McGill
Faculty of Engineering

Course Outline

BIEN 590

Course Title:	**Cell Culture Engineering**
Credits:	**3**
Contact Hours:	**(3-0-6)**
Course Prerequisite(s):	**Permission of instructor**
Course Corequisite(s):	**N/A**
Course Description:	**Basic principles of cell culture engineering, cell line development and cell culture products; genomics, proteomics and post-translational modifications; elements of cell physiology for medium design and bioprocessing; bioreactor design, scale-up for animal cell culture and single use equipment; challenges in downstream processing of cell-culture derived products; process intensification: fed-batch, feeding strategies and continuous manufacturing; scale-down and process modeling; Process Analytical technologies and Quality by Design (QbD) concept.**

Canadian Engineering Accreditation Board (CEAB) Curriculum Content

CEAB curriculum category content	Number of AU's	Description
Math	**0**	Mathematics include appropriate elements of linear algebra, differential and integral calculus, differential equations, probability, statistics, numerical analysis, and discrete mathematics.
Natural science	**0**	Natural science includes elements of physics and chemistry, as well as life sciences and earth sciences. The subjects are intended to impart an understanding of natural phenomena and relationships through the use of analytical and/or experimental techniques.
Complementary studies	**0**	Complementary studies include the following areas of study to complement the technical content of the curriculum: engineering economics and project management; the impact of technology on society; subject matter that deals with the arts, humanities and social sciences; management; oral and written communications; health and safety; professionalism, ethics, equity and law; and sustainable development and environmental stewardship.
Engineering science	**27**	Engineering science involves the application of mathematics and natural science to practical problems. They may involve the development of mathematical or numerical techniques, modeling, simulation, and experimental procedures. Such subjects include, among others, applied aspects of strength of materials, fluid mechanics, thermodynamics, electrical and electronic circuits, soil mechanics, automatic control, aerodynamics, transport phenomena, elements of materials science, geoscience, computer science, and environmental science.
Engineering design	**12**	Engineering design integrates mathematics, natural sciences, engineering sciences, and complementary studies in order to develop elements, systems, and processes to meet specific needs. It is a creative, iterative, and open-ended process, subject to constraints which may be governed by standards or legislation to varying degrees depending upon the discipline. These constraints may also relate to economic, health, safety, environmental, societal or other interdisciplinary factors.

Accreditation units (AU's) are defined on an hourly basis for an activity which is granted academic credit and for which the associated number of hours corresponds to the actual contact time: one hour of lecture (corresponding to 50 minutes of activity) = 1 AU; one hour of laboratory or scheduled tutorial = 0.5 AU. Classes of other than the nominal 50-minute duration are treated proportionally. In assessing the time assigned to determine the AU's of various components of the curriculum, the actual instruction time exclusive of final examinations is

used.

Graduate Attributes

This course contributes to the acquisition of graduate attributes as follows:

Graduate attribute	KB	PA	IN	DE	ET	IT	CS	PR	IE	EE	EP	LL
Level descriptor	A		A	D		A	D					

I = Introduced; D = Developed; A = Applied

KB *- Knowledge Base for Engineering: Demonstrated competence in university level mathematics, natural sciences, engineering fundamentals, and specialized engineering knowledge appropriate to the program.*

PA *- Problem Analysis: An ability to use appropriate knowledge and skills to identify, formulate, analyze, and solve complex engineering problems in order to reach substantiated conclusions.*

IN *- Investigation: An ability to conduct investigations of complex problems by methods that include appropriate experiments, analysis and interpretation of data, and synthesis of information in order to reach valid conclusions.*

DE *- Design: An ability to design solutions for complex, open-ended engineering problems and to design systems, components or processes that meet specified needs with appropriate attention to health and safety risks, applicable standards, economic, environmental, cultural and societal considerations.*

ET *- Use of Engineering Tools: An ability to create, select, adapt, and extend appropriate techniques, resources, and modern engineering tools to a range of engineering activities, from simple to complex, with an understanding of the associated limitations.*

IT *- Individual and Team Work: An ability to work effectively as a member and leader in teams, preferably in a multi-disciplinary setting.*

CS *- Communication Skills: An ability to communicate complex engineering concepts within the profession and with society at large. Such abilities include reading, writing, speaking and listening, and the ability to comprehend and write effective reports and design documentation, and to give and effectively respond to clear instructions.*

PR *- Professionalism: An understanding of the roles and responsibilities of the professional engineer in society, especially the primary role of protection of the public and the public interest.*

IE *- Impact of Engineering on Society and the Environment: An ability to analyse social and environmental aspects of engineering activities. Such abilities include an understanding of the interactions that engineering has with the economic, social, health, safety, legal, and cultural aspects of society; the uncertainties in the prediction of such interactions; and the concepts of sustainable design and development and environmental stewardship.*

EE *- Ethics and Equity: An ability to apply professional ethics, accountability, and equity.*

EP *- Economics and Project Management: An ability to appropriately incorporate economics and business practices including project, risk and change management into the practice of engineering, and to understand their limitations.*

LL *- Life-Long Learning: An ability to identify and to address their own educational needs in a changing world, sufficiently to maintain their competence and contribute to the advancement of knowledge.*

Policies

Academic Integrity

McGill University values academic integrity. Therefore, all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures.
(see www.mcgill.ca/students/srr/honest/ for more information).
(approved by Senate on 29 January 2003)

In accord with McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded.
(approved by Senate on 21 January 2009)

Grading Policy

In the Faculty of Engineering, letter grades are assigned according to the grading scheme adopted by the professor in charge of a particular course. This may not correspond to practices in other Faculty and Schools in the University.

In the event of extraordinary circumstances beyond the University's control, the content and/or evaluation scheme in this course is subject to change.

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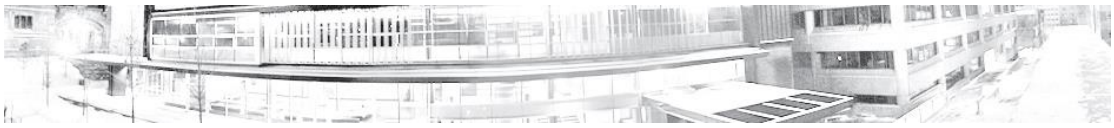


BIEN 590 Cell Culture Engineering

Fall Term 2023

CLASS SCHEDULE: Monday, 8:35 am - 11:25 am (Aug 30, 2023 - Dec 05, 2023)
LOCATION: Birks Building 203

INSTRUCTORS

Dr. Mario A. Jardon, Prof. Amine A. Kamen
Office: McConnell Engineering Building, 707E
3480 University Street, Montreal
Office hours: by appointment, over Zoom or in person

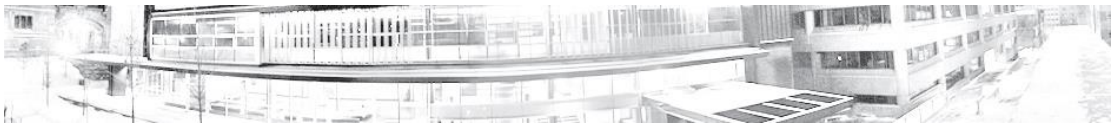
TEACHING ASSISTANTS (TAs): N/A
GRADERS: TBA

LEARNING OUTCOMES

- Integrate new knowledge in cell biology (KB.1, KB.3) and advanced technologies in cell culture engineering for the production of biologics (KB.2, KB.4).
- Apply fundamental knowledge in biology and physiology and process engineering principles, including stoichiometry and bioreactor kinetics (KB.3, KB.7).
- Design and scale-up cell culture bioprocesses for manufacturing of regulated biologics for human health (DE.1, DE.2).
- Integrate science and engineering principles within a framework to contribute within multi-disciplinary teams to develop and design bioprocesses to manufacture complex biological products (KB.4, KB.6, KB.8, DE.3).
- Communicate to peers the outcomes of the team and individual activities (IT.1 to IT.4 and CS.1 to CS.4).

COURSE MATERIALS

- **Cell Culture Bioprocess Engineering.** Hu, Wei-Shou. 2nd Edition, 2020. CRC Press.
- **Cell Culture Technology for Pharmaceutical and Cell-Based Therapies.** Ozturk, Sadettin S. and Hu, Wei-Shou (editors). 2005. CRC Press.
- **Mammalian Cell Cultures for Biologics Manufacturing.** Zhou, Weichang and Kantardjieff, Anne (editors). Advances in Biochemical Engineering/Biotechnology 139. 2014. Springer-Verlag.
- Supplemental course materials, including articles and lecture notes, will be distributed during the semester via MyCourses.



EVALUATION AND ASSESSMENT

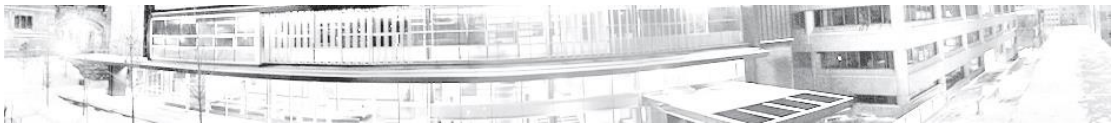
Assignment	Points	Percentage
Team project: Report (20 points) and presentation (15 points each)	35	35
Individual project: Grant proposal (25 points) and presentation (15 points)	40	40
Assignment	15	15
Course participation	10	10

Team Project:
The team project will consist in a **literature review** of a topic related to cell culture biomanufacturing. It will consist of a presentation and a written report. The **written report** should have a maximum of 10 pages (not including figures or bibliography). The **presentation** should not exceed 15 minutes. A list of topics will be made available for teams to choose from. Other topics may be selected by the team, with the approval of the instructor. Students will work in groups (maximum of 4 members per team). The report will be due one week after the presentations.

Individual Project:
Each student will select a topic related to cell culture production of biologics at the beginning of the course, including monoclonal antibodies, vaccines, and gene and cell therapy products. Students will be expected to use the knowledge obtained in the course and the literature to prepare a 10-page original proposal following guidelines from Canadian granting agencies (NSERC or CIHR). Example - NSERC Doctoral Fellowship (will be discussed in detail in the first or second week of the class). The proposal should include a complete design of a novel or inspired manufacturing process, from **vector design, cell line engineering and cultivation (upstream processing - USP) to product purification and formulation (downstream processing - DSP)**. A list of possible topics to consider while writing your proposal will be provided separately. The chosen topic must be approved by the instructor(s). The **presentation** should not exceed 3 minutes, and should be composed of 3 slides. The report will be due one week after the presentations.

Assignment:
One assignment will be part of the assessment plan. It will include calculations, simulations, data analysis, and application of concepts covered in the course. It will be due two weeks after its posting in MyCourses. It can be done working with other students, but each student is expected to submit their own copy.

Course participation:
Students are strongly recommended to be present during all the lectures, as their course participation will contribute 10% of the total grade. At any time during the lecture, quick



attendance may be taken. Participation will also include active class discussion. It will play an integral part in learning and supporting others to learn.

OTHER KEY POINTS

Language of Written Work:
Following McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded.

Academic Integrity:
McGill University values academic integrity. Therefore, all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures (see www.mcgill.ca/students/srr/honest/ for more information).

Disabilities:
If you have a disability, please contact the instructor to arrange a time to discuss your situation. It would be helpful if you contact the Office for Students with Disabilities at (514) 398-8261 before you do this.

COVID-19-related course adaptations for BIEN590:
All lectures will be in person. This may be subject to change based on provincial and university health guidelines**.** Guest lectures may be provided online if given by speakers outside Canada or due to their unavailability to attend in person.

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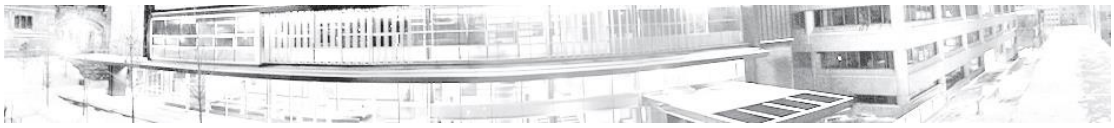

COURSE CONTENT AND SCHEDULE (TENTATIVE)
DRAFT – SUBJECT TO MODIFICATION

Week	Date	Assignment deadlines	Topic
1	11 SEP 2023		Introduction and presentation of course organization. **Lecture 1:** Overview of cell culture engineering
2	18 SEP 2023		**Lecture 2:** Cell biology for bioprocessing **In-class activity:** Introduction to SuperPro Designer
3	25 SEP 2023		**Lecture 3:** Cell physiology. Metabolism and transport. **Guest Speaker:** Prof. Codruta Ignea
4	2 OCT 2023		**Lecture 4:** Stoichiometry and kinetics of cell culture. Media design and optimization **Guest Speaker:** Dr. Jasmin Coulombe-Huntington
5	9 OCT 2023	No class – Thanksgiving	
6	16 OCT 2023	Team project presentations due	**Team project presentations**
7	23 OCT 2023	Team project reports due	**Lecture 5:** Cell line development **Guest Speaker:** Dr. Martin Loignon, NRC (TBC)
8	30 OCT 2023		**Lecture 6:** Large-scale cultivation technology. Bioreactor design. Oxygen transfer in cell culture. **Onsite Visit:** Bioreactor lab tour (TBC)
9	6 NOV 2023	Assignment posted	**Lecture 7:** Large-scale cultivation technology. Modes of operation. Scale up and scale down. **In-class activity:** Bioprocess simulation and analysis
10	13 NOV 2023		**Lecture 8:** Downstream processing: capture, purification and polishing.
11	20 NOV 2023	Assignment due	**Lecture 9:** Formulation, filling and packaging.
12	27 NOV 2023		**Lecture 10:** Product quality in bioprocessing. Introduction to PAT, QbD and cGMP.
13	30 NOV 2023	Make up day	Course review
14.	4 DEC 2023	Individual presentations due	**Individual proposal presentations** Last class.
16.	6 DEC 2023	Proposals due	Individual proposals submission

Classes begin: August 30, 2023
Labour Day: Monday, September 4, 2023
Thanksgiving: Monday, October 9, 2023
Fall Reading Break: Friday, October 6 to Wednesday, October 11
Classes end: December 5, 2023