UNSW Course Outline

BIOM9410 Regulatory Requirements of Biomedical Technology - 2024

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General Course Information

Course Code : BIOM9410
Year : 2024
Term : Term 1
Teaching Period : T1
Is a multi-term course? : No
Faculty : Faculty of Engineering
Academic Unit : Graduate School of Biomedical Engineering
Delivery Mode : Multimodal
Delivery Format : Standard
Delivery Location : Kensington
Campus : Sydney
Study Level : Undergraduate, Postgraduate
Units of Credit : 6

Useful Links

Handbook Class Timetable

Course Details & Outcomes

Course Description

The medical technology industry is highly regulated to ensure the safety of the general

population. The tragedy of thalidomide in the 1950s and 1960s drove home the need for governments around the world to control the release of drugs onto the market. More recently, problems with heart valves, breast implants and pacemakers have shown that medical devices are also capable of causing injury to the patients they are designed to treat. Regulatory bodies around the world monitor the development and marketing of many thousands of medical devices to ensure that the products allowed on the market are of an appropriate quality.

From the point of view of the manufacturer, the successful development of a medical device can be a slow and very expensive process. Typically, an implantable medical device will be “in the pipeline” for at least 5 to 10 years before the regulatory bodies around the world approve it for general sale. The cost of the process of development and regulatory approval depends on the device and its complexity but, typically, $10 million -100 million per device would be indicative industry standards. Furthermore, the longer the time taken to gain regulatory approvals, the longer a company must wait before it can begin to recoup this financial outlay by selling the product on the general market.

It is therefore vitally important for research bodies and companies to understand the regulatory process governing the sale of medical devices in each country. It is also important for them to invest the appropriate funds to ensure that the product development and manufacturing processes are performed according to the standards required and that the regulatory approval process is completed as efficiently and quickly as possible.

Understanding the approval process and the manner in which regulatory bodies operate is critical to success. It is important to liaise with the regulatory bodies frequently and treat the relationship in a positive manner. Their requirements, although sometimes apparently onerous, ultimately improve the performance of a medical device company and their products.

BIOM9410 is designed for people who are, or will be, involved in any aspect of the development, manufacture or distribution of medical technology. This can range from involvement in basic research at a university or research institution through to product development and clinical trials of the product or a position in regulatory affairs in a multinational medical device manufacturing company. All stages of the development process are regulated to various extents, and it is vitally important that each person at each stage is aware of the requirements he or she must meet. The course aims to give you a broad overview of the regulation of medical devices around the world.

Course Aims

The aims of this course are to:

- give a broad overview of the regulation of medical devices around the world and
- relate these regulations to the development and marketing of a variety of medical devices

Relationship to Other Courses

The course is mandatory for all undergraduates in the Biomed degree. It is optional for postgraduate students. It forms a key component of the discipline.

Course Learning Outcomes

Course Learning Outcomes
CLO1 : Describe the concept of regulation and why it is appropriate to regulate medical technology
CLO2 : Explain the regulations that apply to each part of the process of development and marketing of medical technology
CLO3 : Discuss how regulation is applied to medical technology in various countries around the world
CLO4 : Develop and apply regulatory strategies to various medical technologies

Course Learning Outcomes	Assessment Item
CLO1 : Describe the concept of regulation and why it is appropriate to regulate medical technology	• Online Modules • Online Exam • Major Project • Final Exam
CLO2 : Explain the regulations that apply to each part of the process of development and marketing of medical technology	• Online Modules • Online Exam • Major Project • Final Exam
CLO3 : Discuss how regulation is applied to medical technology in various countries around the world	• Online Modules • Online Exam • Major Project • Final Exam
CLO4 : Develop and apply regulatory strategies to various medical technologies	• Online Exam • Major Project • Final Exam

Learning and Teaching Technologies

Moodle - Learning Management System | Zoom | Review - Assessment/Feedback Tool

Learning and Teaching in this course

BIOM9410 is a blended learning course, delivered online via Moodle resources and through face-to-face (online) sessions and tutorials. Course content will be presented through 12 online course modules complemented by guest lectures from industry leaders. A major aspect of this course is a group assignment that is designed to immerse the students in the regulatory process. This is designed not only as an assessment task, but a major learning module in the course, where materials developed by each group will serve as shared learning tools for the whole class. Groups will present their work in an in person presentation session in week 5.

Students are expected to complete at least one Moodle module per week and submit the assessment tasks by the due dates. For information about how to access and use Moodle including the system requirements, please go to the UNSW website, which explains everything students need to know in order to use Moodle.

Additional Course Information

These learning outcomes relate most strongly to the following UNSW graduate outcomes:

- scholarly enquiry
- engagement with the relevant disciplinary knowledge
- critical thinking and creative problem solving and
- collaborative and multidisciplinary work

They are also moderately related to:

- information literacy
- enterprise, initiative and creativity

BIOM9410 is a 6 UOC course and it is expected that students will devote 10 to 11 hours per week to this course reading module and reference materials and working on assessment tasks

Assessments

Assessment Structure

Assessment Item	Weight	Relevant Dates
Online Modules Assessment Format: Individual	5%	Start Date: 13/02/2024 03:00 PM Due Date: 16/04/2024 01:00 PM
Online Exam Assessment Format: Individual	15%	Start Date: 09/04/2024 01:00 PM Due Date: Not Applicable
Major Project Assessment Format: Group	50%	Start Date: Not Applicable Due Date: variable throughout term
Final Exam Assessment Format: Individual	30%	Start Date: Not Applicable Due Date: Not Applicable

Assessment Details

Online Modules

Assessment Overview

There are 12 modules. Each module has a small quiz at the end. You are encouraged to work through these modules at their own pace. A suggested timing is provided in the timetable. All modules must be completed by week 10. These modules aim to help you:

- actively make sense of what you are reading,
- apply what you are reading to real life medical technology, and share your experiences with and learn from other students within the course.

Each quiz is marked automatically in Moodle

Course Learning Outcomes

- CLO1 : Describe the concept of regulation and why it is appropriate to regulate medical technology
- CLO2 : Explain the regulations that apply to each part of the process of development and marketing of medical technology
- CLO3 : Discuss how regulation is applied to medical technology in various countries around the world

Assignment submission Turnitin type

This is not a Turnitin assignment

Online Exam

Assessment Overview

The Online Exam will require interpretation of the dynamics of current regulatory bodies. To

complete the exam, you will use fundamental material from the modules and guest lectures. This is an individual assessment; you are not permitted to discuss this assessment or work together.

The Online Exam is marked automatically in Moodle and feedback is provided on submission.

Course Learning Outcomes

- CLO1 : Describe the concept of regulation and why it is appropriate to regulate medical technology
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- CLO3 : Discuss how regulation is applied to medical technology in various countries around the world
- CLO4 : Develop and apply regulatory strategies to various medical technologies

Assignment submission Turnitin type

Not Applicable

Major Project

Assessment Overview

The objectives of the major project are to consolidate information learned in class and to develop literature research skills. It is intended to simulate the process of bringing a medical device to market.

Specific literature research skills developed and reinforced are critical review of the medical, scientific and engineering literature, written communication of literature research, applications of knowledge from literature and course materials for analysing regulatory applications.

This assessment is a direct measure of the degree to which the learning outcomes described above have been achieved. To ensure adequate progress and provide tailored help for the group assignment, Q&A sessions with course coordinator and content expert will be available each week, as well as Q&A sessions on specific topics with external industry experts.

A statement of individual contributions to the group assignment needs to preface the submission of the
group assignment. Specific guidelines and assignment details will be made available in the Moodle
course.

Part 1 –Device Classification (Individual work) (10%)

This task is to be performed by each student individually and will establish their ability to understand fundamental concepts and conduct relevant research. It will be worth 10% of the overall mark.

Part 2 – Regulatory Pathway Presentation (Group + Individual work) (20%)
This task will involve groups formed from your tutorial class. The objective is to establish comprehension of high-level regulatory processes. It will be delivered as a face to face and/or video presentation in week 5 and is worth 10% of the overall mark.

The presentation will be given by all the individuals in each group and will be based on the group assignment topic. The presentation will be judged on the clarity and accuracy of the information presented and the integration of the individual presentations to provide a complete understanding of the presented topic area for the audience.

An additional individual written task will be performed at the conclusion of the tutorial. This will be peer marked, and participation in both the written task and the peer marking is required, and is worth 10% of the overall mark.

Part 3 - Technical Evidence Report (Group work) (20%)
This task will be performed by the same groupings as Part 2 and establish a comprehension of the detail lying behind gaining market authorisations. It will require detailed analysis of regional regulatory requirements and take the form of a report. It is worth 20% of the overall mark. Each group member is expected to contribute in an equitable fashion, and a group work breakdown sheet will be supplied by each individual. Marks may be adjusted for unequitable work.

Course Learning Outcomes

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- CLO4 : Develop and apply regulatory strategies to various medical technologies

Detailed Assessment Description

NOTE: small change in weighting ot the part 2 section. The presentation will be worth 15%, and the individual written task/peer review is worth 5%

Assignment submission Turnitin type

This assignment is submitted through Turnitin and students can see Turnitin similarity reports.

Final Exam

Assessment Overview

You will have a 24hr take home open book examination at the end of the session during the formal examination period. The exam will consist of short answer questions and/or essay-style questions that give you the opportunity to integrate the key concepts and issues raised in the class. The aim of the exam is to encourage you to review their course material for the session and to do so in ways that are analytical, evaluative and problem solving. This is an individual assessment; you are not permitted to discuss this assessment or work together. More details about the exam format will be provided through Moodle later in the session.

Course Learning Outcomes

- CLO1 : Describe the concept of regulation and why it is appropriate to regulate medical technology
- CLO2 : Explain the regulations that apply to each part of the process of development and marketing of medical technology
- CLO3 : Discuss how regulation is applied to medical technology in various countries around the world
- CLO4 : Develop and apply regulatory strategies to various medical technologies

Assignment submission Turnitin type

This assignment is submitted through Turnitin and students do not see Turnitin similarity reports.

General Assessment Information

Submission of Assignments

Assignments are submitted electronically via Moodle with a cover sheet attached by 1pm Tuesday of the due week.

Please also make sure name and student number are included on the top of each document submitted. The School also requires that a non-plagiarism declaration form is included with each assignment submitted. The forms can be found at https://www.engineering.unsw.edu.au/biomedical-engineering/student-resources/plagiarism and this declaration should form page 1 of each of each assignment. Please do not submit one document for the assignment and another for the non-plagiarism declaration – one document per assignment please. More details about plagiarism are provided in Administrative Matters.

Assignments should be submitted on time. A daily penalty of 5% of the marks available for that

assignment will apply for work received after the due date. Any assignment more than 5 days late will not be accepted. The only exemption will be when prior permission for late submission has been granted by the Course coordinator. Extensions will be granted only on medical or compassionate grounds under extreme circumstances.

Requests for extensions or special consideration must be made online prior to the due date with supporting medical certificates or other evidence attached to the request. More info can be found at https://student.unsw.edu.au/special-consideration.

Details of each assessment component, the marks assigned to it, the criteria by which marks will be assigned, and the dates of submission are set out below:

Grading Basis

Standard

Course Schedule

Teaching Week/Module	Activity Type	Content
Week 1 : 12 February - 18 February	Lecture	Introduction to the course content, course structure and assessments. Online Module 1 & 2
Week 2 : 19 February - 25 February	Lecture	Case study discussion and general Q&A. Online module 3 & 4 Recorded Lecture: Bringing a medical device to market: Regulatory requirements
Week 3 : 26 February - 3 March	Lecture	Case study discussion and general Q&A. Online modules 5 & 6 Recorded Lecture: What are the Quality System requirements?
	Assessment	Device Classification
Week 4 : 4 March - 10 March	Lecture	Case study discussion and general Q&A. Online modules 9 Recorded Lecture: Biocompatibility, GLP & GCP (Laura Poole-Warren)
Week 5 : 11 March - 17 March	Tutorial	Group presentations in tutorial time slots (Monday)
	Module	Online modules 7 & 8
	Assessment	Regulatory Pathways presentations
Week 6 : 18 March - 24 March	Lecture	Case study discussion and general Q&A. Online Module 10 Recorded Lecture: Electrical Medical Device Safety & Essential Performance (IEC 60601-1)
	Assessment	Partner Group Comparisons
Week 7 : 25 March - 31 March	Lecture	Case study discussion and general Q&A. Online modules 11 Recorded Lecture: Usability Engineering
	Assessment	Peer Marking of Partner Group comparisons
Week 8 : 1 April - 7 April	Lecture	Case study discussion and general Q&A. Online modules 12
Week 9 : 8 April - 14 April	Assessment	Online exam during lecture time
Week 10 : 15 April - 21 April	Assessment	Technical Eveidence Report All online modules to be completed

Attendance Requirements

Please note that lecture recordings are not available for this course. Students are strongly encouraged to attend all classes and contact the Course Authority to make alternative arrangements for classes missed.

General Schedule Information

Suggested approach to learning

This course requires students to understand the module material and then apply the knowledge gained to the regulation strategies for medical device applications. It is important to understand the fundamental concepts as soon as possible and to ask for help if they do not understand. Complete all the module materials and if something is unclear, please ask questions. It is important to review all the module notes and read all material that is suggested in the modules. Class participation through on-line discussions is expected and will allow for alternative methods of absorbing the relevant information.

Course Resources

Prescribed Resources

To undertake this course successfully, students will need:

- Access to a computer that supports Moodle. Students are encouraged to read the Moodle guidelines carefully to familiarise themselves with how to use Moodle and the following tools used in the course.
- The Moodle calendar shows when assignments are due. It is strongly suggested that students complete at least one online module per week during the session.
- Please watch Moodle for announcements about the course during the session.
- All assignments must be submitted electronically via the Assignment Submission section of the Moodle site.
- Access to the Internet.
- Access to a USB drive (one per group) for the week 5 presentations
- A UNSW student number and password to enable access to electronic journals and password-controlled databases via the UNSW Library. During the course, students will be asked to access the Australian Standards Database and articles from online journals. Library staff should be advised of any problems with access to journals or databases.
- Access to Lectures through Moodle.
- Access to the subject coordinator via the BIOM9410 Moodle site
- Access to a good medical dictionary. An electronic version can be found at https://www.merriam-webster.com/medical.

Recommended Resources

See resources provided via Moodle.

Course Evaluation and Development

Student feedback on the course and the lecturers in the course is gathered periodically using the university's MyExperience. Your feedback is much appreciated and taken very seriously. Continual improvements are made to the course based in part on such feedback and this helps us to improve the course for future students.

This course has been modified based on feedback from previous years. All guest lectures will be pre-recorded and available anytime. Lecture times will be used to explore case studies that expand on the knowledge conveyed in the online modules and guest lectures. No assessable info will be provided in these sessions, but clarifications as well as examples and case studies may be discussed. The Week 5 presentations will be recorded and placed on the moodle page. This will allow for all class participants to be able to learn about the various regions and devices and allow for revision and easy comparison by the partner groups.

Staff Details

Position	Name	Email	Location	Phone	Availability	Equitable Learning Services Contact	Primary Contact
Convenor	Penny Martens		Samuels 511	9385 3902	Please contact via email in first instance	Yes	Yes
Lecturer	Laura Poole-Warren					No	No
	Daniel Judson		External (industry) Lecturer		Please contact Penny in the first instance if you have questions for Daniel	No	No

Other Useful Information

Academic Information

I. Special consideration and supplementary assessment

If you have experienced an illness or misadventure beyond your control that will interfere with your assessment performance, you are eligible to apply for Special Consideration prior to, or within 3 working days of, submitting an assessment or sitting an exam.

Please note that UNSW has a Fit to Sit rule, which means that if you sit an exam, you are declaring yourself fit enough to do so and cannot later apply for Special Consideration.

For details of applying for Special Consideration and conditions for the award of supplementary assessment, please see the information on UNSW's Special Consideration page.

II. Administrative matters and links

All students are expected to read and be familiar with UNSW guidelines and polices. In particular, students should be familiar with the following:

- Attendance
- UNSW Email Address
- Special Consideration
- Exams
- Approved Calculators
- Academic Honesty and Plagiarism
- Equitable Learning Services

III. Equity and diversity

Those students who have a disability that requires some adjustment in their teaching or learning environment are encouraged to discuss their study needs with the course convener prior to, or at the commencement of, their course, or with the Equity Officer (Disability) in the Equitable Learning Services. Issues to be discussed may include access to materials, signers or note-takers, the provision of services and additional exam and assessment arrangements. Early notification is essential to enable any necessary adjustments to be made.

IV. Professional Outcomes and Program Design

Students are able to review the relevant professional outcomes and program designs for their streams by going to the following link: https://www.unsw.edu.au/engineering/student-life/student-resources/program-design.

Note: This course outline sets out the description of classes at the date the Course Outline is published. The nature of classes may change during the Term after the Course Outline is published. Moodle or your primary learning management system (LMS) should be consulted for the up-to-date class descriptions. If there is any inconsistency in the description of activities between the University timetable and the Course Outline/Moodle/LMS, the description in the Course Outline/Moodle/LMS applies.

Academic Honesty and Plagarism

UNSW has an ongoing commitment to fostering a culture of learning informed by academic integrity. All UNSW students have a responsibility to adhere to this principle of academic integrity. Plagiarism undermines academic integrity and is not tolerated at UNSW. *Plagiarism at UNSW is defined as using the words or ideas of others and passing them off as your own.*

Plagiarism is a type of intellectual theft. It can take many forms, from deliberate cheating to accidentally copying from a source without acknowledgement. UNSW has produced a website with a wealth of resources to support students to understand and avoid plagiarism, visit: student.unsw.edu.au/plagiarism. The Learning Centre assists students with understanding academic integrity and how not to plagiarise. They also hold workshops and can help students one-on-one.

You are also reminded that careful time management is an important part of study and one of the identified causes of plagiarism is poor time management. Students should allow sufficient time for research, drafting and the proper referencing of sources in preparing all assessment tasks.

Repeated plagiarism (even in first year), plagiarism after first year, or serious instances, may also be investigated under the Student Misconduct Procedures. The penalties under the procedures can include a reduction in marks, failing a course or for the most serious matters (like plagiarism in an honours thesis or contract cheating) even suspension from the university. The Student Misconduct Procedures are available here:

www.gs.unsw.edu.au/policy/documents/studentmisconductprocedures.pdf

Submission of Assessment Tasks

Work submitted late without an approved extension by the course coordinator or delegated authority is subject to a late penalty of five percent (5%) of the maximum mark possible for that assessment item, per calendar day.

The late penalty is applied per calendar day (including weekends and public holidays) that the assessment is overdue. There is no pro-rata of the late penalty for submissions made part way through a day. This is for all assessments where a penalty applies.

Work submitted after five days (120 hours) will not be accepted and a mark of zero will be

awarded for that assessment item.

For some assessment items, a late penalty may not be appropriate. These will be clearly indicated in the course outline, and such assessments will receive a mark of zero if not completed by the specified date. Examples include:

- Weekly online tests or laboratory work worth a small proportion of the subject mark;
- Exams, peer feedback and team evaluation surveys;
- Online quizzes where answers are released to students on completion;
- Professional assessment tasks, where the intention is to create an authentic assessment that has an absolute submission date; and,
- Pass/Fail assessment tasks.

Faculty-specific Information

Engineering Student Support Services – The Nucleus - enrolment, progression checks, clash requests, course issues or program-related queries

Engineering Industrial Training – Industrial training questions

UNSW Study Abroad – study abroad student enquiries (for inbound students)

UNSW Exchange – student exchange enquiries (for inbound students)

UNSW Future Students – potential student enquiries e.g. admissions, fees, programs, credit transfer

Phone

(+61 2) 9385 8500 – Nucleus Student Hub

(+61 2) 9385 7661 – Engineering Industrial Training

(+61 2) 9385 3179 – UNSW Study Abroad and UNSW Exchange (for inbound students)

School Contact Information

Student Services can be contacted via unsw.to/webforms.