BIOLOGICAL AND BIOMEDICAL ENGINEERING M.ENG. (NON-THESIS)-CONCENTRATION IN BIOMANUFACTURING

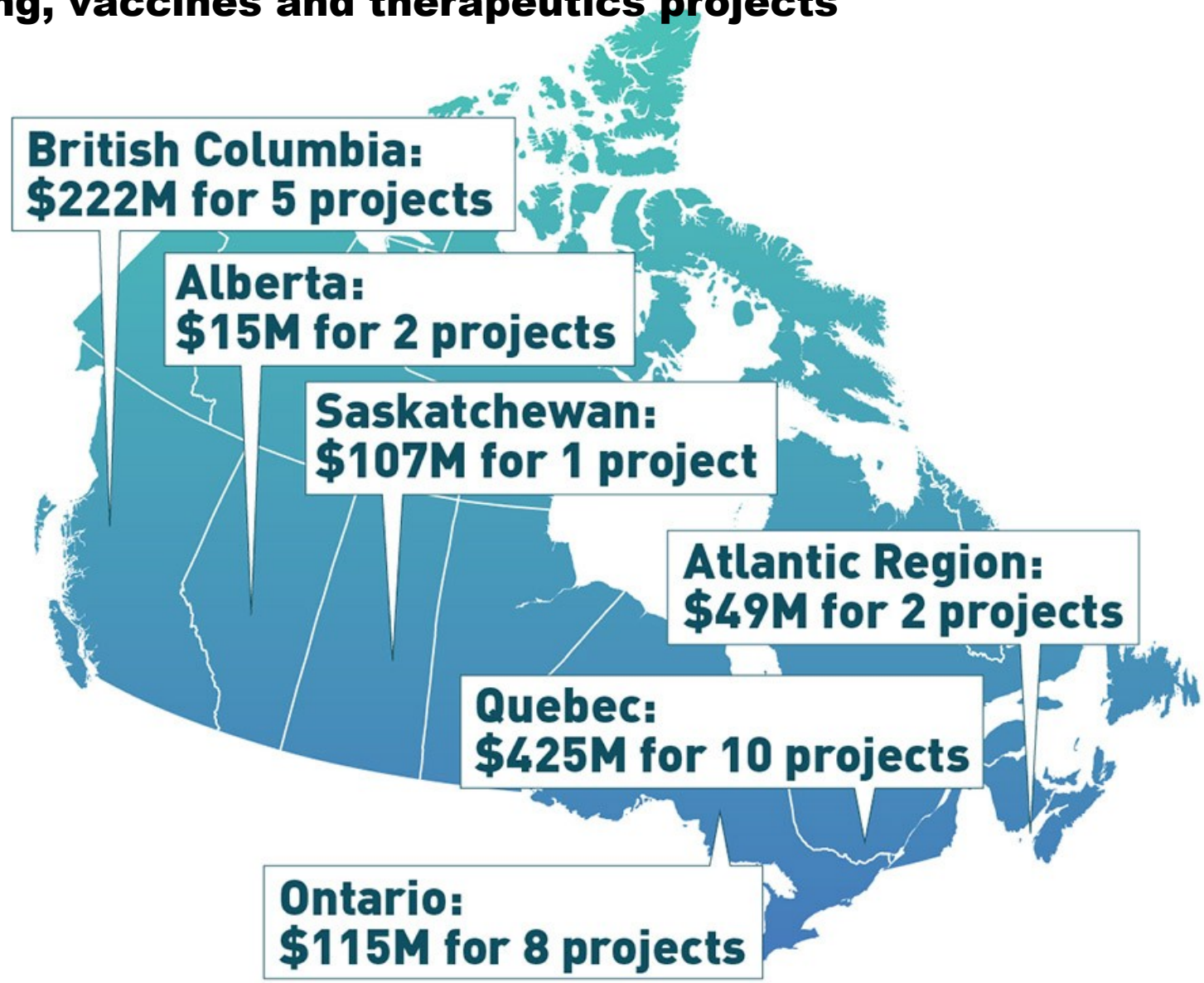
2022 Jun 29

Canada's Biomanufacturing and Life Sciences Strategy,

- Through ***Canada's Biomanufacturing and Life Sciences Strategy***, the Government of Canada is investing more than $2.2 billion over seven years to continue growing a strong, competitive biomanufacturing and life sciences sector, and to ensure Canada is prepared for future pandemics.
- The Strategy includes these foundational investments to help **build Canada's talent pipeline** and research systems, as well as foster the growth of Canadian life sciences firms:
  - **Canada Biomedical Research Fund (CBRF):** Tri-Agency $250M over 4 yrs starting in 2022-23 for high-risk, applied research, training and talent development, contributes to the pipeline of new technologies and supports the translation of academic research into applications and commercial products.
  - **Biosciences Research Infrastructure Fund (BRIF):** CFI $500M over 4 yrs starting in 2021-22 for bioscience infrastructure
- The goals of the funds are to enhance Canada's foundational biomanufacturing excellence and pandemic readiness by
  1) addressing institutional research infrastructure needs
  2) developing the research and **development and talent pipeline that drives downstream manufacturing capacity**
- The two programs are delivered through an integrated competition. This will maximize the Strategy's impact and ensure investments under the two programs complement and reinforce each other. The integrated competition will focus on bio-innovation ecosystem priorities and themes. It will invite proposals for research, training and infrastructure in priority areas identified by the government.

https://www.sshrc-crsh.gc.ca/funding-financement/cbrf-frbc/overview-apercu-eng.aspx

Government of Canada investments of more than $1.3B in 29 COVID-19 domestic biomanufacturing, vaccines and therapeutics projects



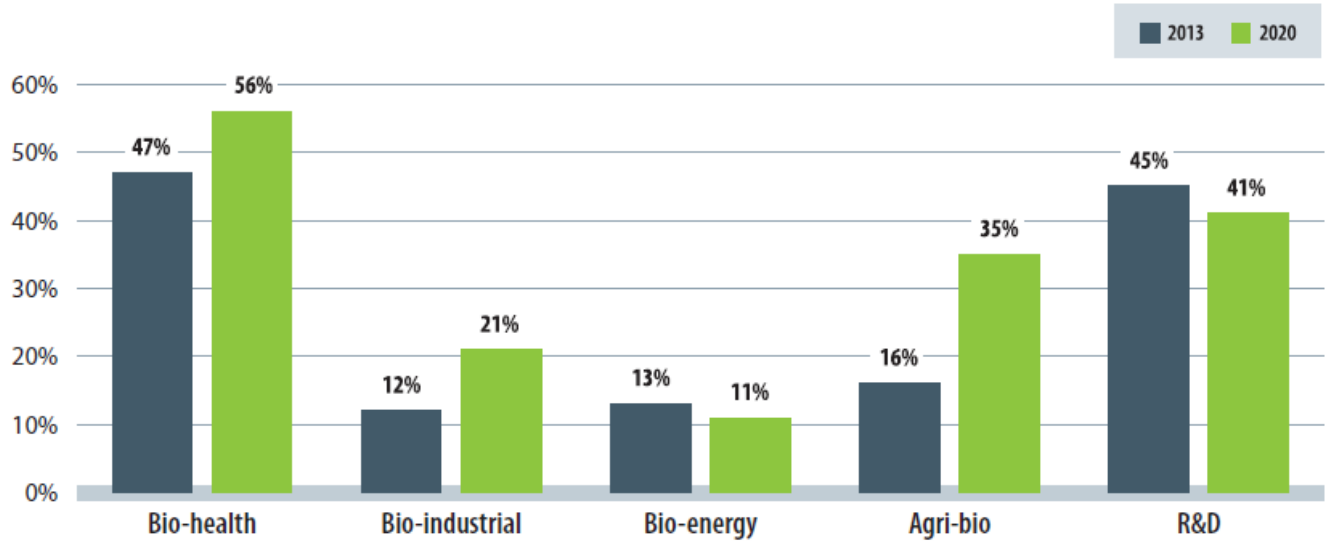
Biomanufacturing: Projects underway

The bio-manufacturing gap

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.

BioTalent Canada Labour Market Intelligence Report 2021



Employers may be able to fill only 25% of bio-manufacturing and processing job openings by 2029.

While labour shortages are expected for all bio-economy job functions throughout the forecast period, three areas stand out as likely to experience persistent, severe shortages until 2029 and beyond:

- Manufacturing and production jobs
- Distribution and logistics jobs
- Management, finance and administration jobs

Program description

The BBME non-thesis Biomanufacturing Concentration aims to provide students with:

- advanced knowledge and competencies in the rapidly evolving fields of biological and biomedical engineering;
- hands-on experience through projects carried out during internships to establish a solid foundation of competencies required for professional activities including agility, adaptability, teamwork, responsibility and life-long learning.

The admission requirements are the same as those for the overall Master’s program in Biological and Biomedical Engineering:

- a Bachelor's degree in engineering or science with a strong emphasis on mathematics and the physical sciences;
- some exposure to the life sciences (physiology, cell biology or molecular biology).

Program description

Courses (27 credits)
At least 12 credits must be chosen from biomanufacturing core courses.
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Seminar course (3 credits over two semesters)

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

Program description

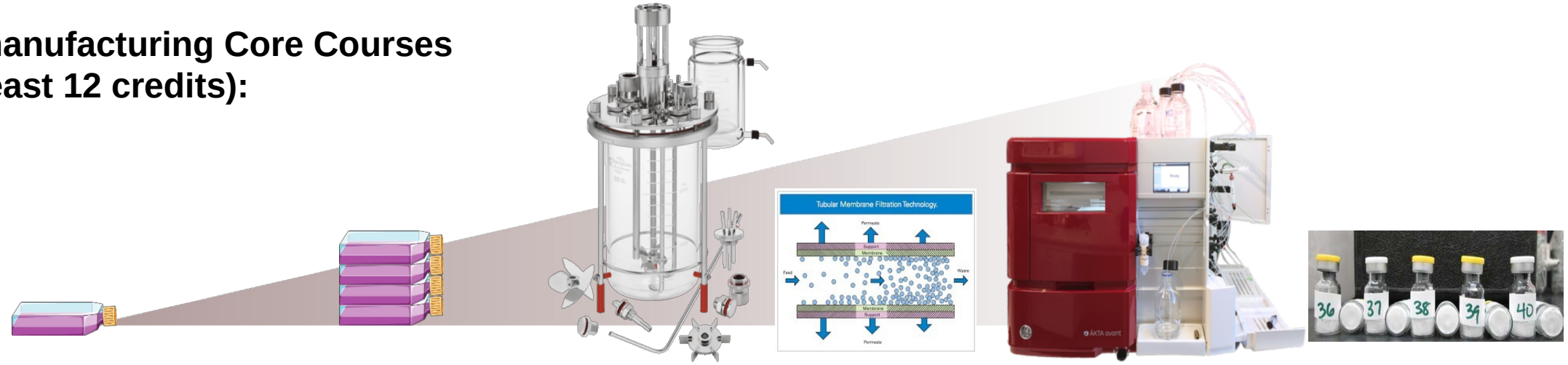
Example of program curriculum

SEMESTER 1 FALL	SEMESTER 2 WINTER	SEMESTER 3 SUMMER	SEMESTER 4 FALL
• BBME 600D1 (1.5) • BIEN 510 (3) • BIEN 550 (3) • BMDE 501 (3) • BMDE 508 (3)	• BBME 600D2 (1.5) • BIEN 590 (3) • BIEN 580 (3) • BIEN 670 (3) • BIEN 675 (3)	• BBME 681 (9) Internship 1	• BBME 682 (9) Internship 2

COURSES
27 CREDITS

INTERNSHIPS
18 CREDITS

Biomanufacturing Core Courses (At least 12 credits):



Cell Line Engineering and Vector Design → Upstream Process Optimization → Scale-up → Downstream Processing → Formulation and Delivery

Process Analytical Technologies and Data Sciences

PROCESS ACCELERATION and INTENSIFICATION for PRODUCTION of BIOLOGICS

BIEN 500 Special Topics in Bioengineering 1 (3 credits)
BIEN 580 Synthetic Biology (3 credits)
BIEN 585 Metabolic Engineering (3 credits)
BMDE 505 Cell and Tissue Engineering (3 credits)

BIEN 675 Process Analytical Technology and Data Sciences (3 credits)
BIEN 680 Bioprocessing of Vaccines (4 credits)
BIEN 685 Biomanufacturing of Viral Vectors for Gene and Cell Therapy (3 credits)
BIEN 590 Cell Culture Engineering (3 credits)
CHEE 651 Advanced Biochemical Engineering (4 credits)
CHEE 512 Stem Cell Bioprocess Engineering (3 credits)

BIEN 670 Downstream Processing of Biologics (3 credits)
BMDE 507 Delivery and formulation of biotherapeutics (3 credits)

Core courses

Biomanufacturing concentration

BIEN 500 Special Topics in Bioengineering 1 (3 credits)

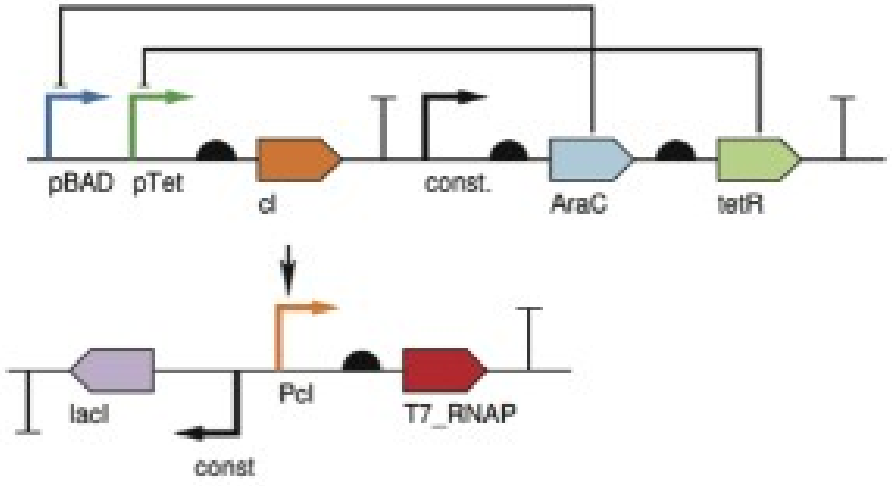
Course Overview

Will cover advanced cGMP biomanufacturing, regulatory requirements and ethics for biomanufacturing through seminars by experts in their fields.

BIEN 580 Synthetic Biology (3 credits)

Course Overview

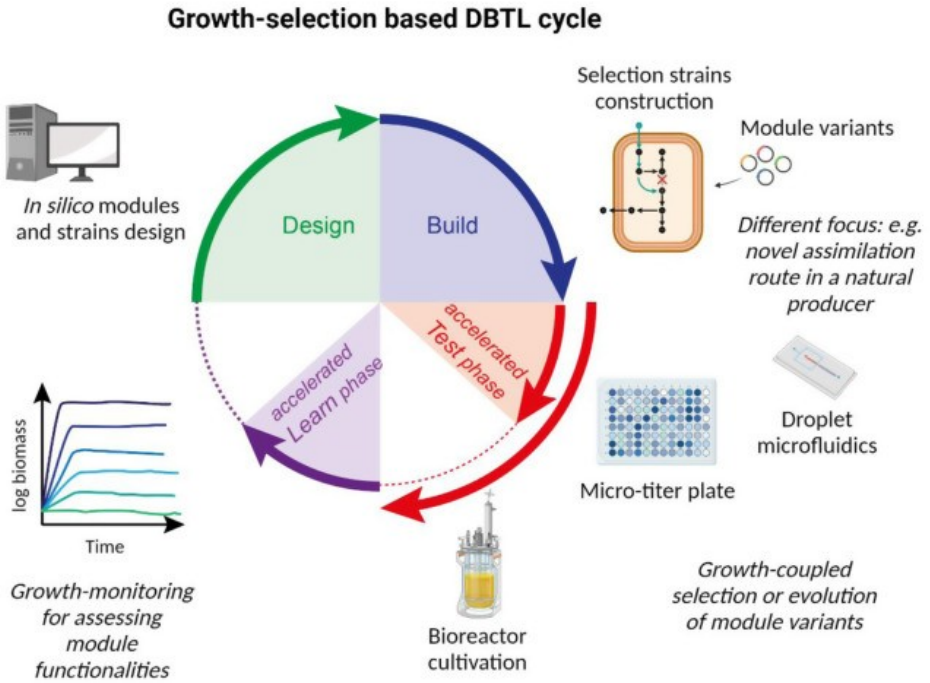
Synthetic Biology: Construction and reconstruction of biological systems for practical applications in research and industry. Topics: engineering principles in biology, BioBricks and standardization of biological components, parts registries, advanced molecular biology tools for DNA assembly, genome editing, high-throughput genetic manipulation methods, strategies for transcriptional control.



BIEN 585 Metabolic Engineering (3 credits)

Course Overview

Metabolic Engineering: General biochemical engineering practices. Recombinant DNA technology, enzyme function, kinetics and regulation. Cell chemistry, structure and function. Growth models, fermentation, strain development. Metabolic network analysis, constraint-based modelling of metabolism, microbial production of valuable chemicals.



BIEN 590 Cell Culture Engineering (3 credits)

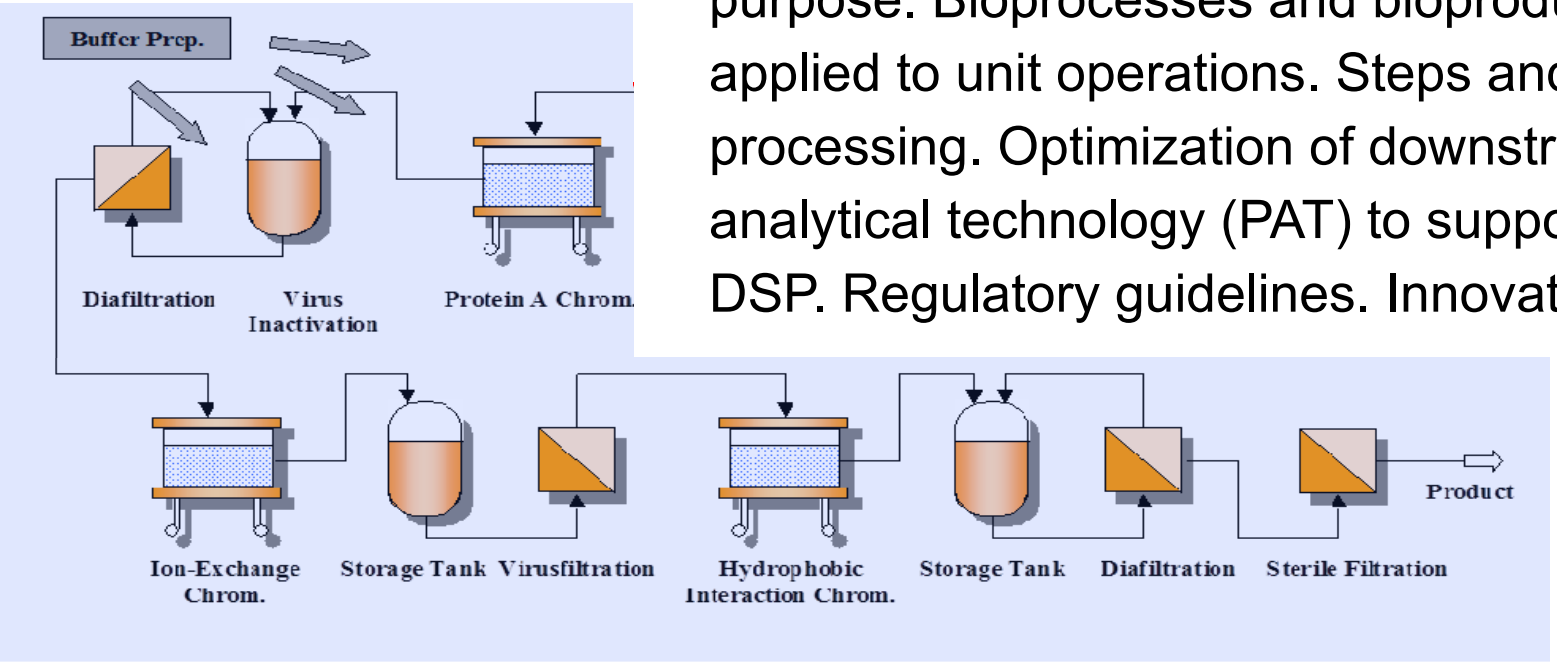
Course Overview

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 (3 credits)

Course Overview

Downstream processing (DSP): Principles, characteristics, purpose. Bioprocesses and bioproducts. Standard practices applied to unit operations. Steps and techniques in downstream processing. Optimization of downstream processing. Process analytical technology (PAT) to support quality by design (QbD) in DSP. Regulatory guidelines. Innovative techniques for DSP.



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

Course Overview

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)

Course Overview

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)

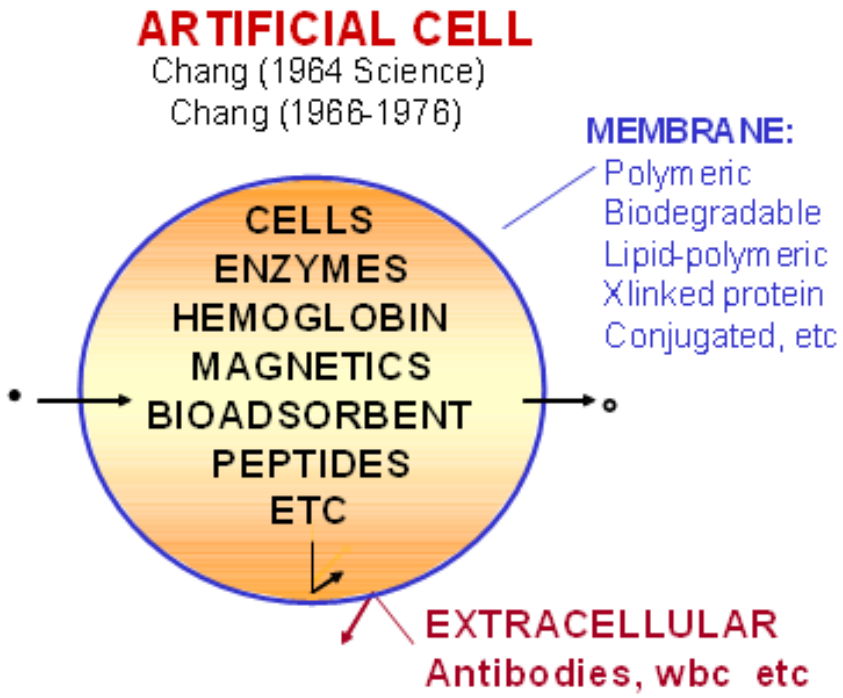
Course Overview

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 Formulation and delivery of biotherapeutics (3 credits)

Course Overview

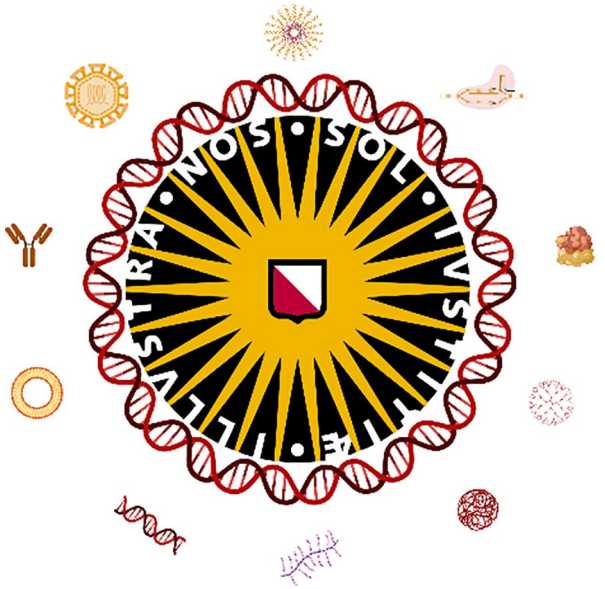
Application of the principles of engineering, physical, and biological sciences to modify and create cells and tissues for therapeutic applications will be discussed, as well as the industrial perspective and related ethical issues.



BMDE 507 Formulation and delivery of biotherapeutics (3 credits)

Course Overview

Biotherapeutics, including nucleic acids, proteins, antibodies, peptides and cells, are a group of important therapeutical agents and have a wide spectrum of clinical applications. This course is designed to introduce the importance of and technologies for formulation and delivery of biotherapeutics, and covers the fundamental principles of formulation and delivery system development, manufacturing and analytical techniques, and biomedical applications. The course will also discuss translational considerations for formulated biotherapeutic products.



CHEE 512 Stem Cell Bioprocess Engineering (3 credits)

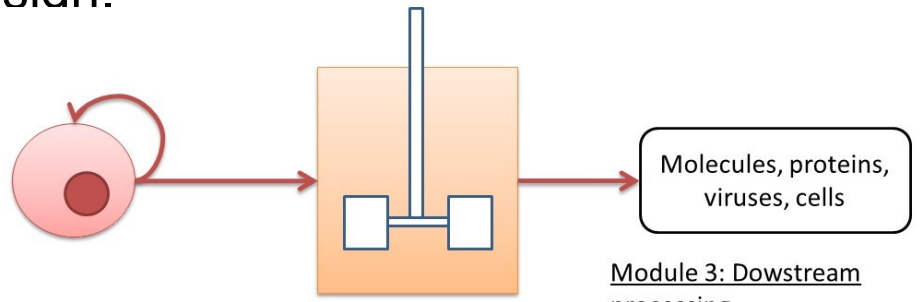
Course Overview

Chemical Engineering: 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)

Course Overview

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.



Module 1: molecular and cell biology overview
- Bioinformatics
- Protein engineering
- Molecular cloning and expression vectors
- Advanced cell growth kinetics models
- Metabolic modeling

Module 2: Upstream processing
- Bioreactor design: mass transfer, mixing, cooling
- Advanced bioreactor configurations
- Enzyme and cell immobilization

Module 3: Dowstream processing
- Centrifugation, filtration, chromatography
- Design heuristics

Module 4: Quality control and regulatory considerations
- Quality management
- Regulatory approval of novel therapeutics

Module 5: Advances and future avenues in biochemical engineering