McGill

New Program/Concentration Proposal Form

(2019)

1.0 Degree Title
Please specify the two degrees for concurrent degree programs

M.Eng.

2.0 Administering Faculty or GPS

GPS

1.1 Major (Subject/Discipline) (30-char. max.)

Biological and Biomedical Engineering; Non-Thesis

Offering Faculty & Department

IFS / Engineering, Bioengineering / Medicine, Biomedical Engineering

1.2 Concentration (Option) (30 char. max.)

Biomanufacturing

3.0 Effective Term of Implementation
(Ex. Sept. 2019 or 201909)
Term

202209

1.3 Complete Program Title (info from boxes 1.0+1.1+1.2+5.2)

M.Eng. in Biological and Biomedical Engineering (Non-Thesis) - Biomanufacturing

4.0 Rationale and Admission Requirements for New Program/Concentration

There is a strong demand from industrial and institutional partners in biomanufacturing for highly qualified personnel who possess thorough knowledge in advanced industrial technologies and process analytical technologies along with hands-on experience in processing of biologics. The Biomanufacturing Option aims to deepen the knowledge of bioengineers through additional specialized courses and expose students to process development, manufacturing, and project management regulatory compliance through projects pursued in an internship at an academic, industrial, or governmental laboratory. Applicants must hold a Bachelor's degree in engineering, science, or medicine with a strong background in mathematics and the physical sciences, and some exposure to the life sciences (physiology, cell biology, or molecular biology).

5.0 Program Information
Indicate an "x" as appropriate

5.1 **Program Type**

- Bachelor's Program
- X Master's
- M.Sc.(Applied) Program
- Dual Degree/Concurrent Program
- Certificate
- Diploma
- Graduate Certificate
- Graduate Diploma
- Professional Development Cert
- Ph.D. Program
- Doctorate Program (Other than Ph.D.)
- Self-Funded/Private Program
- Off-Campus Program
- Distance Education Program
- Other (Please specify)

5.2 **Category**

- Faculty Program (FP)
- Major
- Joint Major
- Major Concentration (CON)
- Minor
- Minor Concentration (CON)
- Honours (HON)
- Joint Honours Component (HC)
- Internship/Co-op
- Thesis (T)
- X Non-Thesis (N)
- Other
- Please specify

5.3 **Level**

- Undergraduate
- Dentistry/Law/Medicine
- Continuing Studies (Non-Credit)
- Collegial
- X Masters & Grad Dips & Certs
- Doctorate
- Post-Graduate Medicine/Dentistry
- Graduate Qualifying

5.4 **Requires Centrally-Funded Resources**

Yes _X_ No ___

6.0 Total Credits or CEUs (if latter, indicate "CEUs" in box)

45

7.0 Consultation with
Related Units Yes X No
Financial Consult Yes X No
Attach list of consultations.

8.0 Program Description (Maximum 150 words)

The M.Eng in Biological and Biomedical Engineering (Non-Thesis) - Biomanufacturing focuses on the life sciences, the physical sciences, and engineering, industrial practices and processes, and data science for application in the field of biomanufacturing. Hands-on experience available through projects carried out during internships in academic, industrial, and governmental laboratories.

9.0 List of proposed new Program/Concentration

If new concentration (option) of existing program, a program layout (list of all courses) of existing program **must** be attached.

Proposed program (list courses as follows: Subj Code/Crse Num, Title, Credit Weight under the headings of: Required Courses, Complementary Courses, Elective Courses)

M.Eng. Biological and Biomedical Engineering (Non-Thesis) - Biomanufacturing (45 credits)

Required Courses (21 credits)

BBME 681 Internship 1 (9 credits)*
BBME 682 Internship 2 (9 credits)*
*must take place in the Biomanufacturing sector

BBME 600D1 Seminars in Biological and Biomedical Engineering (1.5 credits)
BBME 600D2 Seminars in Biological and Biomedical Engineering (1.5 credits)
or
BBME 600N1 Seminars in Biological and Biomedical Engineering (1.5 credits)
BBME 600N2 Seminars in Biological and Biomedical Engineering (1.5 credits)

Complementary Courses (24 credits)

Minimum of 18 credits from the following three lists of core courses. At least 12 credits must be chosen from biomanufacturing core courses. At least 12 credits must be chosen from BBME core courses, of which at least 6 credits must be chosen from quantitative courses.

Biomanufacturing Core:
BIEN 500 Special Topics in Bioengineering 1 (3 credits)
BIEN 580 Synthetic Biology (3 credits)
BIEN 585 Metabolic Engineering (3 credits)
BIEN 590 Cell Culture Engineering (3 credits)
BIEN 670 Downstream Processing (3 credits)
BIEN 675 Process Analytical Technologies and Data Sciences (3 credits)
BIEN 680 Bioprocessing of Vaccines (4 credits)
BIEN 685 Gene and Cell Therapy Viral Vectors Biomanufacturing (3 credits)
BMDE 505 Cell and Tissue Engineering (3 credits)
CHEE 512 Stem Cell Bioprocess Engineering (3 credits)
CHEE 651 Advanced Biochemical Engineering (4 credits)

BBME Core (Quantitative):
BIEN 510 Engineered Nanomaterials for Biomedical Applications (3 credits)
BIEN 530 Imaging and Bioanalytical Instrumentation (3 credits)
BIEN 550 Biomolecular Devices (3 credits)
BIEN 560 Design of Biosensors (3 credits)

[continued]

Attach extra page(s) as needed

9.0 List of proposed new Program/Concentration

If new concentration (option) of existing program, a program layout (list of all courses) of existing program **must** be attached.

Proposed program (list courses as follows: Subj Code/Crse Num, Title, Credit Weight under the headings of: Required Courses, Complementary Courses, Elective Courses)

M.Eng. Biological and Biomedical Engineering (Non-Thesis) - Biomanufacturing (45 credits)

[continued]

BIEN 570 Active Mechanics in Biology (3 credits)
BIEN 590 Cell Culture Engineering (3 credits)
BMDE 502 BME Modelling and Identification (3 credits)
BMDE 503 Biomedical Instrumentation (3 credits)
BMDE 512 Finite-Element Modelling in Biomedical Engineering (3 credits)
BMDE 519 Biomedical Signals and Systems (3 credits)
BMDE 520 Machine Learning for Biomedical Data (3 credits)
BMDE 610 Functional Neuroimaging Fusion (3 credits)

BBME Core (Non-Quantitative):
BIEN 535 Electron Microscopy and 3D Imaging for Biological Materials (3 credits)
BIEN 540 Information Storage and Processing in Biological Systems (3 credits)
BIEN 580 Synthetic Biology (3 credits)
BIEN 680 Bioprocessing of Vaccines (4 credits)
BMDE 501 Selected Topic in Biomedical Engineering (3 credits)
BMDE 504 Biomaterials and Bioperformance (3 credits)
BMDE 505 Cell and Tissue Engineering (3 credits)
BMDE 508 Introduction to Micro and Nano-Bioengineering (3 credits)
BMDE 525D1 Design of Assistive Technologies: Principles and Praxis (3 credits)
BMDE 525D2 Design of Assistive Technologies: Principles and Praxis (3 credits)
BMDE 650 Advanced Medical Imaging (3 credits)
BMDE 654 Biomedical Regulatory Affairs - Medical Devices (3 credits)

Remaining complementary course credits must come from core or non-core complementary courses chosen from BBME courses or from other courses, at the 500 level or higher. The selection of courses must have the prior written approval of the Graduate Program Director.

Attach extra page(s) as needed

10.0 Approvals

Routing Sequence	Name	Signature	Meeting Date
Department	Yu (Brandon) Xia		Feb. 11, 2022
Curric/Acad Committee	Roni Khazzaka		Feb 23, 2022
Faculty 1	Melissa Vollrath- FMHS- FCC		15 March, 2022
Faculty 2	Roni Khazzaka		Mar 15, 2022
Faculty 3	Aimee Ryan- FMHS Assoc. Dean		17 March, 2022
CGPS			
SCTP			
APC			
Senate			

Submitted by

Name	
Phone	
Email	
Submission Date	

To be completed by ES:

CIP Code

REMINDERS:
*Box 5.4 – Must be completed; see section 6.5.4 within the New Program Guidelines at: https://www.mcgill.ca/sctp/guidelines.
**All new program proposals must be accompanied by a 2-3 page support document.

Existing Program: M.Eng.; Biological and Biomedical Engineering Non-Thesis (45 credits)

Internship Courses (18 credits)
BBME 681 Internship 1 (9 credits)
BBME 682 Internship 2 (9 credits)

Required Courses (3 credits)
BBME 600D1 Seminars in Biological and Biomedical Engineering (1.5 credits)
BBME 600D2 Seminars in Biological and Biomedical Engineering (1.5 credits)

OR

BBME 600N1 Seminars in Biological and Biomedical Engineering (1.5 credits)
BBME 600N2 Seminars in Biological and Biomedical Engineering (1.5 credits)

Complementary Courses (24 credits)
Minimum of 12 credits must come from the core courses listed below. At least 6 credits must be chosen from the "quantitative" courses listed below:

Quantitative Core Courses:
BIEN 510 Engineered Nanomaterials for Biomedical Applications (3 credits)
BIEN 530 Imaging and Bioanalytical Instrumentation (3 credits)
BIEN 550 Biomolecular Devices (3 credits)
BIEN 560 Design of Biosensors (3 credits)
BIEN 570 Active Mechanics in Biology (3 credits)
BIEN 590 Cell Culture Engineering (3 credits)
BMDE 502 BME Modelling and Identification (3 credits)
BMDE 503 Biomedical Instrumentation (3 credits)
BMDE 512 Finite-Element Modelling in Biomedical Engineering (3 credits)
BMDE 519 Biomedical Signals and Systems (3 credits)
BMDE 520 Machine Learning for Biomedical Data (3 credits)
BMDE 610 Functional Neuroimaging Fusion (3 credits)
BMDE 660 Advanced MR Imaging and Spectroscopy of the Brain (3 credits)
MDPH 607 Medical Imaging (3 credits)

Non-Quantitative Core Courses:
BIEN 535 Electron Microscopy and 3D Imaging for Biological Materials (3 credits)
BIEN 540 Information Storage and Processing in Biological Systems (3 credits)
BIEN 580 Synthetic Biology (3 credits)
BIEN 680 Bioprocessing of Vaccines (4 credits)
BMDE 501 Selected Topic in Biomedical Engineeirng (3 credits)
BMDE 504 Biomaterials and Bioperformance (3 credits)
BMDE 505 Cell and Tissue Engineering (3 credits)
BMDE 508 Introduction to Micro and Nano-Bioengineering (3 credits)
BMDE 510 Topics in Astrobiology (3 credits)
BMDE 525D1 Design of Assistive Technologies: Principles and Praxis (3 credits)
BMDE 525D2 Design of Assistive Technologies: Principles and Praxis (3 credits)
BMDE 650 Advanced Medical Imaging (3 credits)
BMDE 651 Orthopaedic Engineering (3 credits)
BMDE 654 Biomedical Regulatory Affairs - Medical Devices (3 credits)

The remaining 12 credits of complementary courses must come from core or non-core complementary courses chosen from BBME courses or from other courses, at the 500 level or higher. At least 6 of the 12 credits must have both life sciences content and content from the physical sciences, engineering, or computer science. The selection of courses must have the prior written approval of the Graduate Program Director.

M.Eng BBME (Non-Thesis): Biomanufacturing - Rationale

Background

Biomanufacturing as a government priority

The unprecedented health and economic impact of COVID-19 confirmed the need for a more robust and innovative biomanufacturing sector to rapidly translate Canadian biomedical discoveries to market and support the manufacturing of vaccines and biotherapeutics in emergency situations.

Importantly, the Government of Canada recognizes that a robust domestic biomanufacturing sector is critical to ensuring future pandemic preparedness. As a result, the Government of Canada announced recently a renewed investment strategy to "protect Canadians from COVID-19 and ensure the country is well positioned to fight future pandemics."[1] The biomanufacturing strategy is based on five pillars:

1. **Strong and Coordinated Governance**
2. **Laying a Solid Foundation by Strengthening Research Systems and the Talent Pipeline**
3. **Growing Businesses by Doubling Down on Existing and Emerging Areas of Strength**
4. **Building Public Capacity**
5. **Enabling Innovation by Ensuring World Class Regulation**

Accordingly, the government is allocating **$2.2 billion over seven years** to "continue growing a strong and competitive sector and to ensure Canada is prepared for future pandemics." This follows a broad consultation involving key Canadian stakeholders, including McGill, which contributed through different channels to this consultation.[2] As summarized in the McGill consultation document: "Growth in Canada's biomanufacturing relies on the creation of an ecosystem that includes excellence in *discovery and design of biologics, synthetic biology, process development, optimization, scale up, validation, quality control, operational logistics and, as well as adequate supply chain expertise with strength in artificial intelligence* that will support next generation process analytical technologies to advance bio-innovation and biomanufacturing."

This recent initiative adds to the **$1.2 billion** allocated to the industrial sector for accelerating the development of vaccines & biotherapeutics and increasing manufacturing capacity, including those at Sanofi-Pasteur, Toronto; Resilience biologics, Mississauga; Medicago, Quebec; Biodextris, Laval; NRC-Royalmount site, Montreal. This budget line invests $425 million in Quebec, for 10 projects.[3]

Thus, given the current priority given to the biomanufacturing industry, we are proposing a **Biomanufacturing option/concentration** within the M.Eng (Non-Thesis) degree program. Our proposed program would further meet the needs of the market and for training.

The need for training

Critical to the successful operation of the biomanufacturing facilities is the careful training of personnel that need to be considered at the design stage of any current Good Manufacturing Practice (cGMP manufacturing) capacity. All the pillars listed before and all sustainable renewed industrial biomanufacturing operations stress the critical need for a highly skilled workforce to support the rapid growth of the biomanufacturing activities and to enable sustainable innovation in the sector. We elaborate on this significantly in **Appendix 1**.

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[1] https://www.canada.ca/en/innovation-science-economic-development/news/2021/07/the-government-of-canada-announces-biomanufacturing-and-life-sciences-strategy.html

[2] https://www.ic.gc.ca/eic/site/151.nsf/eng/00018.html

[3] https://www.ic.gc.ca/eic/site/151.nsf/eng/00006.html#Quebec

Employee training and retraining is central to developing highly qualified personnel with up-to-date expertise in synthetic biology, bioprocess engineering, process analytical technologies and data sciences to master the diversity and complexity of biological expression systems and biomanufacturing processes within a highly regulated environment. High level managers from the National Research Council of Canada, responsible of the two recently Government of Canada funded initiatives: the NRC-Royalmount Biomanufacturing facility (BMC, Montreal, QC) and the NRC Royalmount - Clinical Trial Material Facility (CMTF, Montréal, Quebec) underlined their strong desire to enter into long-term agreements with McGill to support the Canadian Biomanufacturing initiative with a short term action plan to support the training and retraining of highly qualified personnel in biomanufacturing.

Preliminary analyses in consultation with experts in the field from industry and governmental partners reveal a talent gap among the graduates with advanced degrees equipped with knowledge, technical and soft skills to support the rapid growth of the biomanufacturing R&D and operations funded by the Government of Canada and Provincial Governments. A lack of infrastructure for dedicated to hands-on training and access to pilot-scale manufacturing facilities has been also identified.

Our program aims to address this gap and respond to the need, by offering relevant and biomanufacturing core courses required for Biomanufacturing students and providing them with a biomanufacturing internship that will equip them with the specific knowledge and skills required to succeed in the field (***please review Appendix 1 for more details***).

Why we are well positioned to offer this program

At McGill, in particular, there are very well-established groups and facilities dedicated to bioprocessing (in the bioengineering and chemical engineering departments) that cover a large scope of bioprocessing and biomanufacturing of viral vectors and vaccines and cellular therapies. These groups and facilities are well connected and operate in synergy with core facilities including the McGill genomics centre, Infectious diseases center, and regenerative medicine center. The groups also built solid alliances with experts from Ecole Polytechnique of Montreal, UdM and Laval University as well as other Canadian Universities (Waterloo, Guelph, Western Ontario) and key industrial partnership such as Sanofi-Pasteur, Biodextris, Resilience Biotech, Medicago, and GSK, which might be the impetus for the creation of a biomanufacturing Hub.

Taking advantage of McGill's existing strengths, and embedded in medium and long-term planning at McGill to create capacity in order to support the biomanufacturing initiative, a short-term action plan consists of contributing to the *talent creation pillar by enabling students with expertise in advanced biological expression systems, bioprocess engineering, process analytical technologies and data sciences, regulatory and quality control frameworks for vaccines and biotherapeutics manufacturing, and soft skills required to support industrial R&D and biomanufacturing operations.* Our program **Biomanufacturing option/concentration** will be building on McGill existing assets to respond to the urgent need of highly qualified personnel.

The program

Th 45-credit **M.Eng in Biological and Biomedical Engineering (Non-Thesis): Biomanufacturing option** program builds on already existing courses in the BBME master degree curriculum, such as:

- BIEN 590 Cell Culture Engineering (3 credits);
- BIEN 680 Bioprocessing of Vaccines (4 credits);
- CHEE 651 Adv Biochemical Engineering (4 credits)

As well as basic biological engineering courses, such as:

- BMDE 505 Cell and Tissue Engineering;
- BIEN 580 Synthetic Biology (3 credits);

- BIEN 585 Metabolic Engineering (3 credits).

Additionally, several new graduate courses have been created , including:

- BIEN 670 Downstream Processing of Biologics (3 credits);
- BIEN 675 Process Analytical Technology and Data Sciences (3 credits);
- BIEN 685 Biomanufacturing of Viral Vectors for Gene and Cell Therapy (3 credits).

These core complementary courses are designed around content related to biomanufacturing and enabling technologies such as fundamental in biological expression systems, engineering principles, data sciences and modeling applied to biomanufacturing, process design, regulatory requirements for manufacturing biologics, GLP and cGMP principles and applications in the field of biomanufacturing. While the selection of biomanufacturing-related courses are positioned as complementary courses given that we wanted to provide students with options, it is important to note that students are required to take 12 credits related to biomanufacturing.

Also at the core of this Option, the M.Eng. (Non-thesis) Biomanufacturing option/concentration will include two full time sessions of an internship in the Biomanufacturing sector (BBME 681 & 682, 9 credits each). The content and assessment of the internships will be aimed at the development of soft skills and professional expertise in the biomanufacturing area. The internships will be designed to expose the student to industrial, pilot scale or laboratory, which may be completed in either the same or different governmental or industrial organizations.

(***Please review Appendix 2 for more details about each course and their relevancy to this program***).

Target audience/admissions

We believe that given the current market noted above, there will be a strong demand for this program, for students aiming to enter the labor force and seeking to learn about process development, manufacturing, and project management regulatory compliance through projects pursued in an internship at an academic, industrial, or governmental laboratory. Applicants should hold a Bachelor's degree in engineering, science, or medicine with a strong background in mathematics and the physical sciences, and some exposure to the life sciences (physiology, cell biology, or molecular biology).

Appendix 1: Need of HQPs in the bio-economy and the biomanufacturing gap

***This is an elaboration to the previous discussion on the needs of the market and for skilled employees**

COVID-19 has led to a massive shift in Canada's attitude toward domestic bio-economy as seen from the labour market intelligence (LMI) National Report 2021 released by BioTalent Canada.[4] The demand for talent is predicted to exceed the supply of available HQPs as soon as 2024 in all bio-economy sub-sectors across Canada, with bio-health making up more than half of it. Insights based on surveys, stakeholder roundtables and interviews, an environmental scan and extensive data analysis revealed a faster employment rate in bio-health than any other sub-sector in 2020 because of increased pharmaceutical and medicine manufacturing. Additional employment demand was generated by hospitals and other organizations conducting clinical trials and related research activities. In total, employment was up by 6.8% in 2020, reaching 124,000 jobs. Even with a slight contraction of 1.1% in 2021, employment will remain above pre-pandemic levels throughout the forecast period (2022 to 2029), with modest 1.0% annual growth expected between 2022 and 2024. Stronger employment growth will be seen over the medium/longer term, approximately 1.5% annually from 2025 to 2029 due to continued increases in health spending as Canada's population ages. The majority of hiring needs are predicted to replace people leaving the workforce. Still, 65,000 additional workers will be needed by 2029. The bio-health sub-sector is projected to employ some 126,000 workers by 2024 and more than 131,000 by 2029. Companies will be challenged to fill those positions due to a highly competitive labour market, relatively low awareness of bio-economy careers and, in many cases, an ongoing lack of HR capacity or capital to attract and retain candidates. Explicitly, nearly two-thirds of employers surveyed by BioTalent Canada said they have difficulty recruiting or retaining qualified staff due to a lack of skilled, experienced talent. Specifically, bio-economy employers need three types of skills:

Soft skills: Almost one-third of employers surveyed (30%) said there is a lack of qualified candidates with practical/non-academic skills — the essential skills for success such as problem solving, collaboration and communication that can be harder to teach than technical skills.

Technical skills: Employers reported two distinct kinds of technical skills gaps: those due to insufficient post-secondary training of new graduates and those in existing employees who do not keep up to date with new technologies or knowledge related to their occupation.

Business skills: Companies looking to grow and commercialize innovations said it is important for workers (especially those in R&D roles) to have strong business-related knowledge and skills, which help them see the bigger picture and understand what's driving their work.

For this reason, most jobs in the bio-economy require some form of post-secondary education or training, even in less scientific areas such as manufacturing or logistics. Overall, employers' top pool of candidates is graduates from biological and biomedical sciences programs, followed by those with engineering qualifications. Greater outreach to students in relevant programs could help address both, as many graduates currently report working in jobs unrelated to their studies and might be willing to relocate for more suitable work that today they don't even know exists.

While labour shortages are expected for all job functions in Canada's bio-economy, they are expected to be most severe in three areas: manufacturing and production, distribution and logistics, and management, finance and administration. By 2029, the hires for roles in manufacturing and production will reach 25%, in R&D 21%, and in management, finance and administration 17%. Approximately 36,000 new workers will be needed in the bio-health sub-sector over the forecast period, nearly 80% of those to replace existing workers. The hiring requirement is projected at more than 4,000 workers in each year except 2025, when rising interest rates will limit the sub-sector's growth. One-quarter (25%) of bio-health job openings will be for R&D roles, with the next most-needed being management, finance and administration functions (16%) and manufacturing roles (14%). After a dip in 2021, employment in Quebec's bio-economy is projected to grow annually at 1.0% to 2024. That rate will fall to 0.7% in the back half of the decade following a contraction in 2025, with total employment reaching 59,500

[4] https://www.biotalent.ca/reports/

workers by 2029. Thus, manufacturing capacity will be a particularly urgent area of need, both in the bio-health sub-sector and more broadly.

The bio-manufacturing gap

Canada has a long and impressive history of achievement in health and life sciences innovation, including discovery of insulin, development of polio, and Ebola vaccines or the first blood thinner. However, COVID-19 highlighted a significant gap in the Canadian bio-economy: bio-manufacturing and processing capacity. Canada was initially unable to produce sufficient personal protective equipment (PPE) to meet its needs and had no domestic capacity to develop and manufacture vaccines. Commitments have been made to build facilities to remedy this, but those facilities will require skilled people to operate them — a supply of talent does not currently exist.

Estimates suggest Canada will need an additional 16,140 bio-manufacturing workers by 2029 (5,160 in bio-health manufacturing alone), even without taking into account expansion growth due to recently announced investments. Only 25% of those positions will be fillable by predicted supply during this time period. The hiring requirements projected at the national level also apply to each region across Canada, with most new hires needed to replace people leaving the workforce, especially for manufacturing and production roles. Roughly 15,500 additional workers will be needed in Quebec by 2029, with 85% of the hiring requirement driven by replacement demand. The largest proportion of new hires will be for positions in manufacturing and production (25%) and R&D (20%).

To address the labour needs of the bio-economy to 2029, based on the findings of the recent labour market intelligence (LMI) study, BioTalent Canada recommends the following:

1. Boost work-integrated learning by incorporating it into more programs
2. Diversify recruitment and human resources practices to reach a broader and more diverse talent pool
3. Create a wage subsidy program for immigrants to reduce the perceived risk of hiring immigrants
4. Forge pathways for international students and IEPs to integrate international talent into the labour market
5. Support reskilling initiatives to expand the talent pool
6. Foster bio-economy mobility to expand the talent pools for companies not located near educational hubs
7. Raise awareness of bio-economy career opportunities through greater outreach to students and graduates

Appendix 2: Core Biomanufacturing courses – rationale and description

BIEN 500 Special Topics in Bioengineering 1 (3 credits)

Rationale: The Bioengineering Program does not yet have a special topics course and we believe that the students will greatly benefit from having specialized or updated content that is not covered by the existing curriculum.

Course content: will cover advanced cGMP biomanufacturing, regulatory requirements and ethics for biomanufacturing through seminars by experts in their fields.

BIEN 580 Synthetic Biology (3 credits)

Rationale: This course is an expected continuation to our existing 300- and 400-level course in bioengineering in which students learn about foundational engineering design in different fields of biology, such as biochemical, biomolecular or biomedical engineering. We have not previously offered a good follow up course in this subject, which resulted in lack of clear overview of the full potential of bioengineering and synthetic biology in the student knowledge and way of thinking.

Course description: Spanning the boundary of biology, engineering, and physics, Synthetic Biology is broadly defined as the construction and reconstruction of biological systems for practical applications in research and industry. Covering major topics in this rapidly evolving field, the planned activities aims to equip students with foundational skills and critical mindsets required for Synthetic Biology research. Emphasis is placed on fundamental knowledge and central technologies: engineering principles in biology, BioBricks and standardization of biological components, parts registries, advanced molecular biology tools for DNA assembly, genome editing, high-throughput genetic manipulation methods, construction of biological pathways, strategies for transcriptional control, examples of engineered systems.

BIEN 585 Metabolic Engineering (3 credits)

Rationale: This course will complement well our existing 400- and 500- Bioengineering courses related to biomolecular, cell culture, and tissue engineering, in particular our existing advanced course on Cell Culture Engineering (BIEN 590) and on Synthetic Biology (BIEN 580). We have not previously offered a course in this subject, which created a gap in student preparation.

Course description: Metabolic engineering role in transition from fossil resources to a bio-based society. Design-build-test-learn cycle of metabolic engineering. Design, genetic engineering and optimization of microbial biocatalysts. Metabolic network analysis, constraint-based modelling of metabolism, microbial production of valuable chemicals. General biochemical engineering practices. Recombinant DNA technology, enzyme function, kinetics and regulation. Cell chemistry, structure and function. Growth models, fermentation, strain development. Case studies.

BIEN 500 Cell Culture Engineering (3 credits)

Rationale: In the past decades there has been a significant shift from traditional bacterial fermentations to mammalian cell productions of biologics, including monoclonal antibodies and vaccines. This trend is currently well established with a global market over 150 billion US-$. and well documented among cell culture engineering

experts. However, with some exceptions, this topic is not covered in any of the usual biochemical engineering courses in academia and the accumulated knowledge and expertise remain confined to a highly specialized cell culture engineering community. Therefore, this course has been designed to address this knowledge gap and better prepare graduate students in Bioengineering to their future professional environment. This would also be available as a complementary course in the B.Eng. Bioengineering and will replace BIOC 311 Metabolic Chemistry.

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.

BIEN 670 Downstream Processing of Biologics (3 credits)

Rationale: This course complements effectively existing 500- Bioengineering courses series related to biomolecular, cell culture, and tissue engineering. Existing advanced course on Synthetic Biology (BIEN 580), Metabolic Engineering (BIEN 585) and Cell Culture Engineering (BIEN 590) are all related to upstream processing. Currently no advanced course on downstream processing of biologics is offered. This course is important for the preparation of students to operate in the biomanufacturing sector and as such it will be listed as a mandatory course for the Biomanufacturing graduate program.

Course description: Introduction to downstream processing (DSP) – principles, characteristics, purpose. Bioprocesses, biomolecules, drug substances, drug products, monoclonal antibodies and Fc fusion proteins, viral vectors, and vaccines. Unit operations - standard practices. Steps and techniques in downstream processing. Harvest and Filtration, Primary capture, Buffer exchange and up-concentration, Purification, Bioconjugation, Formulation. Optimization of downstream processing. Process Analytical Technology (PAT) to support Quality by Design (QbD) in DSP. Regulatory guidelines. Innovative Techniques for Downstream Bioprocessing.

BIEN 675 Process Analytical Technology and Data Sciences (3 credits)

Rationale: This course complements effectively existing 500- and 600- Bioengineering courses series related to biomolecular, cell culture, and tissue engineering. Existing advanced course on Cell Culture Engineering (BIEN 590) and Bioprocessing of Vaccines (BIEN 680) are all related to upstream processing. Currently no advanced course on Process Analytical Technologies for Biomanufacturing Biologics is offered. This course is important for the preparation of students to operate in the biomanufacturing sector and as such it will be listed as a core course for the Biomanufacturing graduate program.

Course description: Introduction to Process Analytical Technologies (PAT) and Quality by Design (QbD)- Concept of Critical Quality Attributes (CQA)/Critical Process Parameters (CPP)-Concept of Design Space-Risk Analysis-Design of Experiments (DoE). Analytical Technologies for Biologics and Biologic Medicines. Process Analytical Technologies for Biomanufacturing: At-line, On-line, Off-line monitoring, and data acquisition. Advanced process control. Scale down systems for process validation. Process data management and secured storage. Mechanistic modeling and Data processing. Basic on Hybrid models and Digital Twin concept.

BIEN 680 Bioprocessing of Vaccines (4 credits)

Rationale: Vaccination is one of the most valuable medical interventions for reducing the morbidity and mortality associated with infectious diseases. Important scientific and technological advancements in vaccinology led to the design of new strategies for antigen presentation. These new vaccination strategies have broadened the vaccine market requiring buildup of strategic capacities and development of advanced and sustainable manufacturing technologies. Canada has a well-established history in vaccines discovery and count a number of key players with manufacturing footprint within Canada in needs of highly qualified personnel. The course has been designed to expose the bioengineering graduate students to advanced bioprocessing and manufacturing technologies enabling cost-effective production of more vaccines in shorter timelines. The course is also designed to provide the bioengineers with a holistic perspective of the vaccine research and development field and the role of vaccines in public health priorities to respond to existing and emerging infectious threats.

Course description: Building on recent developments and expansion in the mammalian cell culture for production of complex biologics such as viral vaccines and viral vectors, the following topics will be covered: Principles of immunology and industrial virology; Cell physiology for vaccine production; Cell lines for vaccine production; Upstream process development and process intensification strategies; Purification and downstream processing of viral vaccines; Analytical and potency assays; Formulations and delivery of vaccines; Basics of clinical trials and regulatory principles; Immunization policies. Case studies on bioprocessing/manufacturing licensed vaccines.

BIEN 685 Biomanufacturing of Viral Vectors for Gene and Cell Therapy (3 credits)

Rationale: This course complements effectively existing 500- and 600- Bioengineering courses series related to biomolecular, cell culture, and tissue engineering. There is an increasing need of HQP in the area of Biomanufacturing Viral Vectors to enable Gene and Cell Therapies. Existing advanced course on Cell Culture Engineering (BIEN 590) and Bioprocessing of Vaccines (BIEN 680) are all related to upstream processing of "traditional" biologics and do not cover the applications in the gene and cell therapy. This course is important for the preparation of students to operate in the biomanufacturing sector and as such it will be listed as a mandatory course for the Biomanufacturing graduate program.

Course description: This course offers the basic knowledge in the design and biomanufacturing of viral vectors for gene and cell therapy interventions. It will combine lecture components with practical examples and case studies to familiarize graduate students with challenges and solutions associated with design and manufacturing of viral vectors such as Adeno-Associated Vectors (AAV), lentivirus vectors and Adenovirus vectors. Featured topics include fundamental principles of gene and cell therapies through in-vivo and ex-vivo interventions. Design of AAV, Lentivirus and Adenovirus vectors: example of targeted diseases, including CAR-T cell therapy. Technologies and modes of vector productions. Downstream processing and process analytical technologies for vectors manufacturing.

BMDE 505 Cell and Tissue Engineering (3 Credits)

Course Description: Application of the principles of engineering, physical, and biological sciences to modify and create cells and tissues for therapeutic applications will be discussed, as well as the industrial perspective and related ethical issues.

CHEE 512: Stem Cell Bioprocess Engineering (3 credits)

Rationale: The number of approved cellular therapy products is rapidly increasing. There is an urgent need to train engineers that can address the manufacturing challenges associated with the clinical scale production of these life-saving products. Compared to conventional pharmaceuticals, assuring the safety and efficacy of a live cell product is significantly more complex. Most cellular therapy products are currently produced at relatively small scale in surface culture with minimal manipulation. To exploit the full potential of stem cells, methods to produce cells at larger scale in a highly reproducible manner must be developed. Since cultures are often heterogeneous, new cell separation methods that can be scaled up must be developed. New approaches to cell distribution, including cryopreservation, must be put in place. Finally, reliable quality assurance methods must be developed to assure the safety and efficacy of the cells obtained in each batch. This course will describe these manufacturing challenges, suggest quantitative strategies to predict cell culture performance, provide an overview of state-of-the art stem cell culture techniques and identify avenues for further process optimization. As of now, there is no similar course in the Faculty of Engineering at McGill. The Department of Biomedical Engineering offers a technical elective BMDE 505 Cell and Tissue Engineering. This course focuses on fundamental aspects of tissue engineering. The Department of Bioengineering offers a technical elective BIEN 590 Cell Culture Engineering that discusses principles of bioprocess operation related to animal cells. Finally, the Department of Chemical Engineering offers an undergraduate core course CHEE 474 Biochemical Engineering and a graduate core course CHEE 651 Advanced Biochemical Engineering that present fundamental bioprocess engineering principles. In each case, there is minimal overlap (between 10% and 20%) with the proposed new course, which will focus on manufacturing challenges specific to stem cell based products.

Course description: Introduction to stem cell biology. Cell growth models applicable to stem cells and their progeny. Upstream processing (cell culture systems, bioreactors), downstream processing (cell separation, purification) and quality management (current good manufacturing practice, regulations) applied to therapeutic cells.

CHEE 651 Advanced Biochemical Engineering (4 credits)

Rationale: Biochemical engineering is a major branch of chemical engineering, and its principles are fundamental to much of the research conducted in chemical engineering. Over 60% of the research laboratories in the Department of Chemical Engineering conduct some form of biochemical engineering research. Therefore, there is a need to ensure that Chemical Engineering graduate students are formally taught and understand the fundamentals of biochemical engineering. Although the Department currently offers a series of bio-based graduate courses on specific topics, no fundamental graduate-level course is available to teach advanced concepts in biochemical engineering. This course will add to the core graduate courses available to our M.Eng. and Ph.D. students (it will be added to the list of complementary courses in both the M.Eng.(Thesis) Chemical Engineering and Ph.D. in Chemical Engineering.

Course description: The use of chemical engineering and biological principles in the study, design, use and creation of biologically-based processes and products. Topics: biochemical thermodynamics, protein engineering, manipulation of gene expression, transport phenomena and bioreactor design.

M.Eng BBME (Non-Thesis): Biomanufacturing – Consultations

- Institute of Parasitology
- Department of Bioresource Engineering
- Department of Bioengineering
- Department of Biomedical Engineering
- Department of Chemical Engineering

CONSULTATION REPORT FORM
RE PROGRAM PROPOSALS

DATE: **12 January 2022**

TO: **Prof. Reza Salavati, Director**
Institute of Parasitology

FROM: **Prof. Yu (Brandon) Xia, Director**
Graduate Program in Biological and Biomedical Engineering

The attached proposal has been submitted to the Curriculum Committee, and it has been decided that your department should be consulted.

Program Title: M.Eng. in Biological and Biomedical Engineering; Non-Thesis (Biomanufacturing)

Would you be good enough to review this proposal and let me know as soon as possible, on this form, whether or not your department has any objections to, or comments regarding, the proposal.

X **NO OBJECTIONS** _____ **SOME OBJECTIONS**

COMMENTS: I am very enthusiastic and excited to learn of the new biomanufacturing concentration that has been developed for the M.Eng. non-thesis program in Biological & Biomedical Engineering.

From reading your proposal, I am delighted to see that the discipline-based research skills of your graduates would address the strong demand from industrial and institutional partners in biomanufacturing for highly qualified personnel. This program would also provide additional courses that our MSc non-thesis-based graduate students in biotechnology program can benefit from.

Good luck and best wishes

Signature: Reza Salavati

Date: 1-13-2022

CONSULTATION REPORT FORM
RE PROGRAM PROPOSALS

DATE: **12 January 2022**

TO: **Prof. Viacheslav Adamchuk, Chair**
Department of Bioresource Engineering

FROM: **Prof. Yu (Brandon) Xia, Director**
Graduate Program in Biological and Biomedical Engineering

The attached proposal has been submitted to the Curriculum Committee, and it has been decided that your department should be consulted.

Program Title: M.Eng. in Biological and Biomedical Engineering; Non-Thesis (Biomanufacturing)

Would you be good enough to review this proposal and let me know as soon as possible, on this form, whether or not your department has any objections to, or comments regarding, the proposal.

X **NO OBJECTIONS** _____ **SOME OBJECTIONS**

COMMENTS:

Signature: В Адамчук

Date: **2022-01-17**

CONSULTATION REPORT FORM
RE PROGRAM PROPOSALS

DATE: **12 January 2022**

TO: **Prof. Dan Nicolau, Chair**
Department of Bioengineering

FROM: **Prof. Yu (Brandon) Xia, Director**
Graduate Program in Biological and Biomedical Engineering

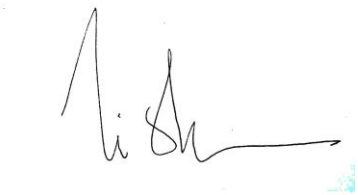
The attached proposal has been submitted to the Curriculum Committee, and it has been decided that your department should be consulted.

Program Title: M.Eng. in Biological and Biomedical Engineering; Non-Thesis (Biomanufacturing)

Would you be good enough to review this proposal and let me know as soon as possible, on this form, whether or not your department has any objections to, or comments regarding, the proposal. Specifically, several courses taught by your department that have been included in the program's list of courses.

X **NO OBJECTIONS** _____ **SOME OBJECTIONS**

COMMENTS:



Signature: _____

Date: **28.1.2022**

CONSULTATION REPORT FORM
RE PROGRAM PROPOSALS

DATE: **12 January 2022**

TO: **Prof. Viviane Yargeau, Chair**
Department of Chemical Engineering

FROM: **Prof. Yu (Brandon) Xia, Director**
Graduate Program in Biological and Biomedical Engineering

The attached proposal has been submitted to the Curriculum Committee, and it has been decided that your department should be consulted.

Program Title: M.Eng. in Biological and Biomedical Engineering; Non-Thesis (Biomanufacturing)

Would you be good enough to review this proposal and let me know as soon as possible, on this form, whether or not your department has any objections to, or comments regarding, the proposal. Specifically, two courses taught by your department that have been included in the program's list of courses: CHEE 512, and CHEE 651.

x **NO OBJECTIONS** _____ **SOME OBJECTIONS**

COMMENTS:

- Our core graduate courses, and technical electives, are not offered every year and are offered only when the teaching workload allows it. We want to indicate that it is not possible for us to increase or predict the frequency of offering of these two courses: CHEE 521 and CHEE 651. It should also be noted that CHEE students will have priority registering for the two CHEE courses, and given the cap in each course, students registered in the M.Eng. program being proposed are not guaranteed registration the two CHEE courses.
- The relevance of retaining the seminar course as a "core" course should be justified - is the content of this seminar course essential to the new biomanufacturing concentration?
- The terms quantitative and qualitative can be problematic and open for interpretation. We recommend removing these terms or using a different terminology.
- It will be important to secure industry internships - there would be limited benefit to internships in academic or other research laboratories. A definition of the type of internship anticipated would be beneficial.
- We understand that it may not be possible to create the new program in a timely manner if new courses must be incorporated as "core". However, we recommend the eventual replacement of the course on medical device regulatory affairs by a more targeted course on regulatory framework of biologics into the future curriculum. The course on medical device regulatory affairs could be considered non-core currently.

Signature: Viviane Yargeau

Date: January 14, 2022

Request for consultation: New biomanufacturing concentration for the M.Eng. non-thesis program in Biological & Biomedical Engineering

Viviane Yargeau, Professor <viviane.yargeau@mcgill.ca> Fri, Jan 21, 2022 at 9:52 AM
To: "Yu (Brandon) Xia" <brandon.xia@gmail.com>
Cc: "Yu Brandon Xia, Prof." <brandon.xia@mcgill.ca>, "Phillip Servio, Prof." <phillip.servio@mcgill.ca>, "W. Robert J. Funnell, Prof." <robert.funnell@mcgill.ca>, "Pina Sorrini, Ms." <pina.sorrini@mcgill.ca>, "Sasha Omanovic, Prof." <sasha.omanovic@mcgill.ca>

Thanks Brandon for these clarifications. The structure is a bit hard to understand but the most important aspects that we wanted to point out are the frequency of offering these courses and the priority for enrollment given to our students, which you acknowledged in your response.

Regards,
Viviane

Viviane Yargeau, ing., PhD
Professor & Department Chair
Department of Chemical Engineering
McGill University
3610 University Street, room 3100
Montreal, Quebec, Canada
H3A 0C5

E-mail: viviane.yargeau@mcgill.ca | **Tel:** 514.398.2273 | **Website:** Yargeau 3Cs Laboratory

On Jan 19, 2022, at 1:24 PM, Yu (Brandon) Xia <brandon.xia@gmail.com> wrote:

Hi Viviane,

Thank you so much for your support of the new concentration. Below please find our response to your comments in the consultation report. Can you take a look and let me know if you are satisfied with our response below?

Thanks,
-Brandon

==

> Our core graduate courses, and technical electives, are not offered every year and are offered only when the teaching workload allows it.
> We want to indicate that it is not possible for us to increase or predict the frequency of offering of these two courses: CHEE 521 and
> CHEE 651. It should also be noted that CHEE students will have priority registering for the two CHEE courses, and given the cap in each
> course, students registered in the M.Eng. program being proposed are not guaranteed registration the two CHEE courses.

Thank you very much for agreeing to include CHEE 521 and CHEE 651 in the list of biomanufacturing core courses for the proposed biomanufacturing concentration of the BBME Master's non-thesis program. We understand that CHEE 521 and CHEE 651 may not be offered every year, and that CHEE students take priority in registering for these two courses. At this moment, the proposed biomanufacturing concentration can successfully operate under these constraints, as there are more than enough biomanufacturing core courses listed for students to choose from in order to meet the 12-credit biomanufacturing core course requirement. In the future, coordination will be needed through McGill dedicated resources to further meet the need of the new concentration, e.g., through additional course sessions with additional lecturers, and through the participation of external partners including NRC.

> The relevance of retaining the seminar course as a "core" course should be justified - is the content of this seminar course essential to
> the new biomanufacturing concentration?

The BBME 600 Seminars in Biological & Biomedical Engineering course is a required course for BBME Master's programs in general (both thesis and non-thesis). The course covers all areas of biological & biomedical engineering, including biomanufacturing. Since the proposed biomanufacturing concentration resides within the BBME Master's non-thesis program, students in the concentration have to meet the requirements of the biomanufacturing concentration as well as the requirements of the parent BBME Master's non-thesis program. At this stage, we are proposing the new biomanufacturing concentration as a minor revision of the parent BBME Master's non-thesis program, while leaving the parent BBME Master's non-thesis program unchanged. Further minor changes to the structure of the biomanufacturing concentration are possible at a later stage, which will have to be done through joint revisions of the biomanufacturing concentration and the parent BBME Master's non-thesis program.

> The terms quantitative and qualitative can be problematic and open for interpretation. We recommend removing these terms or
> using a different terminology.

We wish to clarify that the terms "quantitative" and "non-quantitative" do not apply to the new list of biomanufacturing core courses in the new biomanufacturing concentration. Rather, they only apply to the existing list of BBME core courses inherited from the parent BBME non-thesis program, which were in turn inherited from the existing BBME thesis program. Since the proposed biomanufacturing concentration resides within the BBME Master's non-thesis program, students in the concentration have to meet the requirements of the biomanufacturing concentration as well as the requirements of the parent BBME Master's non-thesis program. At this stage, we are proposing the new biomanufacturing concentration as a minor revision of the parent BBME Master's non-thesis program, while leaving the parent BBME Master's non-thesis program unchanged. Future minor changes to the structure of the biomanufacturing concentration are possible at a later stage, which will have to be done through joint revisions of the biomanufacturing concentration and the parent BBME Master's non-thesis program.

> It will be important to secure industry internships - there would be limited benefit to internships in academic or other research laboratories.
> A definition of the type of internship anticipated would be beneficial.

Thank you very much for this important comment. The definition of the type of internship anticipated is provided in the course description of the already approved BBME 681 and BBME 682 Internship courses: "... supervised by a professional ... within an industrial or institutional research centre environment". We completely agree that it is important to secure industry internships. In addition to support already secured from NRC laboratories, discussions are underway with industrial partners with operational biomanufacturing facility including: Sanofi-Pasteur, Toronto; Medicago, Quebec; Reliance Biotech, Mississauga; Biodextris-Laval; and SMEs through In-vivo Montreal. A more detailed guideline regarding the internship will be provided to the student at the start of the internship.

> We understand that it may not be possible to create the new program in a timely manner if new courses must be incorporated as "core".
> However, we recommend the eventual replacement of the course on medical device regulatory affairs by a more targeted course
> on regulatory framework of biologics into the future curriculum. The course on medical device regulatory affairs could be considered
> non-core currently.

We wish to clarify that the course on medical device regulatory affairs is not listed as a biomanufacturing core course. Rather, it is listed as a BBME core course, which is inherited from the existing BBME thesis and non-thesis programs. We completely agree that it is beneficial to eventually replace the course on medical device regulatory affairs by a more targeted course on regulatory framework of biologics. In the meantime, this knowledge gap is addressed through several lectures in the BIEN 500 Special Topics in Bioengineering 1 course, which is listed as a biomanufacturing core course.

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Yu (Brandon) Xia, Ph.D.
Graduate Program Director, Biological & Biomedical Engineering

Professor of Bioengineering, McGill University
http://bioinfo.lab.mcgill.ca * brandon.xia@mcgill.ca

On Fri, Jan 14, 2022 at 1:53 PM Viviane Yargeau, Professor <viviane.yargeau@mcgill.ca> wrote:

> Brandon,
>
> I am attaching the signed consultation report. If you have questions or need clarifications, please let me know.
>
> Regards,
> Viviane

Viviane Yargeau, ing., PhD
Professor & Department Chair
Department of Chemical Engineering
McGill University
3610 University Street, room 3100
Montreal, Quebec, Canada
H3A 0C5

E-mail: viviane.yargeau@mcgill.ca | **Tel:** 514.398.2273 | **Website:** Yargeau 3Cs Laboratory

> On Jan 12, 2022, at 10:41 PM, Yu Brandon Xia, Prof. <brandon.xia@mcgill.ca> wrote:
>
> Dear Prof. Yargeau,
>
> I am writing to request the consultation from the Department of Chemical Engineering on a new biomanufacturing concentration that has been developed for the M.Eng. non-thesis program in Biological & Biomedical Engineering.
>
> Attached please find the consultation report form, as well as the new concentration proposal documents.
>
> As you probably know, this proposal is developed by Amine Kamen together with a small team of representatives from Chemical Engineering (Corinne Hoesli), Biomedical Engineering (Guojun Chen), and Bioengineering (Codruta Ignea). Two CHEE courses have been included in the proposal: CHEE 512, and CHEE 651.
>
> I'd greatly appreciate it if you can complete and sign the attached consultation report and return it back to me as soon as possible. Please let me know if you have any questions and thanks so much for your help!
>
> Thanks,
> -Brandon
>
> --
> Yu (Brandon) Xia, Ph.D.
> Graduate Program Director, Biological & Biomedical Engineering
> Professor of Bioengineering, McGill University
> http://bioinfo.lab.mcgill.ca * brandon.xia@mcgill.ca
> <consultation_report_CHEE.doc><Proposal_M.Eng. BBME (Non-Thesis) Biomanufacturing.pdf>

CONSULTATION REPORT FORM
RE PROGRAM PROPOSALS

DATE: **12 January 2022**

TO: **Prof. David Juncker, Chair**
Department of Biomedical Engineering

FROM: **Prof. Yu (Brandon) Xia, Director**
Graduate Program in Biological and Biomedical Engineering

The attached proposal has been submitted to the Curriculum Committee, and it has been decided that your department should be consulted.

Program Title: M.Eng. in Biological and Biomedical Engineering; Non-Thesis (Biomanufacturing)

Would you be good enough to review this proposal and let me know as soon as possible, on this form, whether or not your department has any objections to, or comments regarding, the proposal. Specifically, several courses taught by your department that have been included in the program's list of courses.

X **NO OBJECTIONS** _____ **SOME OBJECTIONS**

COMMENTS:

There are 3 new 3-credit courses underlined in the program proposal, for which we have received consultation requests and proposed course outlines (BIEN 670, BIEN 675, and BIEN 685). It will be helpful to clarify who will be the instructors for the set of courses where they have not yet been determined.

There are 2 additional new 9-credit courses specified in the proposal for which we have not yet received consultation requests or course outlines (BBME 681 Internship 1, and BBME 682 Internship 2). We support these two internships, but considering that they will account for 40% of the credit requirements for this new program, we wish to receive more information on these courses in due time, and be consulted with regards to their development.

BMDE 654 Biomedical Regulatory Affairs - Medical Devices is listed as a BBME Core Course (Non-Quantitative), and we believe it could be helpful to students in this concentration. However, it is a core course for the Graduate Certificate in Translational Biomedical Engineering, as well for a new proposed Master's in Translational Biomedical Engineering, so students in these programs will take priority in registration.

We understand that as this is an adaptation of the current BBME program it must follow the same requirements (e.g. emphasis on quantitative courses). It will be helpful to revisit these requirements in the future to better tailor the content to the intent of the Biomanufacturing option.

Overall, this is a timely and important new development for the BBME program.

Signature: 

Date: 11. Feb. 2022

Request for consultation: New biomanufacturing concentration for the M.Eng. non-thesis program in Biological & Biomedical Engineering

Yu (Brandon) Xia <brandon.xia@gmail.com> Mon, Feb 14, 2022 at 10:20 PM
To: "David Juncker, Prof." <david.juncker@mcgill.ca>
Cc: "Yu Brandon Xia, Prof." <brandon.xia@mcgill.ca>, "W. Robert J. Funnell, Prof." <robert.funnell@mcgill.ca>, "Pina Sorrini, Ms." <pina.sorrini@mcgill.ca>
Bcc: "Josephine Nalbantoglu, Dr." <josephine.nalbantoglu@mcgill.ca>, "Amine A. Kamen, Prof" <amine.kamen@mcgill.ca>

Hi David,

Thank you so much for your support of the new biomanufacturing concentration. Below please find our response to your comments in the consultation report. Please let me know if you have any questions.

Thanks,
-Brandon

==

> There are 3 new 3-credit courses underlined in the program proposal, for which we have
> received consultation requests and proposed course outlines (BIEN 670, BIEN 675, and
> BIEN 685). It will be helpful to clarify who will be the instructors for the set of courses
> where they have not yet been determined.

The instructor for BIEN 670 will be Prof. Codruta Ignea. The instructor for BIEN 675 will be Prof. Amine Kamen. The instructor for BIEN 685 will be Dr. Renald Gilbert from NRC, who is also an Adjunct Professor at McGill. Additional resources will be requested to hire course lecturers to assist the delivery of these and other key biomanufacturing core courses.

> There are 2 additional new 9-credit courses specified in the proposal for which we have
> not yet received consultation requests or course outlines (BBME 681 Internship 1, and
> BBME 682 Internship 2). We support these two internships, but considering that they will
> account for 40% of the credit requirements for this new program, we wish to receive more
> information on these courses in due time, and be consulted with regards to their development.

We wish to clarify that the two 9-credit internship courses (BBME 681 and BBME 682) have already been approved by the University last year. They were reviewed and unanimously approved on September 24, 2021 by the BBME Program Executive Committee, which consists of Department Chairs and additional faculty representatives from both Biomedical Engineering and Bioengineering Departments, as well as a student representative from the BBME program. They were further discussed in detail in a meeting on November 3, 2021 involving Prof. Amine Kamen, Chair of the Biomanufacturing Working Group, Prof. Brandon Xia, GPD of BBME, and all faculty members of the Biomedical Engineering Department. All concerns raised have been addressed. The two courses were further reviewed and approved by the Faculty of Engineering, Faculty of Medicine and Health Sciences, Graduate and Postdoctoral Studies, and McGill University committees.

Here, we propose to include these two existing internship courses in the new biomanufacturing concentration, without any changes to their course contents. Hence, the current consultation is limited to the new biomanufacturing concentration only, and we did not seek additional formal consultation regarding the two already-approved internship courses.

We recognize the importance of the internship courses for the success of the new biomanufacturing concentration, and we are taking several measures to ensure that key units are properly consulted with regard to the development and delivery of these courses. First, the design and delivery of the biomanufacturing concentration, including the two internship courses, have been carried out by a small Biomanufacturing Working Group which includes faculty representatives from Biomedical Engineering, Bioengineering, and Chemical Engineering Departments. Second, we are making every effort to secure industry internships for students. In addition to support already secured from NRC laboratories and Sanofi-Pasteur, discussions are underway with industrial partners with operational biomanufacturing facility including: Medicago, Quebec; Reliance Biotech, Mississauga; Biodextris-Laval; and SMEs through In-vivo Montreal. A more detailed guideline regarding the internship will be provided to the student at the start of the internship.

Finally, the design and delivery of the biomanufacturing concentration, including the two internship courses, will be regularly reviewed by the BBME Program Executive Committee, which consists of Department Chairs and additional faculty representatives from both Biomedical Engineering and Bioengineering Departments, as well as a student representative from the BBME program. We welcome feedback with regard to the two internship courses (see attached for the latest syllabi). Further concerns regarding these courses will be addressed through future minor revisions, if needed.

> BMDE 654 Biomedical Regulatory Affairs - Medical Devices is listed as a BBME Core Course
> (Non- Quantitative), and we believe it could be helpful to students in this concentration.
> However, it is a core course for the Graduate Certificate in Translational Biomedical
> Engineering, as well for a new proposed Master's in Translational Biomedical Engineering,
> so students in these programs will take priority in registration.

We understand that students in the translational biomedical engineering programs take priority in registering for BMDE 654. The proposed biomanufacturing concentration can successfully operate under this constraint, as there are more than enough BBME core courses listed for students to choose from in order to meet the 12-credit BBME core course requirement. In addition, the regulatory framework of biologics will be covered through several lectures in the BIEN 500 Special Topics in Bioengineering 1 course, which is listed as a biomanufacturing core course.

> We understand that as this is an adaptation of the current BBME program it must follow the
> same requirements (e.g. emphasis on quantitative courses). It will be helpful to revisit these
> requirements in the future to better tailor the content to the intent of the Biomanufacturing
> option.

We agree completely. Further minor changes to the structure of the biomanufacturing concentration are possible at a later stage, which will have to be done through joint revisions of the biomanufacturing concentration and the parent BBME Master's non-thesis program.

> Overall, this is a timely and important new development for the BBME program.

Thank you very much for the support of the new biomanufacturing concentration for the BBME Master's non-thesis program.

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Yu (Brandon) Xia, Ph.D.
Graduate Program Director, Biological & Biomedical Engineering
Professor of Bioengineering, McGill University
http://bioinfo.lab.mcgill.ca * brandon.xia@mcgill.ca

On Fri, Feb 11, 2022 at 9:56 PM David Juncker, Prof. <david.juncker@mcgill.ca> wrote:

> Dear Brandon,
>
> Please find attached the BME consultation reports.
>
> Thanks for your efforts and leadership in developing this option.
>
> Best wishes
> David
>
> ---
>
> David Juncker, Professor & Chair BME I Genome Centre I McGill University I +1 (514) 398 7676 I
> https://www.mcgill.ca/bme I https://juncker.lab.mcgill.ca

McGill

From: Yu Brandon Xia, Prof. <brandon.xia@mcgill.ca>
Sent: January 12, 2022 22:51
To: David Juncker, Prof. <david.juncker@mcgill.ca>
Cc: W. Robert J. Funnell, Prof. <robert.funnell@mcgill.ca>; Pina Sorrini, Ms. <pina.sorrini@mcgill.ca>
Subject: Request for consultation: New biomanufacturing concentration for the M.Eng. non-thesis program in Biological & Biomedical Engineering

Hi David,

Happy New Year! I am writing to request the consultation from the Department of Biomedical Engineering on a new biomanufacturing concentration that has been developed for the M.Eng. non-thesis program in Biological & Biomedical Engineering.

Attached please find the consultation report form, as well as the new concentration proposal documents.

As you know, this proposal is developed by Amine Kamen together with a small team of representatives from Biomedical Engineering (Guojun Chen), Chemical Engineering (Corinne Hoesli), and Bioengineering (Codruta Ignea). In addition to the proposal, Amine has also secured letter and experts from NRC in support of biomanufacturing internships.

I'd greatly appreciate it if you can complete and sign the attached consultation report and return it back to me as soon as possible. Please let me know if you have any questions and thanks so much for your help!

Thanks,

-Brandon

--

Yu (Brandon) Xia, Ph.D.

Graduate Program Director, Biological & Biomedical Engineering

Professor of Bioengineering, McGill University

http://bioinfo.lab.mcgill.ca * brandon.xia@mcgill.ca