

## 543-803 Drug Info., Regulation and Legal Issues

<b>Credit Points:</b>	20.00
<b>Level:</b>	9 (Graduate/Postgraduate)
<b>Time Commitment:</b>	Contact Hours: 30 contact hours (3 hours per week) Total Time Commitment: Not available
<b>Prerequisites:</b>	Nil
<b>Corequisites:</b>	None
<b>Recommended Background Knowledge:</b>	None
<b>Non Allowed Subjects:</b>	None
<b>Core Participation Requirements:</b>	<p>&lt;p&gt;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.&lt;/p&gt;         &lt;p&gt;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: &lt;a href="http://services.unimelb.edu.au/disability"&gt;http://services.unimelb.edu.au/disability&lt;/a&gt;&lt;/p&gt;</p>
<b>Subject Overview:</b>	<p>This subject aims to provide a background to practical and policy issues in drug regulation in Australia, Europe, USA and Asia, and in particular the regulatory process in Australia at government and industry level. In addition, students should gain an understanding of the drug evaluation process of primary pharmaceutical material in order to facilitate understanding of government regulatory requirements. Consumer issues, pharmacoeconomics and post-marketing surveillance in addition to epidemiology and clinical trial design, are also covered.</p>
<b>Assessment:</b>	50%: Multiple Choice Questionnaire; 50%: Short Essay Examination (Max: 2,500 words).
<b>Prescribed Texts:</b>	None
<b>Breadth Options:</b>	This subject is not available as a breadth subject.
<b>Fees Information:</b>	Subject EFTSL, Level, Discipline & Census Date, <a href="http://enrolment.unimelb.edu.au/fees">http://enrolment.unimelb.edu.au/fees</a>
<b>Related Course(s):</b>	Graduate Diploma in Drug Evaluation and Pharmaceutical Sciences