Faculty of Engineering  
Graduate School of Biomedical Engineering

Session 1, 2017  
BIOM9332 Biocompatibility

COURSE DETAILS

Units of Credit: 6  
Contact hours: 3 hours per week  
Lecture: Thursday, 1:00 – 4:00 p.m.  
Pioneer International Theatre, AGSM

Tutorial/Laboratory: During class

Course Coordinator and Lecturer:  
Professor Melissa Knothe Tate,  
Paul Trainor Chair of Biomedical Engineering  
email: m.knothetate@unsw.edu.au  
office: Samuels 509  
phone: +61 02 9385 3924

Please post questions about course to moodle so I can respond in a timely manner and everyone can benefit from my responses.

Lecturers:  
Dr. Kathryn (Kate) Poole, Senior Lecturer in Department of Physiology, School of Medical Sciences  
email: k.poole@unsw.edu.au

Dr. Jelena Rnjak-Kovacina, Lecturer in GSBmE  
email: j.rnjak-kovacina@unsw.edu.au

Ms. Joanna Ng

Mr. Dan Hageman

Guest Lecturer:  
Dr. Arthur Brandwood, CEO Brandwood Biomedical

INFORMATION ABOUT THE COURSE

This is a fundamental course within the Master of Engineering Science and Master of Biomedical Engineering programs within Biomedical Engineering. BIOM9332 is recommended for all four coursework masters’ programs (four streams across specific interest areas). Other related and recommended classes are BIOM9333 Cellular and Tissue Engineering, BIOM9432 Introductory Polymer Chemistry, and BIOM9561 Mechanical Properties of Biomaterials.

The topic is taking on increasing relevance with the advent of advanced, smart materials, and the capacity for virtual testing and prioritisation of biocompatibility testing for regulatory approval. Toward that end, and with the goal to make the course more related to the R&D translation cycle, the course has been updated this year to include a regulatory conference in which start up companies formed within the class take their products for biocompatibility testing and regulatory approval.

HANDBOOK DESCRIPTION

See link to virtual handbook - for example, for BIOM9332, this would be:  
OBJECTIVES

The course will encourage student learning in the field of biocompatibility, with emphasis on understanding biological responses to a broad range of currently available and future medical devices and advanced materials. Biocompatibility encompasses the host responses to medical devices as well as the material responses to physiological conditions including dynamic loading cycles over the lifetime of the device. The issues encountered when exposing medical devices to the human body include deposition of proteins, cells and tissue growth leading to failure (e.g. thrombus), toxic responses (acute, primary, immune, genotoxic, etc.), abnormal cell/tissue responses (e.g. carcinogenesis), and device degradation leading to failure (e.g. environmental stress cracking, wear, etc.).

Many medical devices are constructed from synthetic materials that have been proven safe and thus are usually tolerated by the body initially. However, exposure to the normal physiological environment alone affects these materials. Initiation of inflammation and foreign body responses can amplify these effects.

Ideally medical devices should be integrate with host tissues rather than tolerated and the next generation of medical devices includes engineered advanced materials and devices. Such next generation devices aim to replace damaged tissues and organs with viable biological constructs with the ultimate aim to regenerate tissue rather than to simply replace tissue or repair damage. Such devices are increasingly combining materials, cellular and pharmaceutical approaches and thus new regulations have had to be developed (combination products).

List of programme attributes:
- An in-depth engagement with the relevant disciplinary knowledge in its inter-disciplinary context
- Capacity for analytical and critical thinking and for creative problem solving
- Ability to engage independent and reflective learning
- Information literacy
- Skills for collaborative and multi-disciplinary work
- A respect for ethical practice and social responsibility
- Skills for effective communication

TEACHING STRATEGIES

Each week there will be a three hour lecture period which may incorporate practical exercises, group analysis and discussions, and other methods to integrate concepts and to facilitate critical thinking.

The lectures are designed to provide students with a basis knowledge of the many topics covered in the class. This knowledge will be needed to understand in depth learning through reading of the literature and successful completion of major assignments.

<table>
<thead>
<tr>
<th>Private Study</th>
<th>Lectures</th>
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</thead>
<tbody>
<tr>
<td>• Review lecture material and textbook</td>
<td>• Find out what you must learn</td>
</tr>
<tr>
<td>• Do set problems and assignments</td>
<td>• See methods that are not in the textbook</td>
</tr>
<tr>
<td>• Join Moodle discussions of problems</td>
<td>• Follow worked examples</td>
</tr>
<tr>
<td>• Reflect on class problems and assignments</td>
<td>• Hear announcements on course changes</td>
</tr>
<tr>
<td>• Download materials from Moodle</td>
<td>• Keep up with notices and find out marks via Moodle</td>
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<table>
<thead>
<tr>
<th>Tutorials</th>
<th>Assessments (multiple choice questions, quizzes, tests, examinations, assignments, site visit reports, hand-in tutorials, laboratory reports etc.)</th>
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</thead>
<tbody>
<tr>
<td>• Be guided by demonstrators</td>
<td>• Demonstrate your knowledge and skills</td>
</tr>
<tr>
<td>• Practice solving set problems</td>
<td></td>
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<tr>
<td>• Ask questions</td>
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• Private Study

| Assessments (multiple choice questions, quizzes, tests, examinations, assignments, site visit reports, hand-in tutorials, laboratory reports etc.) | • Demonstrate your knowledge and skills |

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EXPECTED LEARNING OUTCOMES

For each hour of contact it is expected that you will put in at least 1.5 hours of private study.

The overall learning outcomes of this course are to
- understand fundamental concepts related to biological performance of materials used in medical devices.
- apply knowledge of biological performance concepts to development of preclinical evaluation programs for medical materials and devices, in particular combination devices that incorporate biological materials, cultured cells, and/or pharmaceuticals.

**Knowledge**
On completion of this course, the student should be able to:

a. Describe biomaterial classes, their general properties and how these may be altered following exposure to the body for different periods
b. Outline definitions of tissue engineering and define types of biological materials and cells that may be used in their fabrication
c. Predict how specific materials may be affected by physiological conditions
d. Explain how material processing, sterilisation and handling may affect device/material function
e. Describe the host responses that occur in blood, soft-tissue and bone
f. Outline the factors influencing development of device related infection
g. Describe the range of preclinical tests and their specific uses in preclinical biological performance testing

**Skills**
On completion of this course, the student should be able to:

a. Critically review the literature and apply knowledge gained from the course to predict material and host responses in a range of specific device applications
b. Develop a biological performance testing strategy according to ISO10993 guidelines
c. Using knowledge gained from this course and critical review of the literature, select appropriate materials for medical devices, including tissue engineered devices
d. Clearly summarise and communicate findings from literature research using oral and written methods

These learning outcomes relate most strongly to the following UNSW graduate capabilities:
- capable of independent and collaborative enquiry
- capable of effective communication
- information literate
- enterprising, innovative and creative
- collaborative and effective team workers

They are also moderately related to the following UNSW graduate capabilities:
- understanding of their discipline in its interdisciplinary context
- rigorous in their analysis, critique and reflection
- able to apply their knowledge and skills to solving problems
- capable of independent, self-directed practice
- capable of lifelong learning
ASSESSMENT
Course performance will be evaluated through an in class assessment, quizzes, an individual assignment and group assignment involving reports and oral presentations and a Final Theory Exam. In general, marks are given for content, presentation, and proper referencing (where appropriate). Specific criteria for individual tasks will be supplied when the assessment task is handed out.

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:

ASSIGNMENTS

In class assessment and Quizzes (20%)
Two Quizzes will be scheduled.
Each quiz will be made up of 5-10 short answer and/or multiple choice questions in a similar format to that given in the final exam.
This assessment is a direct measure of the knowledge based learning outcomes listed above. The aims of this assessment are to encourage student revision during the course, and to allow students to gauge their progress in different topics and receive feedback on that progress.

Final Theory Exam (40%)
The final exam may be made of any of the following: true/false, multiple choice, matching, short answer and an essay question.
This assessment is a direct test of the degree to which the knowledge based learning outcomes listed above have been achieved. The aims of this assessment are to encourage students to review the entire course, and to allow students to apply all of the knowledge disseminated to solve problems.
NOTE: You MUST pass the final exam to pass the class.

Assignments (40%)
The entire major assignment is made up of 3 parts:
Individual Assignment (10%)
Company Dossier part 1 (10%)
Final Company Dossier (10%)
Regulatory Decisions (10%)
# COURSE PROGRAM

A table of lecture and tutorial or practical class topics for each week, indicating the name of lecturer involved (where multiple lecturers teaching in course), online activities, such as discussion forums, and relevant readings from textbook and other reference material identified for the course.

## SEMESTER 1, 2017

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Lecturer</th>
<th>Assessments Due</th>
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</table>
| 1    | 2 March 2017 | Course Outline and Objectives  
‘The perfect material’: utopia  
How does the body know what’s its own?  
The foreign body response: reality | MKT      | In class assessment           |
| 2    | 9 March 2017 | First line of defense: the immune system | JN       |                                |
| 3    | 16 March 2017 | The R&D cycle:  
From creation of intellectual property to regulatory considerations for translation  
- Biocompatibility testing guidelines  
- Exercise on ISO 10993 | MKT      | Individual assignment due    |
| 4    | 23 March 2017 | Cells, matrix and cell-matrix interactions | JRK      |                                |
| 5    | 30 March 2017 | How cells and tissues and organ systems view different materials used in medical devices, from sutures to organ replacements | MKT      | Quiz 1: Weeks 1-4             |
| 6    | 6 April 2017  | Host response I-II:  
Inflammatory response and wound healing  
Specific immune responses | MKT      |                                |
| 7    | 13 April 2017 | Host response II - III:  
Specific immune responses  
Device related infection | MKT      | Quiz 2: Weeks 5-7             |
|      | Break       | 20 April 2017                                                        |          |                                |
| 8    | 27 April 2017 | How cells sense their surroundings  
How can we test this in the lab? | KP       |                                |
| 9    | 4 May 2017   | Next generation biocompatibility: interfacing with the brain and the body | DH       |                                |
| 10   | 11 May 2017  | Post manufacturing considerations: from sterilisation to monitoring device failure  
Company set up: | MKT      |                                |
| 11   | 18 May 2017  | From the ‘trenches’ at the cutting edge of commercialisation: the biocompatibility guru talks compliance | AB       | Company dossier part 1        |
| 12   | 25 May 2017  | Company set up: preparing the dossier | MKT      |                                |
| 13   | 1 June 2017  | Medical Device Convention  
Major Assignment | MKT      | Final company dossier  
Regulatory Decisions          |

## RELEVANT RESOURCES

Moodle is the main resource for this class. [http://moodle.telt.unsw.edu.au/my/](http://moodle.telt.unsw.edu.au/my/)

Many of the lecture notes will be provided on this website, as well as other references and information. You should check Moodle regularly. Any announcements or other important information for the class will be posted here. Marks will also be made available on Moodle.

No specific textbooks will be used in this course. Some lecturers will provide additional notes, or other references for further reading.
Students seeking resources can also obtain assistance from the UNSW Library. One starting point for assistance is: http://www.library.unsw.edu.au/

COURSE EVALUATION AND DEVELOPMENT
Student feedback has helped to shape and develop this course, including feedback obtained from online evaluations as part of UNSW’s myExperience process.

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

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 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/