

Course Outline

1. COURSE INFORMATION

Session Offered	Fall 2015	
Course Name	Biotechnology Regulations	
Course Code	BIOTECH 4BS3	
Date(s) and Time(s) of lectures	Tuesdays, 8:30am – 10:20 am Fridays, 11:30 am – 12:20 pm	
Program Name	Biotechnology	
Calendar Description	This course will familiarize students with current methods of laboratory safety and good lab and manufacturing practices in biotechnology; bioethics issues, benefits and risks of biotechnology applications; provincial, federal and international guidelines/regulations.	
Instructor(s)	Dr. Ana Tomljenovic-Berube	E-Mail: tomljeam@mcmaster.ca Office Hours & Location: Tuesdays 1:30-2:30, ETB 209

2. COURSE SPECIFICS

Course Description			
Instruction Type	Code	Type	Hours per term
	C	Classroom instruction	36
	L	Laboratory, workshop or fieldwork	N/A
	T	Tutorial	N/A
	DE	Distance education	N/A
	Total Hours		36
Resources	ISBN	Textbook Title & Edition	Author & Publisher
	N/A	"Biotechnology Regulations"	Tomljenovic-Berube, A. Custom Courseware; Department of Technology, McMaster University, Fall 2015.
	Other Supplies		Source
	Additional Readings TBD		http://avenue.mcmaster.ca
Prerequisite(s)	BIOTECH 3PM3; and one of BIOTECH 2M03; ENGTECH 4EE0, and registration in level IV of the Biotechnology program.		
Corequisite(s)	N/A		
Antirequisite(s)	N/A		
Course Specific Policies	<p>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 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 to Learn, web pages, Moodle, Thinking Cap, etc.</p> <p>**E-mail communication should be strictly through the official McMaster University Account.</p>		

	<p>Attendance Lectures are an integral part of this course, regular attendance at lectures will be expected throughout the semester.</p> <ul style="list-style-type: none"> • There may be many unannounced quizzes – there will be no make-up. • Lectures may not cover all the required material from the textbook and supplementary material. • Lectures may cover material that is not available elsewhere, e.g. in the textbook, postings on Avenue, etc. <p>Students will be required to know all lecture material. Attendance will not officially be taken, however absences will be considered for assignment of participation grades.</p> <p>Assignments Answers to assignments must be typed and must include bibliography of all sources in ACS format or as stated for the individual assignment. Late submissions of assignments and projects will be penalized 10% per day (including weekends and holidays) up to a maximum of 5 days. Assignments may serve as a basis for class discussion; in that case, your grade will be based on the typed answers and your class participation.</p> <p>Quizzes Unannounced quizzes will be given periodically throughout the term during the lecture period on all recently covered course material, including lectures, assignments, online postings, readings, fellow student presentations, etc. Absences without a well documented and approved report for the absence (See MSAF information below) will result in a mark of zero for that quiz. Quizzes may involve written evaluations but may also take other formats.</p> <p>Participation Participation in classroom discussions both during regular lectures and during presentations by other students will be an important part of this course.</p> <p>Midterm Exams There is no make-up policy. If the student misses an exam then the percentage of the final will be increased to compensate the missing exam (only if the student has well documented and approved report for the absence (See MSAF information below).</p>
Departmental Policies	<p>Students must maintain a GPA of 3.5/12 to continue in the program.</p> <p>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.</p> <p>Where group work is indicated in the course outline, such collaborative work is mandatory.</p> <p>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.</p> <p>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.</p> <p>Instructor has the right to submit work to software to identify plagiarism.</p>

3. SUB TOPIC(S)		
Week 1	<ul style="list-style-type: none"> • Introduction • Bioethics <ul style="list-style-type: none"> ○ Ethics and Biotechnology ○ Approaches to ethical decision making ○ GM crops and species integrity 	Section II, Chapter 13 + supplements
Week 2	<ul style="list-style-type: none"> • Bioethics <ul style="list-style-type: none"> ○ Embryos for Research ○ Navigating the Ethics of Human Research - Canada 	Section II, Chapter 13 + supplements
Week 3	<ul style="list-style-type: none"> • Biotechnology – Business Structure <ul style="list-style-type: none"> ○ From discovery to production ○ R&D, QC, QA, RA ○ Intellectual property in biotechnology <p style="text-align: center;">Assignment 1 – Due Date</p>	Section I, Chapter 2
Week 4	<ul style="list-style-type: none"> • The Lifecycle of Pharmaceuticals <ul style="list-style-type: none"> ○ Pharmaceutical phases and milestones ○ Biopharmaceutical development 	Section I, Chapter 3
Week 5	<ul style="list-style-type: none"> • Introduction to Product Quality Systems <ul style="list-style-type: none"> ○ Workplace quality systems ○ Change management ○ Corrective and preventative actions 	Section I, Chapter 4
<i>Mid-term recess (Monday, October 12 to Saturday, October 17)</i>		
Week 6	<ul style="list-style-type: none"> • Biotechnology and Regulations <ul style="list-style-type: none"> ○ Regulation history and international harmonization ○ US Code of Federal Regulations – FDA/GMP ○ Food regulations and safety <p style="text-align: center;">MIDTERM EXAM Assignment 2 – Due Date</p>	Section I, Chapter 5 + Section II, Chapter 12
Week 7	<ul style="list-style-type: none"> • Documentation and Standard Operating Procedures <ul style="list-style-type: none"> ○ Laboratory documentation ○ Standard Operating Procedures ○ Batch Records ○ Electronic Documentation 	Section I, Chapter 6
Week 8	<ul style="list-style-type: none"> • GMPs and Quality Systems in Production <ul style="list-style-type: none"> ○ Facilities and equipment ○ Product specification ○ Validations 	Section I, Chapter 7 + supplements
Week 9	<ul style="list-style-type: none"> • GLPs and Quality Systems in the Laboratory <ul style="list-style-type: none"> ○ Laboratory controls 	Section I, Chapter 8 + supplements
Week 10	<ul style="list-style-type: none"> • GLPs and Quality Systems in the Laboratory <ul style="list-style-type: none"> ○ Managing quality in the laboratory ○ Out-of-specification results <p style="text-align: center;">Project Submission – Due Date Assignment 3 – Due Date</p>	Section I, Chapter 8 + supplements
Week 11	<ul style="list-style-type: none"> • Safety Hazards in the Workplace <ul style="list-style-type: none"> ○ Laboratory safety management <ul style="list-style-type: none"> • Canada and US regulations • Responsibilities ○ Hazard and risk assessment ○ Physical hazards 	Section I, Chapters 9 and 10
Week 12	<ul style="list-style-type: none"> • Working Safely with Chemicals 	Section I,

	<ul style="list-style-type: none"> ○ Good practices and safety procedures ○ Routes of chemical exposure ○ Chemical fume hoods and safety equipment ● Working Safely with Biological Materials <ul style="list-style-type: none"> ○ Biohazards and Regulations ○ Biosafety Levels ○ Biological Cabinets ○ Cleanrooms in Biotechnology 	Chapters 11 and 12 + supplements
Week 13	Review	
Classes end – Tuesday December 8, 2015 Final examination period: Wednesday December 9, 2015 to Tuesday, December 22, 2015 All examinations MUST BE written during the scheduled examination period.		
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.		
4. ASSESSMENT OF LEARNING *dates subject to change*		Weight
Assignments / Quizzes		20%
Assignment 1 – September 22, 2015		
Assignment 2 – October 20, 2015		
Assignment 3 – November 20, 2015		
Quizzes – TBA in course		
Mid-term test – October 23 th , 2015		20%
Project – Week of November 16, 2015		20%
Class Participation		5%
Final examination (tests cumulative knowledge)		35%
TOTAL		100%
Percentage grades will be converted to letter grades and grade points per the University calendar.		
5. LEARNING OUTCOMES		
1. Evaluate bioethical problems using established ethics approaches.		
2. Explain biotechnology guidelines and regulations in Canada, the United States, and world-wide.		
3. Outline the lifecycle of (bio)pharmaceutical products and its associated regulations and policies.		
4. Develop quality control documents and discern their appropriate usages.		
5. Distinguish between quality systems, cGMP and cGLP in the biotechnology industry.		
6. Defend and argue positions regarding current topics in bioethics.		
7. Summarize biosafety guidelines and identify their importance in all aspects of biotechnology regulations.		
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. http://www.mcmaster.ca/policy/General/HR/Anti-Discrimination%20policy.pdf		
Academic Integrity		
You are required to exhibit honestly and use ethical behaviour in all aspects of the learning process. Academic credentials you earn are rooted in principles of honesty and academic integrity.		
Academic dishonesty is to knowingly act or 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>.

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 a self-reporting tool for **Undergraduate Students** to report absences that last up to 3 days and provides the ability to request accommodation for any missed academic work. Please note, this tool cannot be used during any final examination period.

You may submit a maximum of 1 Academic Work Missed requests per term. It is YOUR responsibility to follow up with your Instructor immediately regarding the nature of the accommodation.

If you are absent more than 3 days or exceed 1 request per term you MUST visit your Associate Dean's Office (Faculty Office). You may be required to provide supporting documentation.

This form should be filled out immediately when you are about to return to class after your absence. <http://www.mcmaster.ca/msaf/>

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-StudentsWithDisabilities.pdf>

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://judicialaffairs.mcmaster.ca/pdf/SCC.pdf>