
N/A

**Recommended Texts**
- BioDesign. Zenios, Yock, Makower. Cambridge