421-449 Biomedical Design & Regulation

Credit Points:	12.500
Level:	Undergraduate
Dates & Locations:	2008, This subject commences in the following study period/s: Semester 2, - Taught on campus.
Time Commitment:	Contact Hours: Thirty-six hours of lectures, 12 hours of tutorials, 12 hours of project work. Total Time Commitment: 96 hours
Prerequisites:	421-285 bioengineering Systems Modelling 1 and 436-387 Cellular and Tissue Biomechanics.
Corequisites:	None
Recommended Background Knowledge:	None
Non Allowed Subjects:	None
Core Participation Requirements:	For the purposes of considering request for Reasonable Adjustments under the Disability Standards for Education (Cwth 2005), and Student Support and Engagement Policy, academic requirements for this subject are articulated in the Subject Overview, Learning Outcomes, Assessment and Generic Skills sections of this entry. It is University policy to take all reasonable steps to minimise the impact of disability upon academic study, and reasonable adjustments will be made to enhance a student's participation in the University's programs. Students who feel their disability may impact on meeting the requirements of this subject are encouraged to discuss this matter with a Faculty Student Adviser and Student Equity and Disability Support: http://services.unimelb.edu.au/disability
Coordinator:	Emmanuel Koumoundouros
Subject Overview:	Product development including conceptualisation, design, development and testing protocols. The ethical standards to be met, and regulatory framework, for devices and/or therapeutic agents in Australia and overseas. Consideration of the technical, managerial, economic, financial, environmental and society factors impacting on the development of new device and/or therapeutic agent. At the conclusion of this subject students should: # Be able to describe the factors that contribute to the development of new devices or theraputic agent; # Understand the ethics, standards, and regulations aplicable to the development of therapeutic devices and/or agents in Australia and overseas.
Assessment:	One 3-hour examination (60%) and assignments/reports (40%).
Prescribed Texts:	None
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:	At the end of this subject students should have an: # Ability to communicate effectively,not only with engineers but also with the community at large; # In depth technical competence in at least one engineering discipline; # Ability to undertake problem identification formulation and solution; # Ability to utilise a systems approach to design and operational performance; # Ability to function effectively as an individual and in multi-disciplinary and multi-cultural teams, with the capacity to be a leader or manager as well as an effective team leader;

	# Understanding of the social, cultural, global, and environmental responsibilities of the professional engineer, and the need for sustainable development. # Understanding of the principles of sustainable design and development.
Related Course(s):	Bachelor of Engineering (Biomedical) Biomechanics Bachelor of Engineering (Biomedical)Biocellular Bachelor of Engineering (Biomedical)Bioinformatics Bachelor of Engineering (Biomedical)Biosignals