Analysis of post-secondary training in biomanufacturing in Québec

Prepared for Montréal In Vivo by Patrick Daoust, independent consultant

This study was commissioned and financed by the ministère de l'économie, l'innovation et l'énergie

Table des matières

1. Executive summary 5
2. Introduction and purpose of the study 6
   2.1. Context 6
   2.2. Aim of the study 7
   2.3. Labour requirements 8
   2.4. Cellular and gene therapies 9
   2.5. The importance of training in biomanufacturing 10
   2.6. Training programs in Québec 11
3. Methodology used 11
   3.1. Analysis of biomanufacturing job descriptions posted in Québec and elsewhere in North America 11
   3.2. Analysis of statistical data and other studies to identify trends in educational programs leading to jobs in biomanufacturing 11
   3.3. Tables comparing job descriptions and skills taught in relevant training courses 12
   3.4. Meetings with program leaders 12
4. Results and Analysis 12
   4.1. Analysis of College Programs - DEC and AEC 12
      4.1.1. Analysis of Statistical Data 13
      4.1.2. DEC Programs 16
      4.1.2.1. Analysis of the Alignment of DEC Programs with Skills Sought in the Industry 17
      4.1.3. AEC Programs 19
   4.2. Analysis of Training Programs Offered by Universities 20
      4.2.1. Analysis of Statistical Data 20
      4.2.2. Université de Montréal, Faculty of Pharmacy 22
      4.2.2.1. Baccalauréat en sciences biopharmaceutiques (BSBP) 22
      4.2.2.2. Drug Development Programs (DESS) 22
      4.2.2.3. Master in Pharmaceutical Sciences 23

4.2.2.4. Analysis of the Correspondence of Programs with Skills Sought in Industry 23
4.2.3. École Polytechnique, Département de génie chimique 24
4.2.3.1. Maîtrise professionnelle ou DESS en génie chimique - axe Bioprocédés pharmaceutiques et agroalimentaires 24
4.2.3.2. Analysis of the Correspondence of Programs with Skills Sought in Industry 25
4.2.4. McGill University, Faculty of Engineering 26
4.2.4.1. Bachelor's Program in Engineering with a Specialization in Bioengineering 26
4.2.4.2. Master's of Engineering (non-thesis) in BBME - biomanufacturing concentration 27
4.2.4.3. Analysis of the Correspondence of Programs with Skills Sought in Industry 28
4.2.5. Université de Sherbrooke, Département de génie chimique et de génie biotechnologique 29
4.2.5.1. Bachelor's in Biotechnological Engineering, Co-op Program 29
4.2.5.2. Analysis of the Correspondence of Programs with Skills Sought in Industry 30
4.2.6. Université Laval, Département de génie chimique 31
4.2.6.1. Bachelor's in Chemical Engineering, Concentration in Biochemical and Biopharmaceutical Engineering 31
4.3. Analysis of Private Training Programs and Programs Offered by Non-Profit Organizations (NPOs) 31
4.3.1. Specialized Biomanufacturing Training in Canada 31
4.3.2. Specialized Training in Skills Required in the Biopharmaceutical Industry in North America and Europe 33
5. Findings 35
5.1. Cégep programs 35
5.1.1. DEC programs 35
5.1.1.1. Matching programs to industry needs 35
5.1.1.2. Update of the 210.AA program 37
5.1.1.3. Graduate wages 37

5.1.2. AEC programs 38
5.2. University programs 39
6. Areas to think about 40
6.1. Internships in the current economic climate 40
6.2. Industry-specific challenges 41
6.3. Synergies between pharmaceutical manufacturing and biomanufacturing 41
7. Références 43

List of acronyms

AEC - Attestation d'études collégiales

CAPA - Corrective and Preventive Actions

CEGEP - Collège d'enseignement général et professionnel

DEC - Diplôme d'études collégiales

DESS - Diplôme d'études supérieures spécialisées

FDA - Food and Drug Administration

GMP - Good Manufacturing Practices

MEIE - Ministère de l'Économie, de l'Innovation et de l'Énergie

MES - Ministère de l'Éducation Supérieure

SOP - Standard Operating Procedure

STEM- Science, Technology, Engineering, and Mathematics

1. Executive summary

Introduction: The aim of this study is to establish the degree of correspondence between the skills acquired in post-secondary training and those demanded by the biomanufacturing industry in the field of life sciences.

In this report, biomanufacturing is defined as all processes for manufacturing complex molecules in the biopharmaceutical field using biological processes involving cells or any other living organism. These molecules can be proteins (enzymes, antibodies), peptides, viruses, cell therapies, blood product fractions and nucleotide chains such as RNA or DNA.

Biomanufacturing products include all vaccines, several biopharmaceuticals used to treat autoimmune diseases (rheumatoid arthritis, etc.), several cancer treatments and treatments for rare diseases.

Analysis tool: A grid of skills required for scientific positions, ranging from technical tasks to the development of new manufacturing processes, was drawn up based on a review of job postings in the field. This grid was validated by industry professionals. It was then used to assess the level of correspondence with the content of programs available in Québec, in discussions with several cégep and university program managers (see tables in Section 4 'Results and analysis').

Overall finding: The results showed that the various skills required are included in the various courses offered but are scattered across different programs. In addition, there is a lack of practical training, particularly in sterile environments.

2. Introduction and purpose of the study

2.1. Context

The COVID-19 pandemic highlighted the need for versatile facilities on Canadian soil that are not dedicated to a single product, in order to be ready to face a future health crisis.

Canada is the world's second largest consumer of organic products, per capita. In 2021, 131 companies manufacturing pharmaceutical products and medicines were present, employing more than 11,830 people [1].

While the global market for biologics is growing rapidly, mammalian cell manufacturing is the most popular process in Canada, and this demand is likely to increase in the near future.

Back in 2017, Québec identified that the presence of a mammalian cell biomanufacturer on Québec soil was necessary to ensure a secure supply of drugs, maintain competitive prices and position itself as a major player locally and internationally. As one of the objectives of the 2017-2027 Quebec Life Sciences Strategy of the Ministère de l'Économie, de l'Innovation et de l'Énergie is to attract at least one major biomanufacturing project, Moderna's arrival in Laval, Québec, meets this objective in part.

For several years now, biopharmaceuticals have been taking an increasing share of the drug market. In addition to population safety considerations, market studies predict annual growth in global sales of biopharmaceuticals (products derived from biomanufacturing) of between 7.5% and 12% (Figure 1).

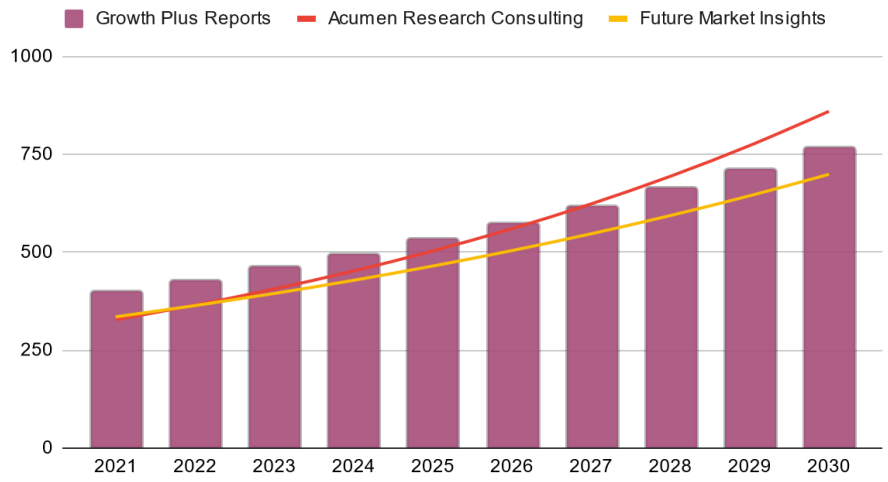

Figure 1: Sales Forecast - Biopharmaceutical Market

2.2. Aim of the study

This study is limited to biomanufacturing in the field of life sciences. Sometimes referred to as the life sciences and health technologies (LSHT) industry, this acronym is designed to encompass a wide range of technologies and companies. Not all of them respond to the same market pressures or face the same labour challenges.

For example, contract research organizations (CROs) are outside the scope of this study. According to a BIOQuébec study[2], these companies employed 7,363 people in Québec in 2023. This industry segment includes companies involved in pre-clinical research (CellCarta, Altasciences), toxicology studies (Charles River, ITR) and clinical study management (IQVIA, formerly Quintiles). CROs require multi-skilled technicians capable of undertaking a variety of tasks independently.

Product development companies (Repare, Congruence, 35 Pharma, etc.) have approaches or platforms that enable them to validate targets for the development of new drugs. The skills required for this work are very different from those for the biomanufacturing industry, and so these companies and their needs are not included in this study.

In many ways, biomanufacturing labour needs are similar to those of traditional pharmaceutical manufacturing companies such as Delpharm, Pharmascience, Jubilant, etc.

What's more, Québec's rich academic environment and generous tax credit programs for scientific research and experimental development (SR&ED) have helped this sector of the economy to flourish. The latter has influenced the development of training programs such as the college diploma (DEC) in Laboratory Technology: Biotechnology.

2.3. Labour requirements

Labour shortages exist in all developed countries[3], largely due to demographic trends. In Canada, Québec [4] and British Columbia [5] are particularly affected by this demographic labour shortage. This shortage has the potential to have more adverse effects in the high-tech sector, for two reasons:

1. Unfilled positions pay higher than average and;
2. A shortage of personnel is a limiting factor for foreign investment in the development of manufacturing capacity in Canada.

This second point may have repercussions on the ability to produce drugs within Canadian borders in times of pandemics or other emergencies that could affect the supply of essential goods.

The average salary in the LSHT sector in Greater Montréal was $71,000 in 2019, about 30% higher than the Québec average [6,7].

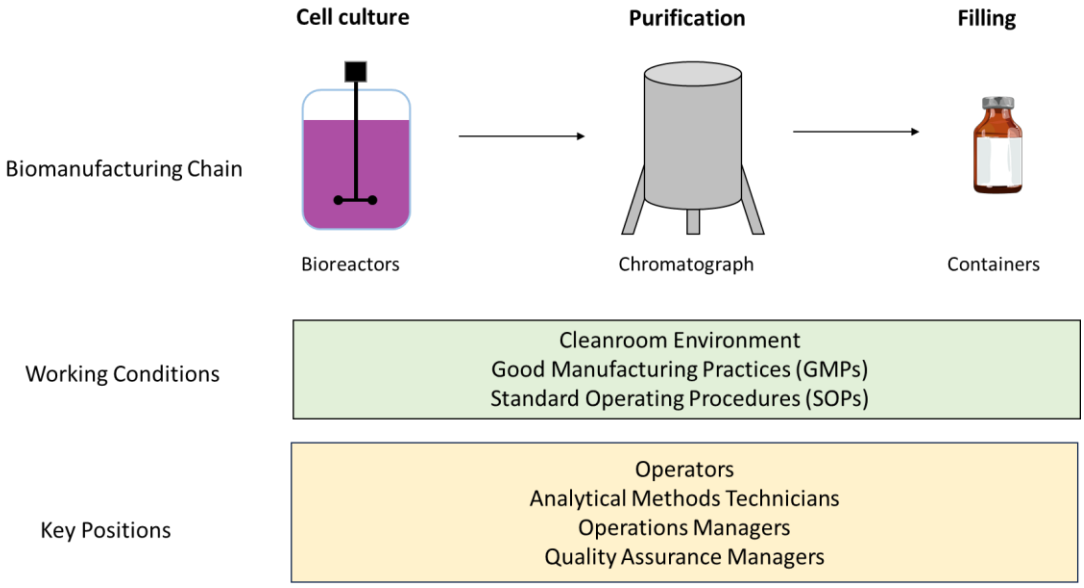

Figure 2: Simplified Representation of a Biomanufacturing Process Highlighting Regulatory Requirements for the Work Environment and Key Positions.

Each stage of the process requires operators, sample analysis by analytical methods technicians, one or more operations managers, and review by quality assurance managers. It is worth noting that regulatory requirements become more stringent as we move towards filling.

2.4. Cellular and gene therapies

Cell therapies are medical treatments in which living cells are transferred to the treated patient [8]. Gene therapies are treatments in which genes are transferred into a patient's cells for therapeutic purposes[9].

The production of these new therapies will put additional pressure on the biomanufacturing industry, as they draw on the same skills and are subject to the same regulatory requirements as traditional biomanufacturing (those shown in Figure 2).

The Alliance for Regenerative Medicine has issued a report[10] on the US workforce. It is estimated that the industry will need 32,000 people by 2025. In Canada, OmniaBio[11] is a fine example of the industry's growth. The company plans to hire over a hundred operators in the coming months. In Québec, LOEX[12] is a recognized center for tissue engineering, and C3i[13] biomanufactures clinical devices.

2.5. The importance of training in biomanufacturing

Operator training is more critical in biomanufacturing than in many other industries. The reasons for this stricter regulation are:

- The safety of the patients treated. Biotherapeutics (bio-manufactured) are often administered intravenously. These products must be sterile. The regulatory system is designed to minimize these risks.
- The possibility of being in default vis-à-vis the regulatory authorities if staff are not trained in all the tasks required to comply with procedures and GMPs.
- The risks of batch loss due to human error, which can result in major financial losses.

The time and effort invested in training the employees who operate, monitor and manage the processes is therefore more costly and consequential than in other industries. Only the aerospace industry has similar regulations and training requirements.

The skills required to perform operator tasks are generally protocol-based, and limited to a small number of steps in the overall process. Short, modular training courses are often effective in ensuring that each task is properly mastered.

There is a high turnover of technical operators. Industry veterans put forward a series of arguments to explain this phenomenon:

- The work is often organized in shifts.
- The work is demanding, and all the operators' tasks are reviewed. Errors can have far-reaching consequences, involving the entire team.
- The work is physical, often involving extensive standing, and dressing and undressing require balance.

2.6. Training programs in Québec

The analysis covers cégep training (DEC and AEC programs), university programs (undergraduate and graduate), as well as programs offered by private institutes and non-profit organizations (NPOs) specialized in biomanufacturing training. A mapping of training programs (in French) was created. The results of the analyses are presented in Section 4 (Results and analysis).

3. Methodology used

3.1. Analysis of biomanufacturing job descriptions posted in Québec and elsewhere in North America

The majority of job postings used are in Québec (see Schedule 3). A few positions come from Moderna's U.S. sites, given that production in Québec will not begin until 2024-2025, and that job descriptions for other vaccine production centers require the same skills.

3.2. Analysis of statistical data and other studies to identify trends in educational programs leading to jobs in biomanufacturing

The data comes from reports or from the official statistics database on Québec.

3.3. Tables comparing job descriptions and skills taught in relevant training courses

The tables below show the level of correspondence between each of the skills acquired in the various training courses and the job requirements of the different organizations involved in biomanufacturing.

There are three possible degrees of matching:

- XX represents a high level of proficiency in the listed skill;
- X represents partial proficiency in the listed skill;
- An empty box means that the skill is not part of the training program.

3.4. Meetings with program leaders

Relevant training courses offered by cégeps and universities were catalogued and analyzed.

The skills listed in the evaluation grids were validated by industry experts. The evaluation grids were presented to program managers to validate which of the skills requested by industry are covered by the courses for which they are responsible.

4. Results and Analysis

4.1. Analysis of College Programs - DEC and AEC

In 2021, 173,111 students were enrolled in colleges (all programs, all colleges) in the fall semester, and an increase of approximately 22% in the number of students is projected in the next 10 years. A nearly 6-fold increase in the number of international students attending colleges has been observed in the last 10 years [14]. In 2019-2020, 16,505 international students, just over 9% of the total, were enrolled in colleges.

The analysis includes only public network colleges since 90% of Quebec's college students attend

4.1.1. Analysis of Statistical Data

Over the ten years between 2011 and 2021, an increase in the level of educational attainment has been observed:

- +32% of the population holding a university degree
- +9,6% of the population holding a DEC (College Diploma)

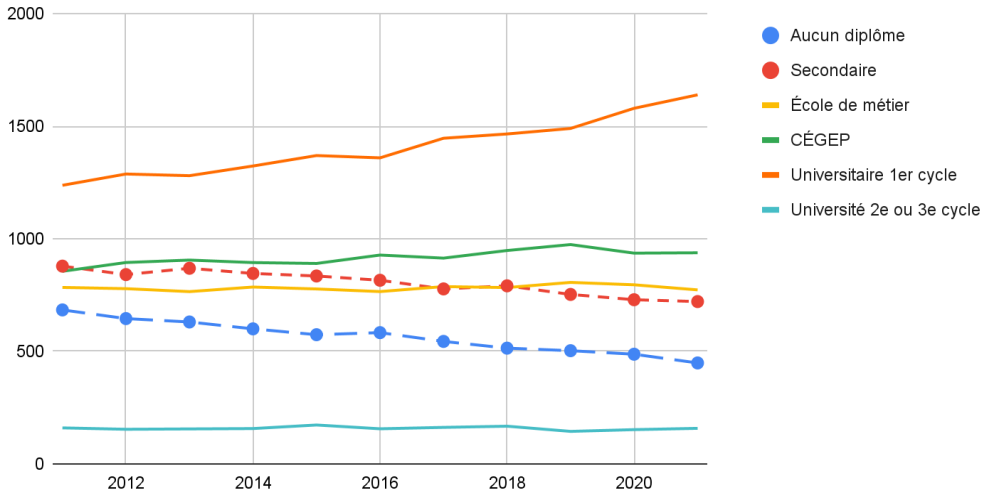

Figure 3 : Distribution of the population according to the level of educational attainment over the 10 years between 2011 and 2021 (in thousands of people)

So, in general, the level of formal education of the population is increasing.

The following are graphical representations of the annual number of enrollments and graduates in the three analyzed DEC programs. The data is from MES and was provided by the federation of colleges. As shown in the graphs below, over the same period as the previous analysis on the level of education in Quebec (between 2011 and 2021), there is no increase in DEC programs leading to careers in biomanufacturing.

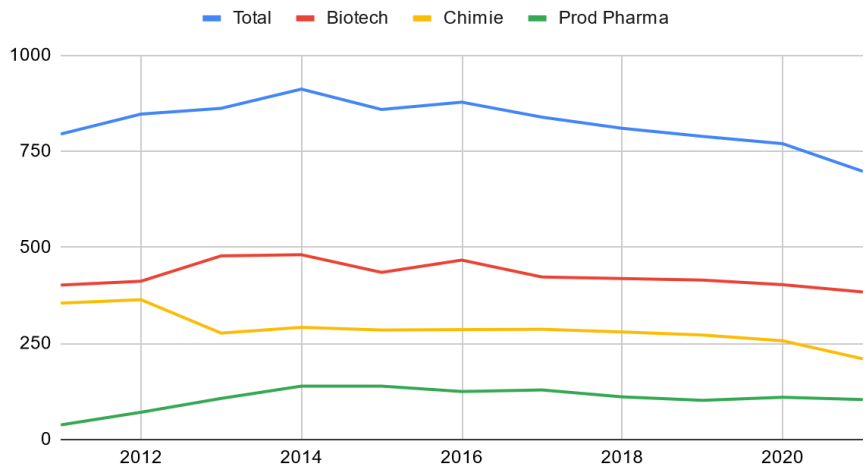

Figure 4 : Number of enrollments and graduates per year in Quebec for the DEC in Laboratory Techniques, with profiles in Analytical Chemistry and Biotechnology for the 10-year period between 2011 and 2021.

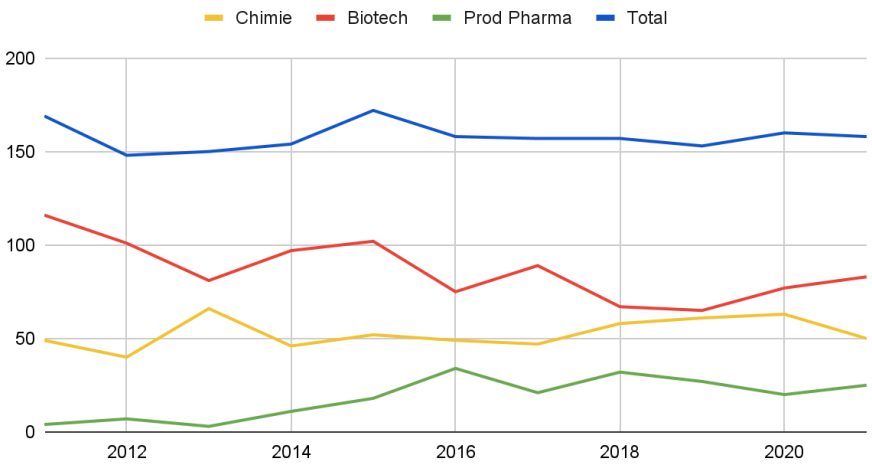

Figure 5 : Number of enrollments and graduates per year in Quebec for the DEC in Pharmaceutical Production Technologies for the 10-year period between 2011 and 2021.

In 2021, there were 83 graduates in Laboratory Techniques, Biotechnology, 50 graduates in the Analytical Chemistry, and 25 graduates in Pharmaceutical Production Technologies, totaling 158 graduates in Quebec across all three programs. For both programs, approximately 50% of the graduates continue

their studies at the university.

The number of graduates per cohort varies significantly from one college to another. Here are some examples:

- Biotechnology in 2022
    - Ahuntsic: 25
    - Outaouais: 4
    - Shawinigan: 2
    - Sherbrooke: 13 (in 2021)
- Analytical Chemistry
    - Lévis: 10 to 15 per year
    - Dawson: 9 (in 2022)

These data raise two issues:

- Underutilization of training resources in certain colleges: The Cégep de l'Outaouais typically has around ten graduates.
- The social impact of such a small number of graduates in certain cohorts: Collaboration, team learning, and group spirit become challenging to maintain if the group is too small.

For Laboratory Techniques programs (Biotechnology and Analytical Chemistry profiles combined), the graduation rate is approximately 25% in 3 years and 40% after 5 years (information provided by the Federation of Colleges).

There is a high dropout rate in the first year, with about 60% re-enrollment in the 3rd session (at the beginning of the second year).

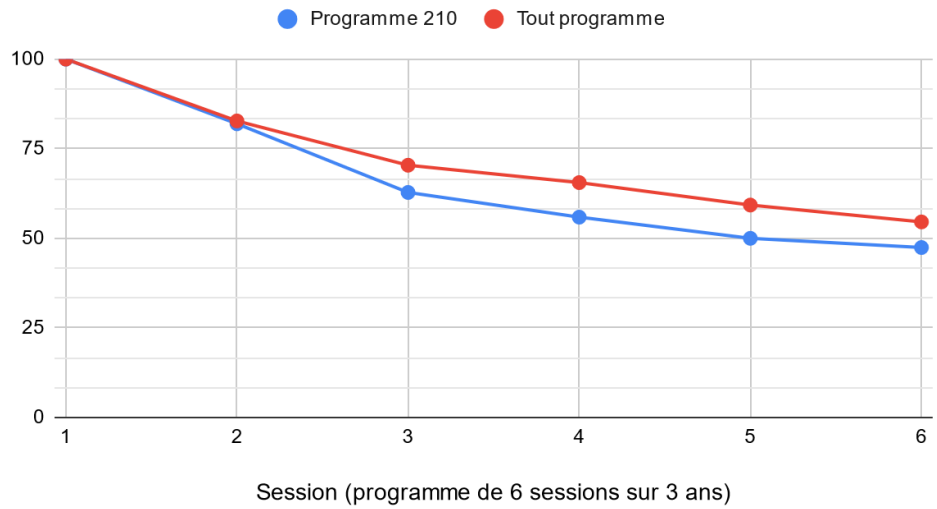

Figure 6 : Percentage of continuous re-enrollment on average from 2012 to 2021.

4.1.2. DEC Programs

DECs are primarily attended by students from secondary school, with a growing number of international students. Two DEC programs provide skills in biomanufacturing:

- The Pharmaceutical Production Techniques program (235.C0)
    - This program is offered by two colleges in the west of Montreal, Cégep Gérald Godin and John Abbott College.
- The Laboratory Techniques program, particularly in the Biotechnology (210.AA) and Analytical Chemistry (210.AB) profiles.
    - Skills are consistent across all colleges, but there are regional differences in terms of certain equipment and training emphases, depending on the needs of various regional employers. Each variation (210.AA and 210.AB) is offered in 6 colleges in Quebec. The Biotechnology profile covers a larger portion of the skills sought in biomanufacturing, as students engage in microbiology and cell culture. In addition to practical techniques learned in these

courses, basic aseptic concepts and techniques are conveyed, including how to work under a laminar flow hood.

4.1.2.1. Analysis of the Alignment of DEC Programs with Skills Sought in the Industry

These tables have been validated by industry experts and were discussed with training coordinators in the colleges.

OPERATORS	Biotechnology 210.AA	Analytical Chemistry 210.AB	Pharmaceutical Production Techniques 235.C0
Calculations for the preparation of solutions involve various mathematical operations such as proportional reasoning (règle de trois in French), conversions.	XX	XX	XX
Preparing Buffers	XX	XX	XX
Ability to follow SOPs (Standard Operating Procedures) and good documentation practices	X	X	XX
Ability to work in an aseptic manner	X	X	XX
Software (Word, Excel) and data entry	XX	XX	XX
General knowledge of GMP			XX
Link between one's work and other manufacturing stages	X	X	XX

ANALYTICAL METHODS TECHNICIANS	Biotechnology 210.AA	Analytical Chemistry 210.AB	Pharmaceutical Production Techniques 235.C0
Calculations for the preparation of solutions involve various mathematical operations such as proportional reasoning (règle de trois in French), conversions.	XX	XX	XX
Preparing Buffers	XX	XX	XX
Ability to operate analytical methods (HPLC, ELISA, A280, etc.)	XX	XX	X
Software (Word, Excel) and data entry	XX	XX	XX
Follow SOP	X	X	XX

OPERATIONS MANAGERS	Biotechnology 210.AA	Analytical Chemistry 210.AB	Pharmaceutical Production Techniques 235.C0
Good knowledge and experience with GMP			XX
Batch Release			X
Review of SOPs			X
Review of CAPA			X

The DEC 235.C0 aligns well with the needs of the biomanufacturing industry. This program is specifically designed to train future technologists in the pharmaceutical and biopharmaceutical sectors. Half of the students entering the

industry quickly find placements, typically in traditional pharmaceutical companies.

The DEC 210.AA is tailored to train laboratory technicians for the entire life sciences industry. Among the half of the graduates entering the industry, many will secure employment in contract research organizations (details on this industry branch: link).

4.1.3. AEC Programs

AECs (Attestation of College Studies) are attended by adults, often from immigrant backgrounds. Two colleges offer AECs relevant to the industry: Ahuntsic and Gérald Godin. An AEC in biomanufacturing is under development at John Abbott College.

Ahuntsic College offers an AEC in Biotechnology - ECA.0J:

- Duration of 12 months (1185 hours), in the evening (from 4 pm to 11 pm).
- Typically, there are 5 to 10 graduates per year.

Gérald Godin College offers four AECs relevant to the industry:

- Pharmaceutical and Biotechnological Quality Assurance - EJN.1C
  - Distance learning
  - Duration of 15 months - 1350 hours, Monday to Friday from 3 pm to 10 pm
  - There were 102 enrollments and 52 graduates in 2022.

- Pharmaceutical Production Enhancement - EJN.0W
  - Partially offered through distance learning
  - Duration of 12 months - 600 hours, two evenings per week from 6 pm to 10 pm, and several Saturdays.

- Biopharmaceutical Processes - EJN.1R
    - Duration of 9 months - 900 hours, full-time, regular hours.

- Supervision Enhancement in Pharmaceutical and Bioprocess - EJN.1Q
    - Duration of 600 hours
    - Two evenings per week and Saturdays
    - This program is new as of 2023 and was developed in partnership with Pharmabio Développement.

4.2. Analysis of Training Programs Offered by Universities

4.2.1. Analysis of Statistical Data

In 2019-20, 80% of university students in Quebec were residents of Quebec, 16%, or 48,406 students, came from international origins. International students increased from 9% to 16% of the total over the 10 years between 2009-10 and 2019-20. Four percent (4%) of students were Canadians from outside Quebec.

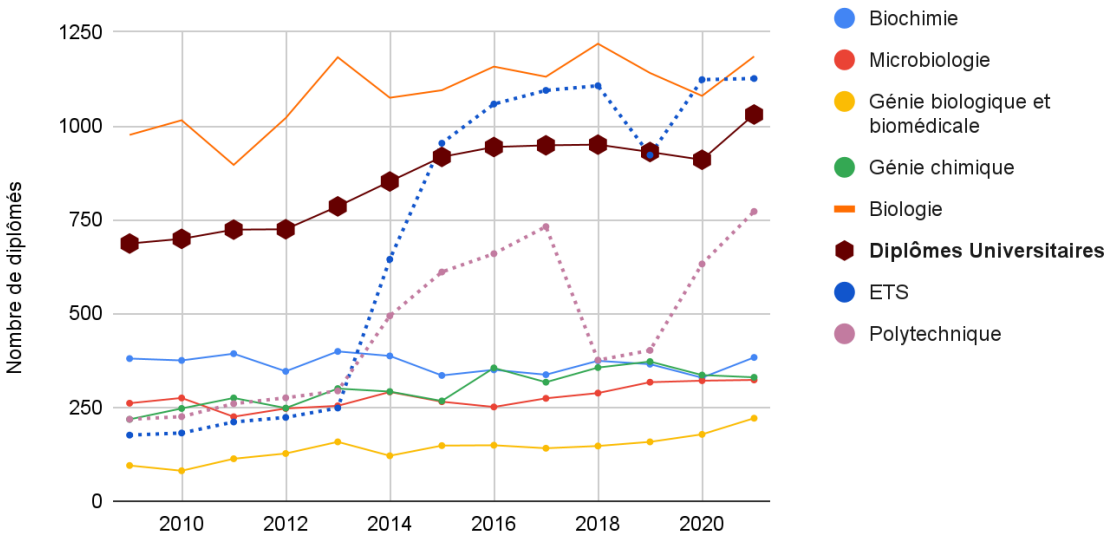

Figure 7 : Evolution of university graduation in Quebec between 2009 and 2021[15].

Note: Total university graduation has been divided by 100 to highlight the trend in scientific programs of interest to biomanufacturing.

As explained earlier, a significant increase in the level of university graduation has been observed in recent years. The addition of ETS and École Polytechnique (absolute figures divided by 5 to show trends on the same graph) demonstrates that, overall, the number of students enrolled in science and engineering programs is increasing.

The large number of graduates in biology is indicative of what is known as the STEM paradox (STEM being an acronym for science, technology, engineering, and mathematics). This means a high number of graduates but a shortage of specialized workforce. The majority of bachelor's degree programs do not provide directly applicable skills in the job market.

Programs	2018	2019	2020	2021
Biochemistry	275	264	265	281
Microbiology	194	223	223	227
Biological Sciences	696	652	625	715
Biological and Biomedical Engineering	56	59	73	94
Chemistry	215	221	195	181
Chemical Engineering	196	214	214	194

Table 1 : Total number of annual graduates from various programs that most commonly form part of the career paths in the biomanufacturing industry (source: Official Quebec Statistics Database [15]).

Note to the reader: The term "bioengineering" is widely used in the descriptions of university-level courses and programs. Bioengineering is a broad field that encompasses the development of medical devices, biomaterials, optimization of agri-food (genetically modified organisms optimized for yield or pesticide resistance), etc. Biofabrication is one aspect of programs in bioengineering.

The programs selected in this study provide skills directly applicable to the biomanufacturing industry. There are skills and courses related to biofabrication in other institutions, as well as stimulating educational approaches (e.g., problem-based learning in biology at UQAM). We have focused here on programs and courses directly related to biofabrication (production of biopharmaceutical drugs).

4.2.2. Université de Montréal, Faculty of Pharmacy

4.2.2.1. Baccalauréat en sciences biopharmaceutiques (BSBP)

This bachelor's degree is based on the drug development process (link). Unlike the vast majority of undergraduate programs in biological sciences, this program provides skills that are immediately applicable in the job market.

The program prepares students to work in clinical study management and product development but does not cover biomanufacturing. SBP2060 is the only course that teaches biomanufacturing concepts (link).

4.2.2.2. Drug Development Programs (DESS)

Several courses directly correspond to the needs of the biofabrication industry:

- PHM 6084 Good Manufacturing Practices (2 credits)
- SBP 6116 Electronic Submissions and Regulation (1 credit)
- SBP 6109 Good Laboratory Practices and Good Clinical Practices (1 credit)

Some courses address important related skills for the manufacturing of products in development (in clinical studies):

- PHM 6010 Drug Development
- SBP 6105 Project Management in Drug Development

4.2.2.3. Master in Pharmaceutical Sciences

Course-based Master's (not based on a research project).

Note: An 8-month internship can be added to the DESS program to turn it into a Master's (the Master's has not been added to the evaluation grid).

4.2.2.4. Analysis of the Correspondence of Programs with Skills Sought in Industry

PROCESS DEVELOPMENT	BSBP	DESS
Technical know-how (bioreactor, chromatography, TFF)		
Understanding the regulatory context		XX
Understanding of GMP		XX
Ability to write and follow SOPs		X
Knowledge of QMS		

ANALYTICAL, DEV + MANAGEMENT	BSBP	DESS
Understanding of GMP		XX
Ability to write and follow SOPs		X
Understanding method development and validation		
Management of Certificates of Analysis		

OPERATIONS MANAGERS	BSBP	DESS
Good knowledge and experience with GMP		XX

Batch Release		X
Review of SOPs, CAPA		X
Project Management and Supply Chain		XX

QUALITY ASSURANCE	BSBP	DESS
Application of the Quality System		X
Conducting Investigations/CAPA		X
Understanding Regulatory Requirements and GMP		XX

4.2.3. École Polytechnique, Département de génie chimique

4.2.3.1. Maîtrise professionnelle ou DESS en génie chimique - axe Bioprocédés pharmaceutiques et agroalimentaires

The program comprises 45 credits, including 15 credits for internships or projects (the DESS consists of only 30 credits of courses). Several courses provide a foundation or advanced training in bioengineering (link).

The program includes courses on bioprocesses that provide the fundamentals for working on the development or improvement of biofabrication processes. Courses that provide skills directly applicable to the biofabrication industry include:

- Clean Process Regulation (GCH8615)
- Biopharmaceutical Process Analysis (GCH8610)
- Biopharmaceutical Processes (GCH8640)

The course that provides the foundation for research and development (R&D) in the field is:

- Plasmon Resonance-Based Biosensors (GCH8405)

Note: l'École Polytechnique now offers a concentration in biomanufacturing for undergraduate students in chemical engineering (limited to 20 spots). The concentration (30 credits) begins in the second year of the bachelor's program. New specialized courses are under development.

4.2.3.2. Analysis of the Correspondence of Programs with Skills Sought in Industry

PROCESS DEVELOPMENT	Maîtrise ou DESS
Technical know-how (bioreactor, chromatography, TFF)	XX
Understanding the regulatory context	X
Understanding of GMP	XX
Ability to write and follow SOPs	X
Knowledge of QMS	

ANALYTICAL, DEV + MANAGEMENT	Maîtrise ou DESS
Understanding of GMP	XX
Ability to write and follow SOPs	X

Understanding method development and validation	XX
Management of Certificates of Analysis	

OPERATIONS MANAGERS	Maîtrise ou DESS
Good knowledge and experience with GMP	XX
Batch Release	
Review of SOPs, CAPA	X
Project Management and Supply Chain	

QUALITY ASSURANCE	Maîtrise ou DESS
Application of the Quality System	X
Conducting Investigations/CAPA	
Understanding Regulatory Requirements and GMP	X

4.2.4. McGill University, Faculty of Engineering

4.2.4.1. Bachelor's Program in Engineering with a Specialization in Bioengineering

The program combines engineering courses with courses in molecular and cellular biology, as well as general and organic chemistry (link). There are 45 credits dedicated to scientific concepts applicable to bioengineering. This includes

thermodynamics and transport systems in biological systems.

Courses directly related to biomanufacturing are:

- Tissue Engineering and Regenerative Medicine (link)
- Cell Culture Engineering (link)

4.2.4.2. Master's of Engineering (non-thesis) in BBME - biomanufacturing concentration

The program covers all aspects of manufacturing processes (link). The Master's program comprises 45 credits, with 27 dedicated to specialized courses. The remaining credits are allocated for internships in the biomanufacturing industry. The program spans four consecutive sessions, including two sessions of coursework and two sessions for an 8-month paid internship in the biomanufacturing industry.

The program includes the following courses (link): Synthetic Biology, Metabolic Engineering, Cell Culture Engineering, Purification Processes, Process and Analytical Technologies, Data Sciences, Vaccine Biofabrication, Cellular Therapies, Gene Therapies, Cell and Tissue Engineering, Formulation and Administration of Biotherapeutics, Bioprocessing for Stem Cells, Advanced Biochemical Engineering.

The enrollment target is 25 to 30 students for the 2023-24 cohort and 50 students per cohort in the future. The program focuses on the technical aspects of biomanufacturing.

Note 1: The 8-month internship involves variable knowledge depending on the placement.

Note 2: The program is not designed for operations management but rather to train technical experts in the development and operation of specific bioprocesses.

4.2.4.3. Analysis of the Correspondence of Programs with Skills Sought in Industry

PROCESS DEVELOPMENT	B Eng, Bioeng	MSc Bioeng
Technical know-how (bioreactor, chromatography, TFF)		XX
Understanding the regulatory context		
Understanding of GMP		
Ability to write and follow SOPs		X
Knowledge of QMS		

ANALYTICAL, DEV + MANAGEMENT	B Eng, Bioeng	MSc Bioeng
Understanding of GMP		
Ability to write and follow SOPs		X
Understanding method development and validation		X
Management of Certificates of Analysis		

OPERATIONS MANAGERS	B Eng, Bioeng	MSc Bioeng
Good knowledge and experience with GMP		
Batch Release		
Review of SOPs, CAPA		

Project Management and Supply Chain		

QUALITY ASSURANCE	B Eng, Bioeng	MSc Bioeng
Application of the Quality System		
Conducting Investigations/CAPA		
Understanding Regulatory Requirements and GMP		

4.2.5. Université de Sherbrooke, Département de génie chimique et de génie biotechnologique

4.2.5.1. Bachelor's in Biotechnological Engineering, Co-op Program

The program covers the foundations of engineering, cell biology (prokaryotes and eukaryotes), industrial culture (bioreactors, fermentation), and bioengineering operations units (link). The program includes 5 internships of 4 months each in the industry.

Courses directly related to biomanufacturing are:

- GBT110 - GMP-GLP Standards, Safety, and Biosafety (link)
- GBT322 - Reaction Systems and Bioreactors (link)
- GBT315 - Separation and Purification Operations (link)

4.2.5.2. Analysis of the Correspondence of Programs with Skills Sought in Industry

PROCESS DEVELOPMENT	B Ing
Technical know-how (bioreactor, chromatography, TFF)	X
Understanding the regulatory context	X
Understanding of GMP	XX
Ability to write and follow SOPs	X
Knowledge of QMS	X

ANALYTICAL, DEV + MANAGEMENT	B Ing
Understanding of GMP	XX
Ability to write and follow SOPs	X
Understanding method development and validation	
Management of Certificates of Analysis	

OPERATIONS MANAGERS	B Ing
Good knowledge and experience with GMP	XX

Batch Release	
Review of SOPs, CAPA	X
Project Management and Supply Chain	

QUALITY ASSURANCE	B Ing
Application of the Quality System	X
Conducting Investigations/CAPA	
Understanding Regulatory Requirements and GMP	XX

4.2.6. Université Laval, Département de génie chimique

4.2.6.1. Bachelor's in Chemical Engineering, Concentration in Biochemical and Biopharmaceutical Engineering

In this program, the course directly related to biomanufacturing is BCM-2101: Introduction to Quality Assurance (link). This course is available to students enrolled in biochemistry, microbiology, and biomedical sciences.

4.3. Analysis of Private Training Programs and Programs Offered by Non-Profit Organizations (NPOs)

4.3.1. Specialized Biomanufacturing Training in Canada

There are several training programs offered by various colleges to businesses (link), as well as numerous thematic courses. Here are the courses for the pharmaceutical and biopharmaceutical industries:

- Synor (link, St-Hyacinthe) offers knowledge maintenance in good manufacturing practices (link) and CAPA (link).
- Pharmabio Développement offers a course in GMP (link) and validation techniques (link).

Several organizations dedicated to biomanufacturing training have emerged in Europe and North America in recent years. In the context of the lack of manufacturing capacity in Canada, the Biomanufacturing strategy (link) was implemented. There are two main organizations offering specialized biomanufacturing training in Quebec and elsewhere in Canada, CASTL and CATTI. These two organizations have been involved with universities in biomedical research and infrastructure funding applications (link).

- CASTL (link), operations in Charlottetown and Montréal
  - Online training (link)
  - Biomanufacturing training (production of monoclonal antibodies and other biotherapeutics). Training centers in Charlottetown and Montreal. Average cost of about $1,000/day of training.
  - The training provided has been developed by NIBRT (link) in Ireland.
- CATTI (link), operations in Guelph, and Montréal
  - Training in cell and gene therapies, GMP, and quality systems. Online and in-person training.
  - Specialized courses on the handling of stem cells for human use.
  - Emphasis on qualifying operators for specific techniques (protocol execution, cell manipulation, pipetting, dressing, etc.).

These two organizations aim to impart the knowledge required for working in the biomanufacturing industry. The various courses offered align well with the different criteria presented in the evaluation frameworks in this study. Any initiative to integrate their curricula into existing academic programs would enhance the alignment of training with the needs of biomanufacturing.

4.3.2. Specialized Training in Skills Required in the Biopharmaceutical Industry in North America and Europe

The following is a non-exhaustive overview of organizations dedicated to training in Canada, the United States, and Europe. In general, several training centers have emerged in recent years or are in development to meet the workforce needs of the industry.

- Canada:
    - adMare (link), with locations in Montreal and Vancouver

Specialized programs for scientists with advanced degrees or for business managers. Small cohorts (a total of approximately 500 individuals trained since their establishment).

    - Toronto Institute of Pharmaceutical Technology (link)

Private college specializing in traditional pharmaceuticals.

- United States:
    - Jefferson Institute for Bioprocessing (link), Philadelphie, PA
    - Biomanufacturing Training and Education Center (link), North Carolina State University
    - National Center for Therapeutics Manufacturing (link), Texas

    - University Lab Partners (link), Californie
- Europe :
    - NIBRT (link), Irlande
    - Advanced Therapies Skills Training Network (link), United Kingdom
    - National Horizons Centre (link), Tesside University, United Kingdom (Investissement de £22,3M) - Liste de cours avec prix (link)
    - EASE, France (link) Partenaire du PRATIQc
    - EU Campus Biotech Gosselies (link)
    - Bio3 Institute (link)
    - IBioIC (link)
- International:
    - ISPE - International Society for Pharmaceutical Engineering (link).

Online courses and specialized in-person courses offered sporadically in various major urban centers.

- In development in the United States:
    - Life sciences workforce training center, Boston (link)
    - Worcester Polytechnic Institute Biomanufacturing Education & Training Center, région de Boston (link)
    - Programme court pour la formation d'adultes sans diplômes (link)
    - Biomanufacturing workforce training center (BWTC), Oklahoma City (link)
    - Georgia BioScience Training Center (link)

5. Findings

Generally speaking, academic training courses cover different aspects of drug development, but there is no program that combines the three essential points in the development of any drug:

- Manufacturing best practices (GMP, link)
- Quality management systems (link)
- Regulatory affairs (Health Canada link, general definition link)

GMPs require the manufacturing organization to maintain documentation demonstrating the training of all employees assigned to a manufacturing task. These documents are often requested during an audit by Health Canada.

In addition, it would be interesting to include courses on project management, inventory management and procurement, as well as providing a course on the overview of the production chain and the reality of the documentation to be kept.

5.1. Cégep programs

5.1.1. DEC programs

5.1.1.1. Matching programs to industry needs

The Pharmaceutical Production Technology (235.CO) program is designed for work in pharmaceutical or biopharmaceutical production. It is well suited to the needs of the biomanufacturing industry. The only important skill not taught is that of working in an aseptic environment.

The placement rate for graduates of this program is very high (95% at Cégep Gérald Godin and 100% for the latest cohort at John Abbott College). Industry demand thus exceeds supply from this program. As mentioned, there were 25

graduates in 2021 (total Cégep Gérald Godin and John Abbott College graduates).

The Laboratory Techniques, Biotechnology (210.AA) and Analytical Chemistry (210.AB) programs train future employees for all divisions of the LSHT industry. There is a very high placement rate for graduates, and cégeps are receiving requests from industry for more graduates.

In 2021, there were 83 graduates in the Biotechnology stream and 50 in the Analytical Chemistry stream. Each stream is taught in six different cégeps. This number of graduates is low given the current and future needs of the industry. It is even more so when one considers the resources required to maintain the programs in place at the various cégeps.

Dropout rates are high. In fact, for Laboratory Techniques programs (biotech and chemistry profiles together), the graduation rate is around 25% after three years and 40% after five years (information provided by the Fédération des cégeps).

Around 50% of graduates from the Biotechnology program (210.AA) go on to university. They feel that these skills will contribute to their academic success, and so these programs serve as extended pre-university programs. At Collège Ahuntsic, nearly fifteen DEC-BAC agreements have been entered into with universities (Sherbrooke, Laval, UQAM, UdeM, Trois-Rivières).

Students in both programs have been eligible for the Québec Perspective Scholarship since September 2022 ($1,500/successful session, total of $9,000 for 3 years). According to the faculty interviewed, the program does not seem to be well known among future students.

5.1.1.2. Update of the 210.AA program

Many cégep stakeholders are calling for the program to be modernized. For example, as detailed in interviews with teachers from the Ahuntsic and Outaouais cégeps, working with animals is demanding, costly and poses ethical problems for many students.

There are many requests from industry partners for greater ability to follow SOPs and work using good documentation practices. These skills overlap with the needs of the biomanufacturing industry, and the program needs to be modernized.

The Cégep de l'Outaouais has done an exemplary job of adapting the program to the needs of industry, while meeting the requirements demanded by the Ministère de l'Éducation Supérieure. An update of the Laboratory Techniques program is planned within the next 5 years. The work planned would benefit from local initiatives to adapt to the evolution of science and industry needs.

5.1.1.3. Graduate wages

Several speakers mentioned that average wages for entry-level positions repel potential students. The 2023-24 Cégep Gérald Godin booklet advertises an average starting wage of $19-21/hr (link). By way of comparison, other technical training programs in science and technology at Gérald Godin include:

- Computer Science Technology, $24/hr
- Nursing, $25/hr

The information page of Collège Ahuntsic leads to a job centre (link) and lists a wage of $18/hr throughout Québec.

In an economic context of labour shortages, it will be difficult to convince future students to enroll in technical programs that offer such uncompetitive entry-level wages. This phenomenon contributes to a shortage of skilled workers, with consequences for the industry as a whole, and therefore for our ability to produce the medicines we will need in the event of future shortages or pandemics.

5.1.2. AEC programs

The majority of students enrolled in the AEC in Biotechnology are adult immigrants with relevant but unrecognized foreign qualifications (pharmacists, physicians, etc.).

The AEC offered at Collège Ahuntsic is under-utilized. This is probably the result of a combination of four factors:

1) The labour shortage;
2) The 12-month period during which students must live off their savings;
3) The intensive nature of the training (7-hour evening courses);
4) Entry-level wages of about $20/hr.

The training is rigorous, and students develop extensive laboratory skills. Graduates are versatile, and can find jobs in the agri-food industry, the traditional pharmaceutical industry or environmental chemistry.

Enrolment has fallen in recent years. One solution to increase enrolment would be to subsidize people to take the training, as has been the case in the past and is often the case for AECs at Cégep Gérald Godin. The additional cost of $16,500 per person could be a good investment when you consider the impact of a generalized labour shortage in the sector. Another factor to consider would be streamlining the program to less than 12 months of training. Lighter versions,

presented in 3-month modules, might be better adapted to current labour market conditions and the target clientele.

It could be beneficial to transfer part of the theoretical portion of the training to asynchronous (pre-recorded courses viewed online followed by discussion periods during in-person classes), which would lighten the schedule, which is currently from 4pm to 11pm.

5.2. University programs

The majority of employees in the biomanufacturing industry develop their skills in their work environment, despite the fact that a significant proportion of the skills required are theoretical in nature and could be imparted in a traditional lecture course.

Many universities now offer courses directly applicable to the biomanufacturing industry. The philosophy of the Université de Montréal's Bachelor degree in biopharmaceutical sciences is a case in point. This is an undergraduate program that prepares graduates for the job market. The program focuses more on clinical development, but the approach can be replicated to impart the skills universally required to work in industries dealing with drug development (biomanufacturing, pharmaceuticals, vaccine development, cell therapy, etc.). Courses dealing with regulatory affairs and GMP principles can be delivered in a lecture-based format (with asynchronous components), thus not requiring significant resources or additional equipment and facilities.

6. Areas to think about

6.1. Internships in the current economic climate

As explained in the introduction, the operator's job is a demanding one, requiring meticulousness and precision. Everything has to be done by the book, and everything has to be well documented and reviewed.

The courses and laboratories of DEC programs are a very different environment from the regulated setting of biomanufacturing. Even when students are well trained, they often haven't had enough exposure to the real work environment to determine if it is really right for them. It is therefore possible to do well in the classroom without really being aware of the actual working environment.

It would be essential to have a greater number of industry internships to enable students to experience the real constraints of good manufacturing practices. In this respect, the approach taken by McGill's course-based master's program might be an example to follow. Framework agreements are established with various companies for paid internships.

Agreements of a similar nature could be negotiated between training establishments and companies involved in biomanufacturing. Experts predict that the current labour shortage will last for years to come (being the product of demographic trends). In this context, the employee’s value rises considerably, and a constant flow of new employees doing several internships with the same company pays competitive salaries.

This would help bridge the skills gap by eliminating the current problem of less attractive salaries for entry-level positions.

Exposure to the real working environment would thus better address the need to recruit and retain individuals with traits compatible with the demanding biomanufacturing work environment.

Companies that offer permanent positions to graduates who have completed several months of internship at their company will be able to offer much higher salaries, which will encourage more future students to enroll in the targeted training programs.

6.2. Industry-specific challenges

On the one hand, the risks of error and contamination make on-the-job training particularly complex in a biomanufacturing environment, a problem that is difficult to solve compared to other fields.

That said, the current job market context means that a more certain flow of new employees could be sufficiently attractive to enable companies to set up agreements of this nature.

Implementing such a program would require government support, although in the long term it should be self-sustaining.

This model could be applied to all sectors of economic and strategic importance, and could be synergistic with the Perspective Scholarships.

6.3. Synergies between pharmaceutical manufacturing and biomanufacturing

The skills of biomanufacturing operators are also required in the manufacture of traditional medicines.

Employers will often prefer to hire staff with sterile pharmaceutical manufacturing experience, rather than cell culture experts to carry out technical

work. Work experience testifies to the individual's ease in a GMP environment, often prioritizing technical knowledge such as cell culture. An employee's compatibility with the demanding constraints of biomanufacturing work can thus be seen as a form of insurance for the employer in question.

There is therefore a common pool of talent for operator positions in the pharmaceutical and biopharmaceutical sectors. This similarity is reflected throughout the traditional pharmaceutical manufacturing industry in Québec, and by the training and hiring policies in biomanufacturing, whose impact benefits pharmaceutical manufacturing and vice versa.

7. Références

[1]https://pharmabio.qc.ca/veille-sectorielle/portrait-de-lindustrie/

[2]https://static1.squarespace.com/static/57c496ac6b8f5bb965c464d3/t/645a80169d5ed86268c9f133/1683652632524/2023_02_23_BQ-Rapport+ORC+2022_FR.pdf

[3]https://www.oecd.org/publications/the-post-covid-19-rise-in-labour-shortages-e60c2d1c-en.htm

[4]https://www.ledevoir.com/interactif/2022-08-23/penurie-maindoeuvre/index.html

[5]https://www.statcan.gc.ca/fr/sujets-debut/travail_/tendances-penurie-main-oeuvre-canada

[6]https://pharmabio.qc.ca/wp-content/uploads/2020/08/diagnostic-dadequation-en-svts-2019-etude-complete-compressed-1pdfio.pdf

[7]https://statistique.quebec.ca/vitrine/egalite/dimensions-egalite/revenu/revenu-moyen

[8] https://fr.wikipedia.org/wiki/Th%C3%A9rapie_cellulaire

[9] https://fr.wikipedia.org/wiki/Th%C3%A9rapie_g%C3%A9nique

[10]https://alliancerm.org/wp-content/uploads/2023/03/ARM-Workforce-Gap-Analysis.pdf

[11]https://omniabio.com/

[12]http://www.loex.qc.ca/

[13] https://centrec3i.com/

[14]https://www.education.gouv.qc.ca/fileadmin/administration/librairies/documents/Ministere/acces_info/Statistiques/Statistiques_ES/Portrait-stat-etudiants-internationaux.pdf

[15]https://bdso.gouv.qc.ca/pls/ken/ken213_afich_tabl.page_tabl?p_iden_tran=REPERYN8YT938-41984525714~Q8Y5&p_lang=1&p_m_o=MES&p_id_ss_domn=1098&p_id_rapport=3420#tri_cycle=1&tri_typ_diplm=1&tri_sexe=1&tri_lang=1&tri_domn_etud=1&tri_discp=0