

## IMPLANTED BIOMATERIALS

**CHEMBIO 3BM3 (Jan – April 2017)**

**ROOM TBD; Tues; Thurs; Fri 8:30-9:20**

**Instructor:** Dr. Mike Brook (Office ABB 459; email: [mabrook@mcmaster.ca](mailto:mabrook@mcmaster.ca))

**Office Hours:** by appointment

**Objectives - Summary:** Students will develop a better appreciation of biomedical materials, the challenges associated with integrating a synthetic material to local biology – the biomaterials interface – and the regulatory hurdles faced by device manufacturers.

**Objectives:** Medicine in the developed world is increasingly about quality of life, which includes “being younger longer.” An important aspect of that paradigm involves implantable biomaterials that (partly or completely) restore mobility (e.g., through hip and knee implants), improve blood pressure (stents), improve vision (contact lenses, intraocular lenses), and provide aesthetic benefit (collagen injections, breast implants), among many others. In this course, we will examine the materials commonly used in implantable devices, including metals, ceramics and particularly polymers. The biological environment into which they will be placed will be considered in the context of wound healing (inflammation, the foreign body response). The preclinical testing required for a medical device, prior to regulatory approval, will provide context to the course. The capstone activity will involve developing, as a group, a premarket application for a biomedical device to Health Canada, which will involve both a presentation and completion of a formal application for device approval.

**Evaluation (some of these, particularly the major assignment, will be group work):**

- |    |   |            |                   |
|----|---|------------|-------------------|
| 1. | 1 minor assignment  | <b>10%</b> | February 7, 2016  |
| 2. | 1 midterm test  | <b>15%</b> | February 14, 2016 |
| 3. | 1 major assignment – create a PMA for a medical device (premarket approval) to present to Health Canada | <b>25%</b> | March 28, 30      |
| 4. | Final exam (2 hours)  | <b>50%</b> | TBD               |

Notes: 1. Any assignments, tests or exams written in pencil will not be eligible for re-grading. 2. The mark value of any missed tests or assignments (with acceptable excuse, as per the Dean’s office) will be added to the value of the final exam. 3. **Assignment 1 and the midterm test are completely optional. If you elect not to write them, OR IF THEIR VALUE BRINGS DOWN YOUR FINAL MARK, the final exam will take on greater value.**

**Textbook:**

Buddy D. Ratner (Editor), Allan S. Hoffman (Editor), Frederick J. Schoen (Editor), Jack E. Lemons (Editor), Biomaterials Science: An Introduction

to Materials in Medicine Paperback – 1996 (hardcopy or paperback, or the second edition)

**Overview: (Subjects will NOT be presented linearly as shown)**

**Biology**

- Proteins and their behavior at interfaces
- Cells and their behavior at interfaces
- Wound healing
  - Inflammatory response (non-blood contacting, in blood)
  - Immunogenic response

**Chemical Topics**

What is a Metal; Glass; Ceramic; Polymer (a: (Thermo) Plastic; b: Elastomer; c: Gel)?

What is surface chemistry (Hydrophobic/hydrophilic, Surface energy, How to modify surfaces.

**Engineering (brief)**

What mechanical properties matter?

- Strength (e.g., fibres) (Elongation at Break; Tensile)
- Toughness (Impact; Shear)
- Brittleness (Impact; Bending)
- Hardness (Durometer)
- Adhesion (Peel tests)

**Special Topics**

Orthopedic day (Hip, knee)  
Ophthalmic day (IOL, Contact lens, Retinal tamponade)  
Plastic Surgery day (Dermal filler, Breast/butt/penile implants)  
Heart day

**Regulatory Issues**

- Classes of devices
- How to get a device approved for use in Canada.

**Website:** Information on the course (including class notes, assignments, solutions, etc.) will be posted on McMaster's Avenue system. A discussion board will also be available for you to post questions and answer questions from your peers.

**McMaster's Policy on Academic Dishonesty**

Academic dishonesty consists of misrepresentation by deception or by other fraudulent means and can result in serious consequences, e.g., a grade of zero on an assignment, loss of credit with a notation on transcript and/or suspension or expulsion from university.

It is your responsibility to understand what constitutes academic dishonesty. For information on the various kinds of academic dishonesty please refer to the Academic Integrity Policy, specifically Appendix 3:

[http://www.mcmaster.ca/senate/academic/ac\\_integrity.htm](http://www.mcmaster.ca/senate/academic/ac_integrity.htm)

The following illustrates only three forms of academic dishonesty most relevant to experimental research and scientific ethical behavior:

1. *Plagiarism*: Submission of work (e.g., report, manuscript, presentation) that is not one's own work or for which other credit (e.g., citation, permission) has not been obtained. Transcribing passages from other references in lab reports is an example.

2. *Fraudulent Data*: The intentional use of fraudulent, inauthentic and misleading data in experimental research that cannot be reproduced independently by other groups; submitting data collected by someone else and passing it off as your own.

3. *Improper Collaboration*: Taking credit for work performed in a group without reasonable and/or equitable effort consistent with other members of the group .

The university requires that every act of academic dishonesty be reported and subjected to a penalty depending on specific context.

To avoid any conflicts with this policy:

- Limit any discussion of academic work with your peers, avoiding specific details of assignments or laboratory reports (unless instructed otherwise)
- Record authentic data and all observations during an experiment in an unaltered laboratory notebook as a permanent record.
- Consult your instructors or TAs in case of any doubts in these matters

*Note: The instructor and university reserve the right to modify elements of the course during the term. The university may change the dates and deadlines for any or all courses in extreme circumstances. If either type of modification becomes necessary, reasonable notice and communication with the students will be given with explanation and the opportunity to comment on changes. It is the responsibility of the student to check their McMaster email and course websites weekly during the term and to note any changes.*