

## LAWS90003 Regulation of Biotechnology

<b>Credit Points:</b>	12.50
<b>Level:</b>	9 (Graduate/Postgraduate)
<b>Dates &amp; Locations:</b>	This subject is not offered in 2013.
<b>Time Commitment:</b>	Contact Hours: Eight 4-hour workshops, two workshops for each unit. Total Time Commitment: 120 hours
<b>Prerequisites:</b>	None
<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>Contact:</b>	Coordinator: Dr Matthew Digby Email: <a href="mailto:mdigby@unimelb.edu.au">mdigby@unimelb.edu.au</a> ( <a href="mailto:mdigby@unimelb.edu.au">mailto:mdigby@unimelb.edu.au</a> )
<b>Subject Overview:</b>	<p>The successful commercialisation and marketing of biotechnological products requires extensive documentation and rigorous evaluation by the relevant regulatory bodies.</p> <p>This subject is comprised of four discreet units focusing on: the Australian Pesticides and Veterinary Medicines Authority (APVMA) Office of the Gene Technology Regulator (OGTR) Therapeutic Goods Administration (TGA), Food Standards Australia New Zealand (FSANZ) and their international counterparts such as the USA Food and Drug Administration (FDA).</p> <p>The regulatory requirements of devices, drugs and foods will be examined by a series of case study focused seminars and workshops, providing an understanding of the time frame, rigor, effort, and uncertainty encountered throughout the process of product registration.</p>
<b>Objectives:</b>	To: <ul style="list-style-type: none"> <li># Identify the appropriate regulatory body for a particular product and market</li> <li># Understand the timeframe and technical requirements of the relevant regulatory agency</li> <li># Plan for successfully satisfying the appropriate agency</li> <li># Relate the stringency and expense of registration to the market and projected sales</li> <li># Understand the regulatory steps in international jurisdictions.</li> </ul>
<b>Assessment:</b>	Four 30 minute in-class tests, one for each unit, during semester: 40% Four group assignments, one for each unit, with each individual contributing the equivalent of 750 words for each assignment, during semester: 60%
<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>Generic Skills:</b>	Students will develop: <ul style="list-style-type: none"><li># aptitude for continued self-directed learning</li><li># examine critically, synthesise and evaluate knowledge across a broad range of disciplines</li><li># their analytical and cognitive skills through learning experiences in diverse subjects</li><li># a capacity to participate fully in collaborative learning and to confront unfamiliar problems</li><li># evaluate and judge ideas and processes from disparate disciplines</li><li># create and develop plans and strategies interfacing science, technology and commerce.</li></ul>
<b>Links to further information:</b>	<a href="http://graduate.science.unimelb.edu.au/">http://graduate.science.unimelb.edu.au/</a>
<b>Related Course(s):</b>	Master of Biotechnology