

BMEN90020 Biomedical Design and Regulation

Credit Points:	12.50						
Level:	9 (Graduate/Postgraduate)						
Dates & Locations:	This subject is not offered in 2013.						
Time Commitment:	Contact Hours: 48 hours Total Time Commitment: 120 hours						
Prerequisites:	<p>Prerequisite for this subject is :</p> <table border="1"> <thead> <tr> <th>Subject</th> <th>Study Period Commencement:</th> <th>Credit Points:</th> </tr> </thead> <tbody> <tr> <td>BMEN30008 Biosystems Design</td> <td>Semester 2</td> <td>12.50</td> </tr> </tbody> </table> <p>OR</p> <p>Any equivalent design subject</p> <p>OR</p> <p>Enrolment in Master of Biomedical Engineering</p>	Subject	Study Period Commencement:	Credit Points:	BMEN30008 Biosystems Design	Semester 2	12.50
Subject	Study Period Commencement:	Credit Points:					
BMEN30008 Biosystems Design	Semester 2	12.50					
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:	<p>Dr. Emmanuel Koumoundouros</p> <p>Email: emmanuel@unimelb.edu.au (https://mce_host/faces/htdocs/emmanuel@unimelb.edu.au)</p>						
Subject Overview:	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.						
Objectives:	<p>At the conclusion of this subject students should be able to:</p> <ul style="list-style-type: none"> # Describe the design control factors that contribute to the development of new devices or therapeutic agents; # Be able to utilise appropriate standards in the design of devices and utilise appropriate schedules in the distribution of therapeutic agents; # Understand the regulations that are required to place a new medical device or a therapeutic agent into a clinical trial and then market; # Understand the therapeutic device/agents post-market evaluation and incident reporting schemes; # Discuss the ethics, standards and regulations applicable to the development of therapeutic devices and/or agents in Australia and overseas. 						

Assessment:	In-lab assessment of practical classes during clinical workshops (5%). One 1000-word equivalent Lab Assignment due in week 6 (10%). One mid-semester test of 30 minutes duration (5%). One group presentation in class in week 10 (5%). One 1500 word essay or assignment due in week 10 (15%). One end-of-semester examination of 3 hours duration (60%).
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:	<ul style="list-style-type: none"> # 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
Related Course(s):	Bachelor of Engineering (Biomedical) Biomechanics Bachelor of Engineering (Biomedical) Biocellular Bachelor of Engineering (Biomedical) Biosignals Master of Biomedical Engineering
Related Majors/Minors/Specialisations:	Master of Engineering (Biomedical)