BMEN90020 Biomedical Design and Regulation

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	This subject is not offered in 2014.
Time Commitment:	Contact Hours: 48 hours Total Time Commitment: 200 hours
Prerequisites:	The prerequisite for this subject is: **Subject** | **Study Period Commencement:** | **Credit Points:** BMEN30008 Biosystems Design | Semester 2 | 12.50 OR Any equivalent design subject OR Admission into the Master of Biomedical Engineering (745BM)
Corequisites:	None
Recommended Background Knowledge:	None
Non Allowed Subjects:	**BMEN40004(421-449) Biomedical Design and Regulation (../../view/2010/BMEN40004)**
Core Participation Requirements:	For the purposes of considering request for Reasonable Adjustments under the Disability Standards for Education (Cwth 2005), and Students Experiencing Academic Disadvantage Policy, academic requirements for this subject are articulated in the Subject Description, Subject Objectives, Generic Skills and Assessment Requirements of this entry. The University is dedicated to provide support to those with special requirements. Further details on the disability support scheme can be found at the Disability Liaison Unit website: http://www.services.unimelb.edu.au/disability/
Contact:	Assoc Prof David Grayden Email:**grayden@unimelb.edu.au (mailto:grayden@unimelb.edu.au)**
Subject Overview:	**AIMS** This subject covers biomedical product development including conceptualisation, design control, development and testing protocols, as well as the ethical standards to be met, and regulatory framework, for devices and/or therapeutic agents in Australia and overseas. Also considered are the technical, managerial, economic, financial, environmental and societal factors impacting on the development of a new device and/or therapeutic agent. **INDICATIVE CONTENT** Topics include: Risk Management – Australian regulatory guidelines for medical devices and ISO9000 series of standards Design Control Processes - Design and development planning, Design input, Design control, Design output, Design review, and Design verification Design Control of Medical Devices – the regulations, classifications and standard of Medical Devices. In-particular AS3200 series of standards and AS3551 standard; Ethical standards – can a sponsor place a Therapeutic Device in the market without declaring that it is a therapeutic?

	Drug Regulation in Australia – The Baume Report and the long road to the Pharmaceutical Market International Drug Regulation – Global Regulation and Harmonisation of format of processes, Data, Evaluation reports, Decisions, Clinical Trials and Good Clinical Practices. Institutional Structures, Product Information and Guidelines – Clinical trials notification schemes, human ethics, chemical, synthesis and property drug information, and drug guidelines. These Medical Device topics are complemented by exposure to the Medical Devices in the Clinical Workshops and use of industry standard engineering software tools for design in the laboratory
Learning Outcomes:	**INTENDED LEARNING OUTCOMES (ILO)** Having completed this unit the student is expected to: 1 Describe the design control factors that contribute to the development of new devices or therapeutic agents 2 Be able to utilise appropriate standards in the design of devices and utilise appropriate schedules in the distribution of therapeutic agents 3 Describe the regulations that are required to place a new medical device or a therapeutic agent into a clinical trial and then market 4 Describe the therapeutic device/agents post-market evaluation and incident reporting schemes 5 Discuss the ethics, standards and regulations applicable to the development of therapeutic devices and/or agents in Australia and overseas
Assessment:	One written examination, not exceeding three hours at the end of semester, worth 60%; Continuous assessment of submitted project work completed in small groups (2-3 students), not exceeding 1500 words over the semester, worth 35%; A half-hour mid-semester test, worth 5%. Intended Learning Outcomes (ILOs) 1, 3-5 are assessed in the final written examination and the mid-semester test. ILOs 1-5 are assessed in the submitted project reports.
Prescribed Texts:	TBA
Breadth Options:	This subject is not available as a breadth subject.
Fees Information:	Subject EFTSL, Level, Discipline & Census Date, http://enrolment.unimelb.edu.au/fees
Generic Skills:	# Ability to identify a problem and formulate a design solution to address the problem # Understanding of social, cultural, global, and environmental responsibilities and the need to employ principles of sustainable development # Ability to utilise a systems approach to complex problems and design to a specified operational performance # Proficiency in engineering design # Ability to communicate effectively, with the engineering team and with the community at large # Ability to manage information and documentation # Capacity for creativity and innovation # Understanding of professional and ethical responsibilities, and commitment to them # Ability to function effectively as an individual and in multidisciplinary and multicultural teams, as a team leader or manager as well as an effective team member
Notes:	**LEARNING AND TEACHING METHODS** The subject is delivered through lectures, electronic resources; workshop classes that combine both tutorial and hands-on laboratory activities and site visits for the clinical workshops where students apply the theory. **INDICATIVE KEY LEARNING RESOURCES** Lectures, Electronic resources, Professional instruction, and Site visits **CAREERS / INDUSTRY LINKS**

	Exposure to industry and industry participation is achieved by visits to, and guest lecturers from, a selection of the following sites: Royal Melbourne Hospital, Austin Health Heidelberg, Nucleus Network Alfred Hospital, St Vincent's Hospital Melbourne.
Related Course(s):	Bachelor of Engineering (Biomedical)Biocellular Bachelor of Engineering (Biomedical)Biosignals Master of Biomedical Engineering
Related Majors/Minors/ Specialisations:	Master of Engineering (Biomedical)