Faculty of Engineering
Graduate School of Biomedical Engineering

Term 1, 2020
BIOM9410 Regulatory Requirements of Medical Technology

COURSE DETAILS

Units of Credit: 6
Contact hours: 3 hours per week

Lecture: Mondays, 11:00 – 13:00 in Elec Eng G23

Tutorial/Laboratory: As timetabled
Wed 1-3pm, Week 5 Mathews 307
OR
Wed 3-5pm, Week 5 Mathews 307
OR
Thurs 1-3pm, Week 5 Mathews 307

Course Coordinator: Penny Martens
Biomedical Engineering
Email: p.martens@unsw.edu.au

Primary Lecturer & point of contact: Lionel King (lionel.king@unsw.edu.au)

Lecturers: Laura Poole-Warren (lpoolewarren@unsw.edu.au)
Johanna Wright (external lecturer)
INFORMATION ABOUT 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.

The course aims to give a broad overview of the regulation of medical devices around the world. All essential material will be provided during the course.

HANDBOOK DESCRIPTION


OBJECTIVES

• 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

TEACHING STRATEGIES

BIOM9410 is a blended learning course, delivered online via Moodle and through face-to-face lectures and tutorials. Course content will be presented through 13 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.
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 and suggested dates for the completion of each module. It is strongly suggested that students complete at least one module per week during the session.
- Please watch the Home Page 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

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.

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

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

Assessment for the course has been designed to measure achievement of the learning outcomes and will be via completion of online modules worth 5%, 1 mid-term quiz worth 25%, a group assignment (including presentation) worth 30%, and the final exam worth 40%.

The following criteria will be applied in assessing work:

- Evidence of critical understanding of the concepts developed in the course
- Ability to apply these concepts
- Clarity of description, explanation and attention to the focus of the assessment task
- Capacity to structure an assessment task logically
- Degree to which the material submitted for assessment addresses the specified requirements

Assessment of this course has been designed to maximise learning opportunities for students. The assessment items cover and apply all the main knowledge and skills areas in the course. In particular, they provide students with an opportunity to:

- Synthesise and integrate the core concepts and issues raised in the module material and readings,
- Develop written skills in evaluating and conveying arguments and issues,
- Share ideas, knowledge and different perspectives during online discussions and
- Receive ongoing feedback on learning.

Online Course Modules (5%)

There are 13 modules. Each module has a small quiz at the end. They aim to help students:

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

Mid-Term Quiz (25%)

One Mid-Term Quiz will be given in week 5 or 7 (to be determined in class week 1). This will require interpretation of the dynamics of current regulatory bodies. To complete the quiz, students will use fundamental material from the modules and guest lectures.

Group assignment (30%)

The objectives of the group assignment are to consolidate information learned in class and to develop literature research skills. 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. A statement of individual contributions to the group assignment needs to preface the submission of the group assignment. The group assignment final report is to be submitted in week 10 and is worth 20% of the overall mark. This assessment is a direct measure of the degree to which the learning outcomes described above have been achieved.

A presentation will be a component of the group assignment, worth 7.5%. The presentations will be via video submission due in week 9. The presentation will be given by all of 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.

To ensure adequate progress and provide tailored help for the group assignment, in week 5, each group will present a skeleton of their group assignment in individual tutorials. Details will be provided in class. This presentation will be worth 2.5% of the overall group assignment mark.
Final exam (40%)

Students will sit a 2-hour 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 module material. 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 or in face-to-face sessions later in the session.

Submission of Assignments

Assignments are submitted electronically via Moodle with a cover sheet attached by 4pm Monday 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](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 on-line 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](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 SUMMARY**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Due</th>
<th>Worth</th>
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<tbody>
<tr>
<td>Group assignment skeleton presentation</td>
<td>Week 5</td>
<td>2.5%</td>
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<tr>
<td>Mid-Term Quiz</td>
<td>Week 5 or 7 (to be determined in class week 1)</td>
<td>25%</td>
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<tr>
<td>Group assignment presentation</td>
<td>Week 9</td>
<td>7.5%</td>
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<tr>
<td>Group assignment report</td>
<td>Week 10</td>
<td>20%</td>
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<tr>
<td>Online Modules</td>
<td>Week 10</td>
<td>5%</td>
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<tr>
<td>Final Exam</td>
<td>Exam period</td>
<td>40%</td>
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# COURSE SCHEDULE

**Term 1, 2020**

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Time and Location</th>
<th>Assessments Due</th>
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<tbody>
<tr>
<td>1</td>
<td>17 Feb</td>
<td>Introduction (Penny Martens) Introductory lecture, Introduction to devices/Group assignment details (Lionel King)</td>
<td>Monday 11am-1pm, Elec Eng G23</td>
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<td>2</td>
<td>24 Feb</td>
<td>Guest lecture 1: Biocompatibility, GLP &amp; GCP (Laura Poole-Warren)</td>
<td>Monday 11am-1pm, Elec Eng G23</td>
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<td>3</td>
<td>2 March</td>
<td>Guest lecture 2: Overview of Medical Device Regulatory Process (Johanna Wright)</td>
<td>Monday 11am-1pm, Elec Eng G23</td>
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<td>4</td>
<td>9 March</td>
<td>Quality Systems: Why? (Lionel King)</td>
<td>Monday 11am-1pm, Elec Eng G23</td>
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<td>5</td>
<td>16 March</td>
<td><strong>Possible Mid-Sem Quiz (tbd in class wk 1)</strong></td>
<td>Wed 1-3pm, Mathews 307</td>
<td>Individual tutorials:</td>
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<td>Wed 3-5pm, Mathews 307</td>
<td>Group skeleton presentations</td>
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<td>Thur 1-3pm, Mathews 307</td>
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<td>6</td>
<td>23 March</td>
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<td>7</td>
<td>30 March</td>
<td><strong>Possible Mid-Sem Quiz (tbd in class wk 1)</strong></td>
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<td>9</td>
<td>13 Apr</td>
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<td>Group presentations</td>
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<td>20 Apr</td>
<td>Easter</td>
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<td>10</td>
<td>27 April</td>
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<td>Group report</td>
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<td>Online modules</td>
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RELEVANT RESOURCES
See resources provided via Moodle.

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

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.

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 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 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/