BMEN90026 Clinical Trials and Regulations

Credit Points:	12.5
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2015, Parkville This subject commences in the following study period/s: Semester 1, Parkville - Taught on campus.
Time Commitment:	Contact Hours: 36 hours of lecture (3 x 1 hour lectures per week) and up to 24 hours of workshops Total Time Commitment: 200 hours
Prerequisites:	**Subject** / **Study Period Commencement:** / **Credit Points:** BMEN30008 Biosystems Design / Semester 2 / 12.50
Corequisites:	None
Recommended Background Knowledge:	None
Non Allowed Subjects:	**Subject** / **Study Period Commencement:** / **Credit Points:** BMEN90020 Biomedical Design and Regulation / Not offered 2015 / 12.50
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:	Dr Emmanuel Koumoundouros
Contact:	Email: **bmen-subjectenquiry@unimelb.edu.au (https://mce_host/faces/htdocs/%20bmen-subjectenquiry@unimelb.edu.au)**
Subject Overview:	**AIMS:** This subject teaches fundamentals of probability and statistics, clinical trial processes and regulations of therapeutic goods and specialised health care environments to Master of Engineering (Biomedical) students. **INDICATIVE CONTENT:** Foundations of probability: independence, conditional probability, Bayes' rule; Random variables: cumulative distributions, probability mass and probability density functions, expectation and variance, functions of a random variable, important distributions and their properties and uses; Sums, inequalities and limit theorems: Basic statistical concepts: confidence intervals, hypothesis testing, significance levels, correlation, analysis of variance; Decision testing: maximum likelihood, maximum a posteriori, minimum cost and Neyman-Pearson rules, basic minimum mean-square error estimation, regression. Risk management and international and Australian regulatory guidelines for electrical, chemical, biological and administrative health care processes, in particular medical devices: regulations, classifications and standards; familiarisation with specialised clinical/laboratory environmental control and containment guidelines; ethical standards and sponsor responsibilities. Clinical trials: Design and analysis of experiments; Clinical trials and ethical consent; Principles of drug development: Global regulation and harmonisation of format of processes, decisions

	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; Drug regulation in Australia.
Learning Outcomes:	**INTENDED LEARNING OUTCOMES (ILO)** Having completed this subject it is expected that the student be able to: 1 Demonstrate an understanding of the axioms of probability, random variables, Bayes' rule, and the ability to calculate and interpret probabilities, probability densities, means, variances and covariances 2 Demonstrate the ability to fit probability models to data by both estimating and testing hypotheses about model parameters 3 Apply standard statistical procedures using a statistical computing package 4 Describe the appropriate standards used in the design and maintenance of biomedical devices and the appropriate schedules in the distribution of therapeutic agents 5 Describe the regulations that are required to place a new medical device or a therapeutic agent into a clinical trial and then market 6 Describe important processes of experimental design in pre-clinical and clinical trials 7 Describe the therapeutic device/agents post-market evaluation and incident reporting schemes 8 Discuss the ethics, standards and regulations applicable to the development of therapeutic devices and/or agents in Australia and overseas.
Assessment:	Continuous assessment of submitted project work completed in small groups (2-3 students), requiring 40-45 hours of work per student across the semester (weeks 2-12), worth 30%. ILOs 1-8 are assessed in these workshops One mid-semester test of 50 minutes duration in weeks 6- 8, worth 10% One examination of three hours duration at the end of semester (exam period), worth 60%. Hurdle requirement: Students must pass the end of semester examination to pass the subject. Intended Learning Outcomes (ILOs) 1-8 are assessed in the final exam, and continuous assessment of submitted project work. (ILOs) 1-6 are also assessed in the mid-semester test.
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:	On completion of this subject, students should have developed the following skills: # Understanding of social, cultural, global, and environmental responsibilities and the need to employ principles of sustainable development # Ability to communicate effectively, with the engineering team and with the community at large # Ability to manage information and documentation # 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 Majors/Minors/ Specialisations:	Master of Engineering (Biomedical with Business) Master of Engineering (Biomedical)