Course Outline

1. COURSE INFORMATION

Session Offered  
Winter 2017

Course Name  
Biopharmaceuticals

Course Code  
BIOTECH 4BM3

Date(s) and Time(s) of lectures  
Mondays 10:30-12:20 (ETB 227); Wednesdays 12:30-13:20 (ETB 237)

Program Name  
Biotechnnology

Calendar Description  
An introduction to biopharmaceutical drug development and manufacture. Emphasis will include basic genetic engineering principles used in the development and large-scale manufacture of biopharmaceutical products.

Instructor(s)  
Dr. Rashid Abu-Ghazalah  
abughar@mcmaster.ca  
Office Hours & Location: Thursdays 10:30-12:30 (ETB 217)

2. COURSE SPECIFICS

Course Description  
This introductory Biopharmaceutical course will focus on the process of transforming a biologic macromolecule into a therapeutic agent, while also providing a brief overview of each class of macromolecule with respect to physiological role and clinical application. Various drug delivery strategies and gene and cell therapy strategies are also discussed.

Instruction Type  

<table>
<thead>
<tr>
<th>Code</th>
<th>Type</th>
<th>Hours per term</th>
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</thead>
<tbody>
<tr>
<td>C</td>
<td>Classroom instruction</td>
<td>39</td>
</tr>
<tr>
<td>L</td>
<td>Laboratory, workshop or fieldwork</td>
<td></td>
</tr>
<tr>
<td>T</td>
<td>Tutorial</td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td>Distance education</td>
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</table>

Total Hours  
39

Resources  

<table>
<thead>
<tr>
<th>ISBN</th>
<th>Textbook Title &amp; Edition</th>
<th>Author &amp; Publisher</th>
</tr>
</thead>
<tbody>
<tr>
<td>9781118179796</td>
<td>Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs</td>
<td>Rodney J. Y. Ho Wiley-Blackwell</td>
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</table>

Other Supplies  
avenue.mcmaster.ca

Prerequisite(s)  
BIOTECH 3BP3 and BIOTECH 3PM3

Corequisite(s)  
None

Antirequisite(s)  
None

Course Specific Policies  
This course will be using a range of software. Students should be aware that, when they access the electronic components of this course, private information such as first and last names, user names for the McMaster e-mail accounts, and program affiliation may become apparent to all other students in the same course. The available information is dependent on the technology used. Continuation in this course will be deemed consent to this disclosure. If you have any questions or concerns about such disclosure please discuss this with the course instructor. The instructor may also use other software including: e-
mail, Avenue, LearnLink, web pages, Turnitin, etc. Where group work is identified in a course outline, such work is mandatory. The communications via email strictly is by official McMaster University Account, no reply to commercial emails and/or nicknames. Late submission of assignments will be penalized 10% per day.

**Departmental Policies**

Students must maintain a GPA of 3.5/12 to continue in the program.

In order to achieve the required learning objectives, on average, B.Tech. students can expect to do at least 3 hours of “out-of-class” work for every scheduled hour in class. “Out-of-class” work includes reading, research, assignments and preparation for tests and examinations.

Where group work is indicated in the course outline, such collaborative work is mandatory.

The use of cell phones, iPods, laptops and other personal electronic devices are prohibited from the classroom during the class time, unless the instructor makes an explicit exception.

Announcements made in class or placed on Avenue are considered to have been communicated to all students including those individuals that are not in class.

Instructor has the right to submit work to software to identify plagiarism.

### 3. SUB TOPIC(S)

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Pharmaceuticals, biologics and biopharmaceuticals</th>
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</thead>
<tbody>
<tr>
<td>Week 2</td>
<td>The drug development process</td>
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<tr>
<td>Week 3</td>
<td>The drug manufacturing process and good manufacturing practice</td>
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<td>Week 4</td>
<td>The cytokines—the interferon family</td>
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<tr>
<td>Week 5</td>
<td>Cytokines: interleukins and tumour necrosis factor</td>
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<td></td>
<td><strong>Test #1</strong></td>
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<tr>
<td>Week 6</td>
<td>Haemopoietic growth factors</td>
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<td></td>
<td><strong>Mid-term Recess: Monday, February 20 to Sunday, February 26, 2017</strong></td>
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<tr>
<td>Week 7</td>
<td>Growth factors</td>
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<tr>
<td>Week 8</td>
<td>Hormones of therapeutic interest</td>
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<td>Week 9</td>
<td>Blood products and therapeutic enzymes</td>
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<tr>
<td>Week 10</td>
<td>Blood products and therapeutic enzymes</td>
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<tr>
<td></td>
<td><strong>Test #2</strong></td>
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<tr>
<td>Week 11</td>
<td>Antibodies, vaccines and adjuvants</td>
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<td>Week 12</td>
<td>Nucleic acid therapeutics</td>
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<tr>
<td>Week 13</td>
<td>Nucleic acid therapeutics</td>
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<td></td>
<td><strong>Classes end: Thursday, April 6, 2017</strong></td>
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<td></td>
<td><strong>Final examination period: Tuesday, April 11 to Thursday, April 27, 2016</strong></td>
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<td>All examinations MUST be written during the scheduled examination period.</td>
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Note that this structure represents a plan and is subject to adjustment term by term.

The instructor and the 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.
Quizzes  |  5 %  
---|---  
Mid-term test  |  (2 x 20 %)= 40 %  
Project  |  15 %  
Final examination (tests cumulative knowledge)  |  40 %  
---|---  
**TOTAL**  |  100 %

Percentage grades will be converted to letter grades and grade points per the University calendar.

5. **LEARNING OUTCOMES**
1. Describe and explain the process of biopharmaceutical drug development and manufacture.
2. Use critical thinking to determine possible applications of various types of macromolecules.
3. Explain the role of each class of macromolecule found in the body as well as how they can be transformed into biopharmaceuticals.
4. Understand the purpose and details of good manufacturing practice.
5. Understand the roles of macromolecules as products.
6. Understand the roles of macromolecules as drug delivery entities.

6. **POLICIES**

**Anti-Discrimination**
The Faculty of Engineering is concerned with ensuring an environment that is free of all discrimination. If there is a problem, individuals are reminded that they should contact the Department Chair, the Sexual Harassment Officer or the Human Rights Consultant, as soon as possible.


**Academic Integrity**
You are required to exhibit honestly and use ethical behaviour in all aspects if the learning process. Academic credentials you earn are rooted in principles of honesty and academic integrity.

Academic dishonesty is to knowingly act of fail to act in a way that results or could result in unearned academic credit or advantage. This behaviour can result in serious consequences e.g. the grade of zero on an assignment, loss of credit with a notation on the transcript (notation reads: “Grade of F assigned for academic dishonesty”), and/or suspension or expulsion from the 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, located at: [http://www.mcmaster.ca/policy/Students-AcademicStudies/AcademicIntegrity.pdf](http://www.mcmaster.ca/policy/Students-AcademicStudies/AcademicIntegrity.pdf).

The following illustrates only three forms of academic dishonesty:
1. Plagiarism. E.g. the submission of work that is not own or for which other credit has been obtained.
2. Improper collaboration in group work.
3. Copying or using unauthorized aids in tests and examinations.

**Requests for Relief for Missed Academic Term Work (Assignments, Mid-Terms, etc.)**
The McMaster Student Absence Form is an on-line self-reporting tool for Undergraduate Students to report absences for:

1) Relief for missed academic work worth less than 25% of the final grade resulting from medical or personal situations lasting up to three calendar days:
   • Students may submit a maximum of one academic work missed request per term. It is the responsibility of the student to follow up with instructors immediately (within the 3 day period that is specified in the MSAF) regarding the nature of the accommodation. All work due in that time period however can be covered by one MSAF.
   • MSAF cannot be used to meet religious obligation or celebration of an important religious holiday, for that has already been completed or attempted or to apply for relief for any final examination or its equivalent.
2) For medical or personal situations lasting more than three calendar days, and/or for missed academic work worth 25% or more of the final grade, and/or for any request for relief in a term where the MSAF has not been used previously in that term:

- Students must visit their Associate Dean’s Office (Faculty Office) and provide supporting documentation.

**E-Learning Policy**

Consistent with the Bachelor of Technology’s policy to utilize e-learning as a complement to traditional classroom instruction, students are expected to obtain appropriate passwords and accounts to access Avenue To Learn for this course. Materials will be posted by class for student download. It is expected that students will avail themselves of these materials prior to class. Students should be aware that, when they access the electronic components of this course, private information such as first and last names, user names for the McMaster e-mail account, and program affiliation may become apparent to all other students in the course. The available information is dependent on the technology used. Continuation in this course will be deemed consent to this disclosure. If you have any questions or concerns about this disclosure please discuss this with the course instructor. Avenue can be accessed via http://avenue.mcmaster.ca.

**Communications**

It is the student’s responsibility to:

- Maintain current contact information with the University, including address, phone numbers, and emergency contact information.
- Use the University provided e-mail address or maintain a valid forwarding e-mail address.
- Regularly check the official University communications channels. Official University communications are considered received if sent by postal mail, by fax, or by e-mail to the student’s designated primary e-mail account via their @mcmaster.ca alias.
- Accept that forwarded e-mails may be lost and that e-mail is considered received if sent via the student’s @mcmaster.ca alias.
- Check the McMaster/Avenue email and course websites on a regular basis during the term.

**Turnitin (Optional)**

This course will be using a web-based service (Turnitin.com) to reveal plagiarism. Students submit their assignment/work electronically to Turnitin.com where it is checked against the internet, published works and Turnitin’s database for similar or identical work. If Turnitin finds similar or identical work that has not been properly cited, a report is sent to the instructor showing the student’s work and the original source. The instructor reviews what Turnitin has found and then determines if he/she thinks there is a problem with the work. Students who do not wish to submit their work to Turnitin.com must still submit a copy to the instructor. No penalty will be assigned to a student who does not submit work to Turnitin.com. All submitted work is subject to normal verification that standards of academic integrity have been upheld (e.g., on-line search, etc.). To see the Turnitin.com Policy, please go to http://www.mcmaster.ca/academicintegrity/turnitin/students/.

**Protection of Privacy Act (FIPPA)**

The Freedom of Information and Protection of Privacy Act (FIPPA) applies to universities. Instructors should take care to protect student names, student numbers, grades and all other personal information at all times. For example, the submission and return of assignments and posting of grades must be done in a manner that ensures confidentiality. http://www.mcmaster.ca/univsec/fippa/fippa.cfm

**Academic Accommodation of Students with Disabilities Policy**

Students who require academic accommodation must contact Student Accessibility Services (SAS) to make arrangements with a Program Coordinator. Academic accommodations must be arranged for each term of study. Student Accessibility Services can be contacted by phone 905-525-9140 ext. 28652 or e-mail sas@mcmaster.ca. For further information consult McMaster’s policy for Academic Accommodation of Students with Disabilities http://www.mcmaster.ca/policy/Students-AcademicStudies/AcademicAccommodation-
Students must forward a copy of the SAS accommodation to the instructor of each course and to the Program Administrator of the B.Tech. Program immediately upon receipt. If a student with a disability chooses NOT to take advantage of a SAS accommodation and chooses to sit for a regular exam, a petition for relief may not be filed after the examination is complete.  

http://sas.mcmaster.ca

Student Code of Conduct

The Student Code of Conduct (SCC) exists to promote the safety and security of all the students in the McMaster community and to encourage respect for others, their property and the laws of the land. McMaster University is a community which values mutual respect for the rights, responsibilities, dignity and well-being of others. The purpose of the Student Code of Conduct is to outline accepted standards of behavior that are harmonious with the goals and the well-being of the University community, and to define the procedures to be followed when students fail to meet the accepted standards of behavior. All students have the responsibility to familiarize themselves with the University regulations and the conduct expected of them while studying at McMaster University.

http://studentconduct.mcmaster.ca/student_code_of_conduct.html