BIOM9410

Regulatory Requirements of Biomedical Technology

Term One // 2021

Graduate School of Biomedical Engineering // UNSW Engineering

Course Overview

Staff Contact Details

Convenors

Name	Email	Availability	Location	Phone
Penny Martens	p.martens@unsw.edu.au			

Lecturers

Name	Email	Availability	Location	Phone
Lionel King	lionel.king@unsw.edu.au			
Laura Poole-Warren	l.poolewarren@unsw.edu.au			
Johanna Wright	lionel.king@unsw.edu.au	Please contact Lionel in the first instance if you have questions for Johanna	External (industry) Lecturer	
Daniel Judson	lionel.king@unsw.edu.au	Please contact Lionel in the first instance if you have questions for Daniel	External (industry) Lecturer	

School Contact Information

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

Course Details

Credit Points 6

Summary of the Course

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.

Course Aims

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

Expected learning outcomes
On completion of this course, the student should:

- Understand the concept of regulation and why it is appropriate to regulate medical technology,
- Understand the regulations that apply to each part of the process of development and marketing of medical technology,
- Understand how regulation is applied to medical technology in various countries around the world, and
- Be able to discuss, develop and apply regulatory strategies to various medical technologies.

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

Course Learning Outcomes

After successfully completing this course, you should be able to:

Learning Outcome	**EA Stage 1 Competencies**
1. Describe the concept of regulation and why it is appropriate to regulate medical technology	PE1.3, PE1.6, PE2.2, PE3.1
2. Explain the regulations that apply to each part of the process of development and marketing of medical technology	PE1.6, PE2.2, PE3.6, PE3.2
3. Discuss how regulation is applied to medical technology in various countries around the world	PE1.5, PE2.1, PE2.2, PE3.2, PE3.6
4. Develop and apply regulatory strategies to various medical technologies	PE1.5, PE2.1, PE3.2, PE3.6

Teaching Strategies

BIOM9410 is a blended learning course, delivered online via Moodle and through face-to-face Q&A (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.

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. The following is some basic information only.

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.

Additional Course Information

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.
- 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 Standards Australia (SA) website 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**.

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.

Assessment

Submission of Assignments

Assignments are submitted electronically via Moodle with a cover sheet attached by 12pm Wednesday 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 10% of the marks available for that assignment will apply for work received after the due date. 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:

Assessment Tasks

Assessment task	Weight	Due Date	Student Learning Outcomes Assessed
Online Modules	5%	21/04/2021 12:00 PM	1, 2, 3, 4
Online exam	15%	14/04/2021 12:00 PM	1, 2, 3, 4
Major Project	50%	03/03/2021 12:00 PM	1, 2, 3, 4
Final Exam	30%	Not Applicable	1, 2, 3, 4

Assessment Details

Assessment 1: Online Modules

Details:

There are 12 modules. Each module has a small quiz at the end. Students 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 students:

- actively make sense of what they are reading,
- apply what they are reading to real life medical technology, and

- share their experiences with and learn from other students within the course.

Assessment 2: Online exam

Details:

The Online Exam will be given in **week 9**. This will require interpretation of the dynamics of current regulatory bodies. To complete the exam, students will use fundamental material from the modules and guest lectures.

Assessment 3: Major Project

Details:

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.

Additional details:

Part 1 –Device Description (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 and is due in **week 3**.

Part 2 – Regulatory Pathway Presentation (Group work) (10%)

This task will involve collaboration of 2 groups from the same tutorial. 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 work 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.

Part 3 - Technical Evidence Report (Group work) (30%)

This task will be performed by a single group 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 to be submitted in **week 10**. It is worth 30% 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.

Assessment 4: Final Exam

Details:

Students 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 essay-style questions that give students the opportunity to integrate the key concepts and issues raised in the class. The aim of the exam is to encourage students to review their course material for the session and to do so in ways that are **analytical, evaluative and problem solving.** More details about the exam format will be provided through Moodle later in the session.

Attendance Requirements

Students are strongly encouraged to attend all classes and review lecture recordings.

Course Schedule

View class timetable

Timetable

Date	Type	Content
Week 1: 15 February - 19 February	Lecture	Introduction (Penny Martens & Lionel King)
	Online Activity	Module 1
Week 2: 22 February - 26 February	Lecture	General Q&A (Penny Martens & Lionel King)
	Online Activity	Module 2 & 3
Week 3: 1 March - 5 February	Lecture	General Q&A (Penny Martens & Lionel King)
	Online Activity	Module 4 & 5 Lecture: Bringing a medical device to market: Regulatory requirements (Johanna Wright)
	Assessment	Individual Device Description
Week 4: 8 March - 12 March	Lecture	Guest Q&A: (Johanna Wright)
	Online Activity	Module 6 & 7
Week 5: 15 March - 19 March	Tutorial	Regulatory Pathways Group Presentations
	Assessment	Regulatory Pathways Group Presentations
	Online Activity	Module 8 & 9 Lecture: Bringing a medical device to market: What are the Quality System requirements? (Daniel Judson)
Week 6: 22 March - 26 March	Lecture	Guest Q&A: (Daniel Judson)
Week 7: 29 March - 2 April	Lecture	General Q&A (Penny Martens & Lionel King)
	Online Activity	Module 10 & 11 Lecture: Biocompatibility, GLP & GCP (Laura Poole-Warren)
Week 8: 5 April - 9 April	Lecture	Guest Q&A: (Laura Poole-Warren)
	Online Activity	Module 12 Lecture: Review aspects of Week 3 Lecture
Week 9: 12 April - 16 April	Lecture	General Q&A (Penny Martens & Lionel King)
	Assessment	Online Exam
Week 10: 19 April - 23 April	Assessment	Technical Evidence Group Report
	Assessment	All online modules

Resources

Prescribed Resources

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- 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.
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- 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

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 had a significant revamp this year based on feedback from previous years. All guest lectures will be pre-recorded and available anytime. Lecture times will be used as optional Q&A sessions. No assessable info will be provided in these sessions, but clarifications as well as examples and case studies may be discussed.

Submission of Assessment Tasks

Laboratory reports and major assignments will require a Non Plagiarism Declaration Cover Sheet.

Late submissions will be penalised 10% of the mark for each calendar day late. If you foresee a problem in meeting the nominated submission date please contact the Course Convenor to make an appointment to discuss your situation as soon as possible.

Academic Honesty and Plagiarism

PLAGIARISM

Beware! An assignment that includes plagiarised material will receive a 0% Fail, and students who plagiarise may fail the course. Students who plagiarise will have their names entered on a plagiarism register and will be liable to disciplinary action, including exclusion from enrolment.

It is expected that all students must at all times submit their own work for assessment. Submitting the work or ideas of someone else without clearly acknowledging the source of borrowed material or ideas is plagiarism.

All assessments which you hand in must have a Non Plagiarism Declaration Cover Sheet. This is for both individual and group work. Attach it to your assignment before submitting it to the Course Coordinator or at the School Office.

Plagiarism is the use of another person's work or ideas as if they were your own. When it is necessary or desirable to use other people's material you should adequately acknowledge whose words or ideas they are and where you found them (giving the complete reference details, including page number(s)). The Learning Centre provides further information on what constitutes Plagiarism at:
https://student.unsw.edu.au/plagiarism

Academic Information

COURSE EVALUATION AND DEVELOPMENT
Student feedback has helped to shape and develop this course, including feedback obtained from on-line evaluations as part of UNSW's as part of UNSW's myExperience process. You are highly encouraged to complete such an on-line evaluation toward the end of Term. Feedback and suggestions provided will be important in improving the course for future students.

DATES TO NOTE
Refer to MyUNSW for Important Dates, available at:
https://my.unsw.edu.au/student/resources/KeyDates.html

ACADEMIC ADVICE
For information about:

- Notes on assessments and plagiarism,
- Special Considerations,
- School Student Ethics Officer, and
- BESS

refer to the School website available at
http://www.engineering.unsw.edu.au/biomedical-engineering/

Supplementary Examinations:

Supplementary Examinations for Term 1 2021 will be held on Monday 24th May – Friday 28th May (inclusive) should you be required to sit one.

Image Credit

Synergies in Sound 2016

CRICOS

CRICOS Provider Code: 00098G

Acknowledgement of Country

We acknowledge the Bedegal people who are the traditional custodians of the lands on which UNSW Kensington campus is located.

Appendix: Engineers Australia (EA) Professional Engineer Competency Standard

Program Intended Learning Outcomes	
Knowledge and skill base	
PE1.1 Comprehensive, theory based understanding of the underpinning natural and physical sciences and the engineering fundamentals applicable to the engineering discipline	
PE1.2 Conceptual understanding of the mathematics, numerical analysis, statistics, and computer and information sciences which underpin the engineering discipline	
PE1.3 In-depth understanding of specialist bodies of knowledge within the engineering discipline	✓
PE1.4 Discernment of knowledge development and research directions within the engineering discipline	
PE1.5 Knowledge of engineering design practice and contextual factors impacting the engineering discipline	✓
PE1.6 Understanding of the scope, principles, norms, accountabilities and bounds of sustainable engineering practice in the specific discipline	✓
Engineering application ability	
PE2.1 Application of established engineering methods to complex engineering problem solving	✓
PE2.2 Fluent application of engineering techniques, tools and resources	✓
PE2.3 Application of systematic engineering synthesis and design processes	
PE2.4 Application of systematic approaches to the conduct and management of engineering projects	
Professional and personal attributes	
PE3.1 Ethical conduct and professional accountability	✓
PE3.2 Effective oral and written communication in professional and lay domains	✓
PE3.3 Creative, innovative and pro-active demeanour	
PE3.4 Professional use and management of information	
PE3.5 Orderly management of self, and professional conduct	
PE3.6 Effective team membership and team leadership	✓