

Course Outline

1. COURSE INFORMATION

Session Offered	Fall 2021	
Course Name	Biotechnology Regulations	
Course Code	BIOTECH 4BS3	
Date(s) and Time(s) of lectures	Tuesdays: 12:30-14:20 (Virtually) Thursdays: 12:30-13:20 (Virtually)	
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. Rashid Abu-Ghazalah	E-Mail: abughar@mcmaster.ca Office Hours & Location: Email to schedule a time to meet virtually, or in-person if possible

2. COURSE SPECIFICS

Course Description	Ethical considerations and regulations are two components of this course. While one discusses philosophical aspects in science, the other is a set of frameworks that are put in place to reduce the risk of harm, or death, from the use of products of biotechnology. Those include CGMP, GLP, and the rigorous approval processes involved. Case examples and discussions are critical components of this course		
Instruction Type	Code	Type	Hours per term
	C	Classroom instruction	36
	L	Laboratory, workshop or fieldwork	-
	T	Tutorial	-
	DE	Distance education	-
	Total Hours		36
Resources	ISBN	Textbook Title & Edition	Author & Publisher
	ISBN: N/A	N/A	N/A
	Other Supplies	Source	
	Avenue to Learn		
Prerequisite(s)	BIOTECH 3PM3, BIOTECH 2M03, ENGTECH 4EE0, and registration in level IV of the Biotechnology Co-op (B.Tech.) program		
Corequisite(s)	N/A		
Antirequisite(s)	N/A		
Course Specific Policies	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		

	<p>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"> • Lectures may not cover all the required material from assigned readings. • Lectures may cover material that is not available elsewhere, e.g. in assigned readings, 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 APA 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 2 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>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>There is a no make-up policy for this course.</p>
<p>Departmental Policies</p>	<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>
<p>3. SUB TOPIC(S)</p>	

Week 1	Introduction and Bioethics	
Week 2	Bioethics	
Week 3	Biotechnology: Business Structure Assignment 1 Due	
Week 4	GMO and Lifecycle of Pharmaceuticals	
Week 5	Introduction to Product Quality Systems	
Week 6	Reading Week	
Week 7	Biotechnology Regulations Assignment 2 Due	
Week 8	Documentation and SOPs Midterm	
Week 9	GMPs and Quality Systems in Production	
Week 10	GLPs and Quality Systems in the Laboratory	
Week 11	GLPs and Quality Systems in the Laboratory Project Submission	
Week 12	Safety Hazards in the Workplace Project Presentations	
Week 13	Working Safely with Chemicals and Working Safely with Biological Materials Assignment 3 Due	
Week 14	Review	

Classes end: Wednesday, December 8th, 2021

Final Examination Period: Thursday, December 9 to Wednesday, December 22
 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 *including dates*	Weight
Assignments	20 %
Mid-term test	20 %
Project	20 %
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. 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.

6. COURSE OUTLINE – APPROVED ADVISORY STATEMENTS

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/Discrimination_Harassment_Sexual_Harassment-Prevention&Response.pdf

ACADEMIC INTEGRITY

You are expected to exhibit honesty and use ethical behaviour in all aspects of the learning process. Academic credentials you earn are rooted in principles of honesty and academic integrity. It is your responsibility to understand what constitutes academic dishonesty.

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. For information on the various types of academic dishonesty please refer to the Academic Integrity Policy, located at <https://secretariat.mcmaster.ca/university-policies-procedures-guidelines/>

The following illustrates only three forms of academic dishonesty: The following illustrates only three forms of academic dishonesty:

- plagiarism, e.g. the submission of work that is not one’s own or for which other credit has been obtained.
- improper collaboration in group work.
- copying or using unauthorized aids in tests and examinations.

AUTHENTICITY / PLAGIARISM DETECTION

Some courses may use a web-based service (Turnitin.com) to reveal authenticity and ownership of student submitted work. For courses using such software, students will be expected to submit their work electronically either directly to Turnitin.com or via an online learning platform (e.g. A2L, etc.) using plagiarism detection (a service supported by Turnitin.com) so it can be checked for academic dishonesty.

Students who do not wish their work to be submitted through the plagiarism detection software must inform the Instructor before the assignment is due. No penalty will be assigned to a student who does not submit work to the plagiarism detection software. All submitted work is subject to normal verification that standards of academic integrity have been upheld (e.g., on-line search, other software, etc.). For more details about McMaster’s use of Turnitin.com, please go to www.mcmaster.ca/academicintegrity.

COURSES WITH AN ON-LINE ELEMENT

Some courses may use on-line elements (e.g. e-mail, Avenue to Learn (A2L), LearnLink, web pages, capa, Moodle, ThinkingCap, etc.). Students should be aware that, when they access the electronic components of a course using these elements, 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 a course that uses on-line elements will be deemed consent to this disclosure. If you have any questions or concerns about such disclosure please discuss this with the course instructor.

ONLINE PROCTORING

Some courses may use online proctoring software for tests and exams. This software may require students to turn on their video camera, present identification, monitor and record their computer activities, and/or lock/restrict their

browser or other applications/software during tests or exams. This software may be required to be installed before the test/exam begins.

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.

• CONDUCT EXPECTATIONS

As a McMaster student, you have the right to experience, and the responsibility to demonstrate, respectful and dignified interactions within all of our living, learning and working communities. These expectations are described in the Code of Student Rights & Responsibilities (the "Code"). All students share the responsibility of maintaining a positive environment for the academic and personal growth of all McMaster community members, whether in person or online.

It is essential that students be mindful of their interactions online, as the Code remains in effect in virtual learning environments. The Code applies to any interactions that adversely affect, disrupt, or interfere with reasonable participation in University activities. Student disruptions or behaviours that interfere with university functions on online platforms (e.g. use of Avenue 2 Learn, WebEx or Zoom for delivery), will be taken very seriously and will be investigated. Outcomes may include restriction or removal of the involved students' access to these platforms.

ACADEMIC ACCOMMODATION OF STUDENTS WITH DISABILITIES

Students with disabilities who require academic accommodation must contact Student Accessibility Services (SAS) at 905-525-9140 ext. 28652 or sas@mcmaster.ca to make arrangements with a Program Coordinator. For further information, consult McMaster University's Academic Accommodation of Students with Disabilities policy.

REQUESTS FOR RELIEF FOR MISSED ACADEMIC TERM WORK

McMaster Student Absence Form (MSAF): In the event of an absence for medical or other reasons, students should review and follow the Academic Regulation in the Undergraduate Calendar "Requests for Relief for Missed Academic Term Work".

ACADEMIC ACCOMMODATION FOR RELIGIOUS, INDIGENOUS OR SPIRITUAL OBSERVANCES (RISO)

Students requiring academic accommodation based on religious, indigenous or spiritual observances should follow the procedures set out in the RISO policy. Students should submit their request to their Faculty Office normally within 10 working days of the beginning of term in which they anticipate a need for accommodation or to the Registrar's Office prior to their examinations. Students should also contact their instructors as soon as possible to make alternative arrangements for classes, assignments, and tests.

<http://www.mcmaster.ca/policy/Students-AcademicStudies/Studentcode.pdf>

COPYRIGHT AND RECORDING

Students are advised that lectures, demonstrations, performances, and any other course material provided by an instructor include copyright protected works. The Copyright Act and copyright law protect every original literary, dramatic, musical and artistic work, including lectures by University instructors

The recording of lectures, tutorials, or other methods of instruction may occur during a course. Recording may be done by either the instructor for the purpose of authorized distribution, or by a student for the purpose of personal study. Students should be aware that their voice and/or image may be recorded by others during the class. Please speak with the instructor if this is a concern for you.

EXTREME CIRCUMSTANCES

The University reserves the right to change the dates and deadlines for any or all courses in extreme circumstances (e.g., severe weather, labour disruptions, etc.). Changes will be communicated through regular McMaster communication channels, such as McMaster Daily News, A2L and/or McMaster email.