ME5BIO9 FOUNDATION MEDICAL DEVICE DESIGN – [5 Credits]

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

Semester: 1

Module Organisation
The module runs in semester 1 of the academic year and comprises three lectures every week. Total contact time is approximately 30 hours. At the end of the first semester an examination takes place, which is worth 100% of the overall marks associated with this 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.

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

Updated: 03/09/2018
7. Describe the multifaceted approach that is required to successfully commercialise a medical device.

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 lectures.

**Assessment Modes**
Written Exam (100%).

**Reassessment Mode**
N/A

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