



MALATEST



Future Skills Centre

Evaluation of BioTalent Canada's
Practical Assessment for Certification
in a Biomanufacturing Cleanroom with
Asset Map Project

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FSC is a forward-thinking centre for research and collaboration dedicated to preparing Canadians for employment success. We believe Canadians should feel confident about the skills they have to succeed in a changing workforce. As a pan-Canadian community, we are collaborating to rigorously identify, test, measure, and share innovative approaches to assessing and developing the skills Canadians need to thrive in the days and years ahead. The Future Skills Centre was founded by a consortium whose members are Toronto Metropolitan University, Blueprint ADE, and Signal49 Research.

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Executive Summary

The Future Skills Centre (FSC) provided funding to BioTalent Canada's *Practical Assessment for Certification in a Biomanufacturing Cleanroom with Asset Map* under the Pathways to Jobs and SME Adaptability thematic priorities. Through their project activities, BioTalent Canada aimed to gather foundational information that will help to build a pipeline of talent capable of working in biomanufacturing cleanrooms.

R. A. Malatest & Associates conducted an independent rapid evaluation of the project to assess the extent to which project objectives were met and, where possible, to assess the impact of project activities on the short-term outcomes associated with the project. This evaluation collected data through a survey of employers and subject matter experts engaged in the project, and semi-structured interviews of staff, project partners, employers, and industry associations. This document summarizes the evaluation's design, methods, results and implications.

Key Findings

Results from the evaluation demonstrate that BioTalent Canada is developing the tools and programs that will help to meet industry demand for qualified talent in biomanufacturing roles. FSC's support enabled BioTalent Canada to work with industry experts and biomanufacturers to develop a framework for the practical assessment for certification in a biomanufacturing cleanrooms. Stakeholders agreed that when implemented, the framework will reduce bias in biomanufacturing skills testing by providing a standard through which proficiency in biomanufacturing cleanroom skills could be assessed.

The project also led to the development of an asset map or inventory of the tools needed to complete the practical assessment in a physical lab. Using this inventory BioTalent Canada has begun to explore the extent these tools can be replicated in a digital space. Stakeholders agreed that a virtual reality (VR) digital cleanroom will enhance access to training for those looking to acquire cleanroom skills and could be a viable alternative for employers willing to invest in training.

BioTalent Canada has continued to raise industry awareness and support for this work through their marketing campaign and publishing of their National Skills Standard for Cleanroom Readiness. Participating biomanufacturing companies have indicated a willingness to continue working with BioTalent Canada to help develop a pipeline of qualified talent that meets the labour demands of the biomanufacturing industry.

Recommendations

- Conduct a series of pilot tests to determine how well the framework assesses cleanroom skills and competencies in practice under different scenarios, demonstrates reduced bias, and underscores the benefits of the assessment. Results from the pilots can be used to make adjustments to the framework. The updated framework can be shared with employers and

industry experts to solicit another round of feedback to ensure that the pilot refinements are in line with industry needs.

- Explore the development of a VR digital cleanroom for training basic cleanroom skills and behaviour. The development of an asset map to identify the equipment and materials needed to assess cleanroom skills forms the inventory from which a VR digital cleanroom can be developed. A consultation process similar to that used to develop the practical assessment framework could be implemented to help further the development of a VR digital cleanroom for training cleanroom workers. This would also have the benefit of developing industry trust and support for a VR digital cleanroom.
- Continue the marketing campaign and knowledge mobilization events to help increase support and awareness of the practical assessment framework and the National Skills Standard for Cleanroom Readiness. Creating awareness of the practical assessment framework and National Skills Standards for Cleanroom Readiness will help build industry support and acceptance. Results from the aforementioned pilots could also be shared with employers and industry experts to build industry confidence in the framework as a reliable assessment instrument.

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1. Project Objectives, Activities and Anticipated Outcomes

BioTalent Canada's project, *Practical Assessment for Certification in a Biomanufacturing Cleanroom with Asset Map*, aimed to gather foundational information that will help to build a pipeline of talent capable of working in biomanufacturing cleanrooms. Specifically, the project looked to:

- Build a practical assessment framework that addresses the main cleanroom behaviours needed to show proficiency in a cleanroom environment and validate it by collecting feedback from industry employers, experts and conduct a pilot with the framework if time permits,
- Develop an asset map that includes a detailed assessment of equipment and materials required for cleanroom training and identify which can be replicated in a digital cleanroom,
- Generate support for building a virtual reality (VR) digital cleanroom, and
- Develop a marketing campaign to promote:
 - The development of a practical assessment for certification in a biomanufacturing cleanroom, and
 - BioTalent Canada's National Skills Standard for Cleanroom Readiness.

This report summarizes Malatest's evaluation of and learnings from BioTalent Canada's project activities from June through November of 2024.

1.1 Rationale

BioTalent Canada's 2021 Labour Market Intelligence forecasts that 65,000 more workers are needed in the bioeconomy by 2029.¹ Through previous engagement with biomanufacturers and industry experts, BioTalent Canada found that one of the largest gaps in terms of skilled talent is working in a sterile cleanroom, a critical component of any biomanufacturing facility. With the increased investments driving biomanufacturing after the pandemic,² a lack of qualified cleanroom workers with the required specialized skills and consistent work standards will continue be a challenge in the future.

Few high school, college or university bioscience programs offer students hands on exposure to or training in a cleanroom. While graduates of these programs may have the theoretical knowledge for working in a cleanroom, many do not have the practical experience. In addition, certification demonstrating the ability to work in a cleanroom does not exist. As such, employers have no way to assess whether jobseekers have the necessary cleanroom skills prior to hiring them.³

¹ (BioTalent Canada, 2021).

² The Government of Canada has made investments of more than \$2.2B in 40 projects in the biomanufacturing, vaccine and therapeutics ecosystem. (Government of Canada, 2024).

³ While employers will often train new hires to work in their cleanroom, they are unlikely to test a candidate's skills in a cleanroom as their cleanroom are often in production and rarely idle.

Canada's Biomanufacturing and Life Sciences Strategy recognizes the need to build domestic capabilities in biomanufacturing, including talent capable of working in cleanrooms.⁴ Recent reports note that hands on training is essential to developing a qualified biomanufacturing workforce.⁵ While a few Canadian training providers offer in-person biomanufacturing training, space is limited and their locations are not readily accessible across the country. Although virtual reality (VR) digital cleanrooms can address accessibility issues and the lack of training space available to teach this key skillset,⁶ no Canadian training programs currently offer VR digital cleanrooms as training tools.

1.2 Logic Model

BioTalent Canada engaged 30 biomanufacturing employers and subject matter experts to support the development of a practical assessment framework for cleanroom certification. Through this collaboration, the framework was validated by these industry experts. Together with the National Skills Standard for Cleanroom Readiness, the practical assessment framework, once implemented, will provide an industry recognized standard that can be administered consistently to reduce bias in biomanufacturing skills testing and help ensure workers have the skills to competently work in a cleanroom.

The project funding was also used to create a marketing campaign to promote the published National Skills Standard for Cleanroom Readiness, help biomanufacturing companies to understand the benefits of adopting a practical assessment framework for cleanroom certification, and garner support for the development of a VR digital cleanroom. As a step toward the creation of a VR digital cleanroom, the project worked to develop an asset map that included a detailed inventory of common cleanroom equipment and materials required for training and whether such assets could be duplicated in a virtual space.

A complete logic model, which describes the program's activities, outputs, and anticipated outcomes, can be found in Appendix B. Although the logic model specifies intended short-term, intermediate-term, and long-term outcomes, only short-term outcomes are evaluated in this report as intermediate and long-term outcomes will take more time to be realized. The anticipated short-term outcomes included:

- Reduced bias in biomanufacturing skills testing as a result of the practical assessment framework for cleanroom certification,
- Increased understanding of the benefits for biomanufacturing companies adopting a practical assessment framework for cleanroom certification,
- Increased biomanufacturer support for the development of a VR digital cleanroom, and
- Mapping of equipment and materials to support development of a VR digital cleanroom.

⁴ (Government of Canada, 2021).

⁵ (Fekete, 2023).

⁶ (Fekete, 2023; Government of Canada, 2021)

2. Evaluation Context and Background

The evaluation assessed the extent to which project objectives were met and short-term outcomes were achieved. This included assessing the effectiveness of the approaches used by BioTalent Canada (including industry engagement) to further develop the practical assessment framework for cleanroom certification, establish support for a VR digital cleanroom and encourage industry recognition and adoption of the National Skills Standard for Cleanroom Readiness. Data were collected between August and November 2024 and incorporated both qualitative and quantitative methods.

2.1 Key Evaluation Questions

Six key evaluation questions were developed in collaboration with BioTalent Canada. These questions formed the basis for survey and interview questions, as well as the results summarized in this report. The figure below shows the alignment of evaluation questions with the two focus areas. Please refer to Appendix C for the evaluation matrix.

Figure 2.1 Alignment of Evaluation Questions with FSC’s Thematic Priority Areas

Project Specific Evaluation Questions	Sub-questions
1. To what extent does a practical assessment framework for cleanroom certification help to build a pipeline of qualified talent for biomanufacturing?	<ul style="list-style-type: none"> • Is there a need for a certification assessment program to build a pipeline of qualified talent for biomanufacturing? • Do certification assessment programs for biomanufacturing cleanrooms already exist in the market? • How does a practical assessment framework help workers develop cleanroom skills • How does a practical assessment framework provide workers and jobseekers knowledge to better manage their careers? • How will the practical assessment framework improve SME adaptability? • How will the practical assessment framework reduce bias in skills testing? • How will the practical assessment framework improve SME ability to assess and recognize skills and reduce skills mismatches?
2. To what extent does the design of the assessment framework ensure EDI&R and accessibility is imbedded in the practical assessment and the associated tools to attract a diverse talent pool?	<ul style="list-style-type: none"> • How does embedding EDI&R and accessibility into the design of the assessment framework help attract diverse workers to the industry? • How does embedding EDI&R and accessibility into the design of the assessment framework provide workers and jobseekers knowledge to better manage their careers?

	<ul style="list-style-type: none"> • How does embedding EDI&R and accessibility into the design of the assessment framework help employers to invest in skills and HR development?
3. What is the level of stakeholder satisfaction with the development of a practical assessment framework for cleanroom certification including feedback from industry partners, employers, and trainers?	<ul style="list-style-type: none"> • Are biomanufacturing companies willing to work with BioTalent towards completing a certification program in sterile cleanroom environments? • Are biomanufacturing companies willing invest in a certification program in sterile cleanroom environments?
4. To what extent do biomanufacturing companies support the development of a physical and VR digital cleanroom?	<ul style="list-style-type: none"> • To what extent is there a need for a VR digital twin cleanroom? • Do VR digital twin cleanrooms already exist in the market? • How will a virtual cleanroom help workers develop cleanroom skills? • How will a virtual cleanroom provide workers and jobseekers knowledge to better manage their careers? • How will a virtual cleanroom improve SME ability to assess and recognize skills and reduce skills mismatches? • How will a virtual cleanroom increase employer investment in skills and HR development? • What is the impact of industry consultations on the scalability of VR digital twin cleanrooms? • What is the impact of industry consultations on the effectiveness of VR digital twin cleanrooms in biomanufacturing training?
5. To what extent did feedback from employers and subject matter experts lead to the development of an inventory of the digital assets required to design a VR digital cleanroom?	<ul style="list-style-type: none"> • Are the tools required to make assessments in a digital cleanroom the same as in a physical cleanroom? • What adjustments need to be made to ensure the certification can be done in both physical and virtual settings? • Will an inventory of digital cleanroom assets improve SME ability to assess and recognize skills and reduce skills mismatches?
6. To what extent did/does BioTalent Canada's marketing campaign help to increase awareness and support among the biomanufacturing industry for a practical assessment framework for cleanroom certification?	<ul style="list-style-type: none"> • How did/does BioTalent's marketing campaign help to increase support among the biomanufacturing industry for a physical and virtual digital cleanroom? • How does BioTalent's marketing campaign provide workers and jobseekers knowledge to better manage their careers? • How does BioTalent's marketing campaign increase employer investment in skills and HR development related to cleanroom skills?

The key evaluation questions were also aligned to questions developed by Future Skills Centre which focus on the thematic priority areas for Pathways To Jobs and SME Adaptability. The figure below shows the alignment of evaluation questions with the two focus areas.

Figure 1.2: FSC Thematic Questions and Alignment with Project Specific Evaluation Questions

FSC's Thematic Priority Questions: Pathway to Jobs	Alignment with Project Specific Evaluation Questions					
	Q1) Framework builds qualified talent	Q2) EDI&R embedded	Q3) Satisfaction with framework	Q4) Support for cleanrooms	Q5) Asset map	Q6) Marketing campaign
1. How can the delivery of engaging career guidance remote services be refined (e.g., new tech tools, ICT capacity training)?				X		
2. What interventions best help workers develop stronger labour market attachment (e.g., pre-employment, wrap-around supports)?	X	X	X	X		
3. What do workers and jobseekers need to know to better manage their careers into the 4th Industrial Revolution, the Green Economy, or other major transformation affecting employment in Canada?	X	X		X		X
FSC's Thematic Priority Questions: SME Adaptability	Q1) Framework builds qualified talent	Q2) EDI&R embedded	Q3) Satisfaction with framework	Q4) Support for cleanrooms	Q5) Asset map	Q6) Marketing campaign
1. How can approaches that effectively address SME barriers to investing in training and adopting better HR management practices be scaled up to become sustainable or self-sustaining?			X	X		
2. What approaches or tools are best at helping SME employers to assess and recognize skills in the labour market, and under what conditions can their use reduce or eliminate skills mismatches?	X		X	X	X	

3. How do Canadian SMEs make decisions regarding investing in skills and HR development, and what behaviours or systems are associated with high levels of SME investment in training, use of high-performance HR practices, etc.?	X	X	X	X	X	X
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2.2 Lines of Evidence

Data collection methods to answer the evaluation and learning questions for this project included a brief literature, data and document review, a survey of biomanufacturing employers and industry experts engaged in developing the practical assessment framework, follow up interviews with survey respondents, and a tracking of marketing and knowledge mobilization activities. Although the project developed a practical assessment framework to certify cleanroom skills, the framework has yet to be pilot tested or implemented. As such, there are no test results or other relevant data that can be used to develop a baseline for benchmarking. The figure below summarizes the data collected per line of evidence.

Figure 2.3: Data Collected per Line of Evidence

Evidence	Respondents	Information Collected	Sources or Sampling
Literature, data and document review	Not applicable	Malatest reviewed previous studies, evaluations and reports to find appropriate contextual information and data that could be used to provide comparative information to address the evaluation questions.	Information was sourced from documents and reports provided by BioTalent Canada and online search of related documentation from other jurisdictions conducted by Malatest.
Online survey of focus group participants (administered by Malatest)	n= 9	Survey questions examined perceptions of how a practical assessment framework for cleanroom certification and the development of a VR digital cleanroom could facilitate job pathways and enhance the adaptability of	Malatest provided a link to the online survey for BioTalent Canada to share with focus group participants. ⁷ 12 focus group participants were invited to complete the survey. Those who were

⁷ BioTalent Canada hosted an in-person focus group with employers and industry representatives on August 8, 2024 to vet the draft practical assessment framework.

		SMEs. (Questionnaire is available in Appendix D).	interested could click on the link to access the online questionnaire.
Interviews (administered by Malatest)	n= 10: 3 BioTalent Canada staff 2 project partners 3 employers 2 two industry associations	Questions examined perceptions of how a practical assessment framework for certification in a biomanufacturing cleanroom and the development of a VR digital cleanroom could facilitate job pathways and enhance the adaptability of SMEs (Questionnaire available in Appendix D).	Survey respondents were asked their willingness to participate in an interview; six survey respondents completed an interview. In addition, BioTalent Canada identified three staff and two key partners who were invited to participate in an interview. ⁸
Tracking analytics (BioTalent Canada)	Not applicable	BioTalent Canada tracked and shared the following data points for their marketing campaign with Malatest: <ul style="list-style-type: none"> ○ The number of visits to the project webpage, and ○ Distribution of the project announcement including press release, newsletter, e-blasts, and social media posts. 	

2.3 Evaluating Equity, Diversity, Inclusion and Reconciliation

Malatest evaluated the extent to which the project incorporated an equity, diversity, inclusion, reconciliation (EDI&R) and accessibility perspective through:

- Assessing the extent to which the project helps to lower barriers for underrepresented individuals looking to enter the biomanufacturing field.
- Assessing the extent to which embedding EDI&R principles in the design of the practical assessment framework supports individuals being assessed for certification.
- Employing a gender-based analysis plus lens to assess the extent to which a practical assessment framework and VR digital cleanroom can support individuals from visual minorities,

⁸ One key partner also participated in the survey follow-up interviews.

underrepresented and vulnerable populations to attain the desired skills to work in a biomanufacturing cleanroom.

- Asking participating employers and stakeholders to assess how effectively EDI&R and accessibility considerations have been incorporated into the development of the practical assessment framework.

2.4 Research Ethics

To ensure the study followed protocols and best practices on conducting ethical research including ethics reviews, the following elements were implemented:

- All data from the survey and interviews were aggregated and reported anonymously.
- To establish informed consent all evaluation participants were explained the following:
 - How their data would be collected and securely stored on our servers,
 - How their privacy would be protected according to applicable legislation, and
 - Participation was voluntary, and they could skip any questions they felt uncomfortable answering.

2.5 Limitations

A few limitations were experienced during this evaluation. Malatest took what actions were available to mitigate these limitations and remains confident in the strength of the evaluation. However, the following limitations should be considered when interpreting the findings.

- **Timelines.** The evaluation faced limitations due to time constraints. Data were collected through multiple lines of evidence (surveys, interviews, data tracking) to increase response rates and efficiencies where possible. Malatest designed brief data collection tools validated by BioTalent Canada to help reduce respondent burden. An incentive of a \$25 e-gift card was offered to encourage participation in the survey and follow up interviews.
- **Stakeholder engagement.** The study faced limitations with the level of stakeholder engagement due to the tight timelines. Although several reminders to complete the feedback survey were sent to the 30 focus group attendees, only nine responded. However, six of these respondents completed a follow up interview.
- **Selection bias.** Stakeholders that are already engaged and invested in BioTalent Canada's activities likely hold positive views about the National Skills Standard and level of engagement with subject matter experts and biomanufacturing companies to develop the practical assessment framework.

3. Findings around Implementation

Flexibility in BioTalent’s approach to project activities helped them avoid significant delays in the development of a practical assessment framework.

Interviews with BioTalent Canada staff considered the implementation of the project activities. Discussions with the BioTalent Canada team highlighted their flexibility to adapt to the changes in project implementation. The original plan was to hold a focus group with biomanufacturing companies to develop the assessment criteria based on the skills identified in the National Skills Standard for Cleanroom Readiness.⁹ Following this, a draft practical assessment framework¹⁰ would be developed by industry experts and vetted by biomanufacturing employers. However, a focus group could not be scheduled until early August, leaving a window of time for the development of a draft assessment framework. During this time, BioTalent Canada engaged a consultant and subject matter experts to build a draft framework which was then vetted by biomanufacturing employers and industry representative. Feedback was incorporated and interviews were conducted with additional employers to obtain their feedback on a revised draft framework. BioTalent Canada staff noted that their flexibility avoided significant delays and ensured that they could have a draft framework vetted by experts within project timelines. However, it was not feasible to conduct a pilot of the practical assessment framework during the tight timelines of this project.

“We were able to get into the details of what exactly needs to be assessed and what constitutes a pass or a failure of the assessment.” (BioTalent Canada staff member)

4. Findings around Relevance

The evaluation found that there is demand for a practical assessment framework to examine the extent to which an individual has the required competency to work in a cleanroom. While there are Canadian training providers offering cleanroom training,¹¹ currently, there is no such credential available in Canada.¹² The ability to assess skills against a recognized industry standard will build trust among employers that potential candidates have the cleanroom skills they demand and help to reduce or eliminate skills mismatches.

⁹ The skills identified in the National Skills Standard for Cleanroom Readiness focus on typical skills found in cleanrooms classified as ISO Classes 5-8/EU GMP Grades A-D. This Standard was developed through a previous project funded by the Future Skills Centre. (BioTalent Canada, 2024)

¹⁰ This would include a comprehensive set of questions, tasks, scenarios, and a scoring rubric would be developed to assess the acquisition of identified skills.

¹¹ For example The Canadian Alliance for Skills and Training in Life Sciences (CASTL) offers cleanroom training (<https://www.castlcanada.ca/en/>).

¹² A US institute offers the Biotechnician Assistant Credentialing Exam (BACE) that “assess core skills and knowledge sets defined by the bioscience industry” (<https://biotility.research.ufl.edu/bace/>).

Similarly, the evaluation also found that there is demand for the development of a VR digital cleanroom to train individuals, although wide-spread support for the use of such a cleanroom for assessing skills has yet to be established. Evaluation participants indicated that the development of a VR digital cleanroom has the potential to encourage increased employer investment in training.

5. Summary of Impacts and Outcomes

BioTalent Canada was successful in meeting most of its project’s short-term outcomes. The engagement of biomanufacturing companies and subject matter experts through an in-person focus group and interviews supported the development of a practical assessment framework for cleanroom certification. Employers agreed that having a practical assessment framework would reduce bias in biomanufacturing skills testing among other benefits such as increased SME adaptability, reduced skills mismatches and improved ability to assess workers skills. Participating biomanufacturing companies have indicated a willingness to continue working with BioTalent Canada to validate the practical assessment framework and support in principle, the development of a VR digital cleanroom including an inventory of cleanroom equipment and materials to be replicated in a digital space. Figure 5.1 provides a summary of the project’s achieved short-term outcomes.

5

Intended Outcomes	Actual Outcomes	Assessment
1. Reduced bias in biomanufacturing skills testing as a result of the practical assessment framework for cleanroom certification.	A total of 30 participating biomanufacturing companies of varying sizes agreed that the practical assessment framework will reduce bias in skills testing. However, a pilot of the practical assessment framework was not possible due to the condensed timelines for this project. Therefore, it is not possible to determine whether the practical assessment framework reduces bias in skills testing.	Not possible to assess
2. Biomanufacturing companies understand the benefits of adopting a practical assessment framework.	Participating biomanufacturing companies agreed that the use of a practical assessment framework for cleanroom environments will improve SME adaptability, reduce bias in biomanufacturing skills testing, reduce skills mismatches and improve their ability to assess workers’ skills.	Achieved
3. Biomanufacturing companies support the development of a VR digital cleanroom.	Participating biomanufacturing companies agreed that: <ul style="list-style-type: none"> a. A VR digital cleanroom could be an alternative to a physical cleanroom for training purposes. 	Achieved

	<p>b. They support in principle to work with BioTalent Canada to create a VR digital cleanroom.</p> <p>While the majority indicated that a VR digital cleanroom could also be used to assess cleanroom skills, 25% had reservations as to the accuracy of using the VR digital cleanroom to assess specific skills such as aseptic techniques.</p>	
4. Asset map of equipment and materials supports development of VR digital cleanroom.	Participating biomanufacturing companies identified the typical equipment and materials needed for a cleanroom. A software developer was engaged to discuss the inventory and the extent to which the physical tools could be created in a digital space.	Achieved

6. Findings by Project Specific Evaluation Question

6.1 Development of an Assessment Certification Framework

The evaluation found high levels of satisfaction with the development of a practical assessment framework among interested parties involved. BioTalent Canada staff noted that the practical assessment framework was designed with EDI&R and accessibility in mind will help reduce bias in skills testing and will help attract diverse workers to the industry. Employers and industry representatives agreed that the development of a practical assessment framework will help provide standardization and consistency for assessing proficiency in biomanufacturing cleanroom skills, ensuring that the sector’s workforce have the required skills for cleanroom environments.

To what extent does a practical assessment framework for cleanroom certification help to build a pipeline of qualified talent for biomanufacturing?

Stakeholders agreed that a practical assessment framework for cleanroom skills will help ensure that the sector’s workforce has the required skills for cleanroom environments.

Among the nine employers and industry representatives who responded to the survey, the majority agreed that a practical assessment framework will help to build a pipeline of qualified talent for biomanufacturing by:

- Reducing bias in skills testing (7 of 9 agreed/strongly agreed),
- Reducing skills mismatches (7 of 9 agreed/strongly agreed),

- Improving employers' ability to assess workers' skills (5 of 7 agreed/strongly agreed),¹³ and
- Ensuring the sector's workforce have the required skills to work in cleanroom environments (9 of 9 agreed/strongly agreed).

In addition, five out of seven employers indicated they were very likely or somewhat likely to invest in a practical assessment framework for certification in a biomanufacturing cleanroom.

Stakeholders expressed that a practical assessment framework will help provide standardization and consistency for assessing proficiency in biomanufacturing cleanroom skills.

BioTalent Canada staff indicated that biomanufacturers supported the development of a practical assessment framework noting that it would test individuals on an industry recognized standard. Interviewees were asked to expand on their reasons why an assessment program for certification in a biomanufacturing cleanroom will help to build a pipeline of qualified talent. Reasons included providing assurance that an individual has proficiency in the basic competencies and skills required for working in a cleanroom, having a standard that is recognized across the industry, and consistency in skills testing.

“Having a practical assessment framework would provide a level of assurance, consistency and a baseline of what cleanroom knowledge someone should possess. If they have the certificate when applying for jobs, then we would know that their level of proficiency has been tested.” (Biomanufacturing employer)

Participating employers, industry experts and BioTalent Canada staff all commented that one of the biggest challenges faced by employers is assessing whether a potential candidate is qualified to work in biomanufacturing cleanrooms. While some candidates may have knowledge of the required protocols and behaviours for working in a cleanroom, they may not have practical experience in a cleanroom. While most biomanufacturers provide training for their employees, interviewees noted that if an individual has been assessed for basic cleanroom skills, this helps employers determine what additional training is required for their new hires. Interviews also noted that the practical assessment framework will help to standardize cleanroom training and ensure that manufacturers, training providers and educational institutions are teaching individuals a standardized set of skills. This helps to develop qualified talent for biomanufacturing roles as trained individuals will have standardized skills to perform their duties.

“A benefit of having this model is the standardization; now that we have identified what skills are needed to support or perform well in a cleanroom, then it is easier for employers to identify what areas they can be focusing on to train people. Once you have this standard you have something that you can compare to.” (BioTalent Canada Staff member)

¹³ This question was only asked of employers.

To what extent does the design of the practical assessment framework ensure EDI&R and accessibility is imbedded in the practical assessment framework and the associated tools to attract a diverse talent pool?

The practical assessment framework was designed by champions of equity, diversity, inclusion and accessibility.

A pillar of BioTalent Canada’s values is embracing and fostering inclusion, diversity, equity and accessibility leadership (I.D.E.A.L) among employers and workers in the bioscience economy.¹⁴ Bioscience employers and organizations participating in the development of the practical assessment framework were identified as champions who promoted inclusion equity and diversity in their workplace, many of whom belonged to visible minority groups. In addition, the assessment framework will be reviewed by BioTalent Canada’s EDI Committee to ensure that the program aligns with EDI&R and accessibility principles.

A standardized assessment process designed with EDI&R and accessibility in mind will help reduce bias in skills testing and will help attract diverse workers to the industry.

BioTalent Canada staff noted that the practical assessment framework has been designed to measure the relevant competencies and behaviours required for working in a cleanroom. The standardization of the assessment helps ensure candidates are fairly tested on their skills and abilities, thus reducing bias. Survey respondents agreed that incorporating EDI&R and accessibility principles into the practical assessment framework will:

- Help attract diverse workers to the industry (8 of 9 agreed/strongly agreed),
- Help employers to invest in skills and workforce development (9 of 9 agreed/strongly agreed), and
- Provide workers and jobseekers knowledge to better manage their careers (8 of 9 agreed/strongly agreed).

What is the level of stakeholder satisfaction with the development of a practical assessment framework including feedback from industry partners, employers, and trainers?

All participating stakeholders expressed high levels of satisfaction with the development of a practical assessment framework.

¹⁴ BioTalent Canada has developed several programs and initiatives. The I.D.E.A.L Scholarship is awarded to students from equity-deserving groups who are enrolled in science, technology, engineering, and mathematics (STEM) programs at an accredited Canadian college, university or CEGEP. In its inaugural year (2024) \$10,000 scholarships were awarded to an Indigenous student and a student who identifies as a person with a disability. (BioTalent Canada, 2024) The I.D.E.A.L Bioscience Employer Recognition program to recognize bioscience employers and organizations that incorporate IDEA principles into their workplace or organization. (BioTalent Canada, 2023).

BioTalent Canada staff expressed satisfaction with the development process of the practical assessment framework. They noted that having the draft framework developed by subject matter experts prior to sharing with biomanufacturers enhanced the focus group session as participants provided more specific and detailed feedback on the material presented. Having a draft framework also allowed focus group participants to discuss different scenarios for how skills should be tested and further refine the assessment criteria.

Biomanufacturers interviewed also agreed that it was beneficial to work with a draft framework as it helped spur discussions. Interviewees also mentioned that involving a diverse group of industry representatives in the focus group added valuable perspectives and helped identify the different modalities of the practical assessment framework. As one interviewee explained, biomanufacturing involves different processes depending on the product being developed. Involving individuals with experience and expertise across these various processes helped ensure the assessment framework would be valuable to all biomanufacturers looking to assess the skills of potential candidates and identify gaps to address with additional training.

6.2 Establishing Support for a VR Digital Cleanroom

Most biomanufacturers interviewed were supportive of the development of both a physical and VR digital cleanroom for training purposes, however some questioned the ability of a virtual cleanroom to accurately test proficiency in all cleanroom skills. Despite these reservations about VR digital cleanrooms. Interviewees noted several benefits such as allowing greater access to cleanroom training without the need to travel, and reduced training costs for employers.

To what extent do biomanufacturing companies support the development of a physical and VR digital cleanroom?

Most biomanufacturing companies acknowledged that a physical and VR digital cleanroom will be beneficial for skills development in a cleanroom environment.

The majority of biomanufacturing companies interviewed were supportive of the development of both a physical and VR digital cleanroom for training purposes. Most survey respondents agreed that a VR digital cleanroom will:

- Build a pipeline of qualified talent for biomanufacturing (7 of 9 agreed/strongly agreed),
- Enhance access to training for employees and workers looking to acquire cleanroom skills (8 of 9 agreed/strongly agreed),
- Improve employers' ability to assess workers' skills (5 of 7 agreed/strongly agreed),¹⁵

¹⁵ This question was only asked of employers.

- Encourage employers to invest in cleanroom training (6 of 7 agreed/strongly agreed),¹⁶ and
- Ensure the sector's workforce have the required skills to work in cleanroom environments (9 of 9 agreed/strongly agreed).

Although biomanufacturers fully supported the development of a VR digital cleanroom for training purposes, some questioned its ability to accurately test proficiency in all cleanroom skills.

Follow up interviews with biomanufacturers revealed that although they were supportive of using VR digital cleanrooms for training, a few raised concerns about their use for assessing and ultimately certifying an individual's cleanroom skills. In particular, they were skeptical about how accurately a VR digital cleanroom could assess proficiency in testing for signs of contamination which are more easily assessed in physical testing. They suggested that a VR digital cleanroom be used for training and testing of some skills, with a final in-person assessment of skills that cannot be tested accurately through a VR digital cleanroom.

Benefits of physical and VR digital cleanroom training include reduced amount of in-house training, and more personnel time spent on production line.

Although interviewed biomanufacturers noted that they typically provide cleanroom training to their employees in-house due to lack of training providers and the need to train employees on their proprietary processes, they noted that having new hires trained on basic cleanroom skills will allow employers to reduce the number of in-house training hours provided. Fewer hours of training will also allow for more personnel time spent on the production line, as there will be reduced demand on existing employees to train new hires. While product-specific training will still be required, employers estimated that on average they could potentially shorten the time to fully train an employee by four to six months.

Cleanroom training provides an opportunity for potential workers to determine whether they are suited to such an environment.

According to interviewed employers, determining whether an individual can work in a cleanroom is beneficial to both potential candidates and employers. Cleanroom training provides an individual the opportunity to experience what it would be like to work in such an environment. Interviewees observed that many potential candidates have lab skills that are transferrable to a cleanroom, but without cleanroom experience, they may not be able to determine whether they are suited to work in a cleanroom environment. Some interviewees noted that cleanroom requirements are much stricter than lab requirements and some candidates may not be suited to such a workspace.

“What we observe from screening hundreds of candidates over the years and based on the feedback from those candidates and our staff, there is a gap in what it entails to work in a cleanroom. It is not like working in the traditional lab environment

¹⁶ This question was only asked of employers.

where you just wear lab coats, safety glasses and gloves. It is important that workers appreciate why we have all these stringent controls in place in order for someone to work in a cleanroom environment. Many new hires are surprised about the training that is needed to work in a cleanroom.” (Biomanufacturing employer)

Interviewed employers also believed that the ability to determine whether an individual is suited to work in a cleanroom also reduces the risk and expense for employers. All too often, employers will hire and train an individual only to have them leave because they do not feel suited to work in a cleanroom. With cleanroom training, those looking to work in biomanufacturing have more realistic expectations of their potential work environment and whether they are suited to this type of work.

“This [training] would reduce some of the risk in hiring an individual who, after training in a cleanroom, realizes that this is not the work they want to do, it's not what they imagined it would be.” (Biomanufacturing employer)

VR digital cleanroom training could be a viable alternative if it reduces financial and non-financial barriers for biomanufacturers.

Interviewed employers explained that as most biomanufacturers are small to medium sized companies, their decision to send employees for training or train them in-house is primarily dictated by costs. With relatively few biomanufacturing training facilities in Canada, employers may have to send employees across the country for training, incurring significant costs. The option to train employees in-house is no less costly, as cleanrooms are very expensive to build, and most employers cannot afford to have a cleanroom solely for training. Interviewees noted that they will sometimes use a cleanroom for training when it is not needed for production, but often they simulate a cleanroom in another part of their facility.

While interviewees acknowledged that a VR digital cleanroom could be a viable alternative, the costs for customized software and equipment could potentially be a deterrent for many biomanufacturers. One interviewee stated that the costs for VR digital cleanroom training would need to be proportional to the amount of in-person training it would replace; noting that some in-person training and testing would still be required. Another interviewee observed that equipment and cleanroom vendors do provide training (in-person and virtual) as part of the purchase; however, it is focused on how to use their specific equipment and is not necessarily suitable for general training.¹⁷

6.3 Asset Map of Equipment and Materials

To what extent did feedback from employers and subject matter experts lead to the development of an inventory of the digital assets required to design a VR digital cleanroom?

¹⁷ For example, Cytiva provides VR biomanufacturing training in Canada on how to use their equipment. Retrieved from: [VR equipment training from Cytiva | Cytiva](#).

An inventory of digital assets required to design a VR digital cleanroom was developed with input from employers and subject matter experts.

Discussion between BioTalent Canada staff and biomanufacturing employers led to identification of the cleanroom assets required for a VR digital cleanroom. BioTalent Canada also engaged in preliminary discussions with consultants and software designers to recreate the physical cleanroom tools in a digital space. Among the digital assets interviewees identified for a virtual cleanroom were considerations for gowning and sampling procedures, bringing materials into and out of cleanrooms, transferring materials from lower to higher grade cleanrooms, visualizing the airflow, differential pressure, and equipment such as a biosafety cabinet and incubator. Other considerations included data ownership, security credentials of those accessing the VR digital cleanroom, and equipment to access the virtual space including computers and HoloLens.¹⁸

6.4 Learnings from the Marketing Campaign

Although BioTalent Canada's marketing campaign increased awareness of the development of a practical assessment framework, continued work is needed to garner more support and build industry trust. Staff noted that there was strong support for the practical assessment framework and standardization of cleanroom skills among participating employers and industry experts, they needed to continue promotion to encourage industry adoption.

To what extent did/does BioTalent Canada's marketing campaign help to increase awareness and support among the biomanufacturing industry for a practical assessment framework for cleanroom certification?

BioTalent Canada's marketing campaign increased awareness of the framework; however, continued work is needed to garner more support and build industry trust.

BioTalent Canada staff noted that they had been actively promoting the development of the practical assessment framework to their network of approximately 15,000 people. However, staff noted the need to continue promotion to encourage industry adoption. While they have full support from all employers and industry experts that participated in the development of the practical assessment framework, staff acknowledged that more needs to be done to garner support for and build industry trust in the framework. A summary of data tracking for the project announcement is provided in the Figure below.

"Those who participated in the focus group and interviews understand how important it is, but the rest of industry does not know about what we are doing. So, the marketing people need to convince the target audience that they can trust the tool." (BioTalent Canada staff member)

¹⁸ HoloLens is an [augmented reality \(AR\)/mixed reality \(MR\)](#) headset developed and manufactured by [Microsoft](#). Retrieved from: [Microsoft HoloLens](#) | [Microsoft Learn](#).

Figure 6.1: Marketing Campaign Tracking Data

Venue/Platform	Tracking Results
Project announcement - BioTalent Canada takes steps to future-proof Canadian bio-manufacturing with certification - BioTalent Canada	
Webpage with project announcement	<ul style="list-style-type: none"> • 157 English views • 11 French views
Business Wire	<ul style="list-style-type: none"> • 6,035 release views • 234 link clicks • 687 multimedia views • Syndication and Reach: <ul style="list-style-type: none"> ○ 127 Online postings ○ 127M Potential Audience ○ 22,952 subscriber emails
LinkedIn	<ul style="list-style-type: none"> • 2,465 Impressions • 89 clicks • 19 likes • 7 reposts
X Announcement post	<ul style="list-style-type: none"> • 11 clicks English • 3 click French • 1 like English
eBlasts to approximately 15,000 subscribers	<ul style="list-style-type: none"> • Open rate: 30% (a good open rate is between 15-25%) • Opened: 4,524 (people who opened) • Total opens: 6,630 (includes those who opened it more than once) • Click rate: 0.64%; Total clicks: 269 • Clicks per unique opens: 2.12% • Bounce rate: 0.33%

7. Findings by FSC Thematic Question

The development of a practical assessment framework, asset map, and industry support for the development of a VR digital cleanroom, along with publishing of the National Skills Standards for Cleanroom Readiness aligns with FSC’s Pathways to Jobs theme by providing new training technology that will help workers and job seekers attain the skills needed to work in a cleanroom. These tools are designed to help employers assess cleanroom skills and eliminate skills mismatches. Developing these tools collaboratively with the biomanufacturing industry builds trust among employers, encourages investment in training and the adoption of better HR management practices. The figure below summarizes the alignment of BioTalent Canada’s project with FSC thematic areas.

Figure 7.1: Summary of Project Alignment with FSC Thematic Areas

Thematic Area and Questions	Project Alignment
<p>Pathways To Jobs</p> <ol style="list-style-type: none"> 1. How can the delivery of engaging career guidance remote services be refined (e.g., new tech tools, ICT capacity training)? 2. What interventions best help workers develop stronger labour market attachment (e.g., pre-employment, wrap-around supports)? 3. What do workers and jobseekers need to know to better manage their careers into the 4th Industrial Revolution, the Green Economy, or other major transformation affecting employment in Canada? 	<p>A VR digital cleanroom will help individuals make informed decisions about working in cleanroom environments.</p> <p>The development of a practical assessment framework, skills standards and a VR digital cleanroom will help develop a qualified talent pool.</p> <p>Participating employers indicated a willingness to hire candidates with cleanroom training and noted that those with cleanroom certification would be sought after for biomanufacturing positions.</p>
<p>SME Adaptability</p> <ol style="list-style-type: none"> 1. What approaches or tools are best at helping SME employers to assess and recognize skills in the labour market, and under what conditions can their use reduce or eliminate skills mismatches? 2. How do Canadian SMEs make decisions regarding investing in skills and HR development, and what behaviours or systems are associated with high levels of SME investment in training, use of high-performance HR practices, etc.? 3. How can approaches that effectively address SME barriers to investing in training and adopting better HR management practices be scaled up to become sustainable or self-sustaining? 	<p>The practical assessment framework is specifically designed to help employers assess cleanroom skills.</p> <p>Involving SMEs in the development of the practical assessment framework, skills standards and garnering employer support for the development of a VR digital cleanroom helps to encourage investment in training.</p> <p>BioTalent Canada has developed partnerships with industry employers, trainers and experts to provide input and guidance on the development of a practical assessment framework, skills standards and a VR digital cleanroom. These partnerships will help to ensure the scale up and sustainability of these tools with industry support.</p>

7.1 Pathways To Jobs

7.1.1 Remote career guidance

How can the delivery of engaging career guidance remote services be refined (e.g., new tech tools, ICT capacity training)?

Support for a VR digital cleanroom demonstrates how virtual training can help individuals looking to pursue a career in bioscience make informed decisions.

BioTalent Canada established support for a VR digital cleanroom, as stakeholders agreed it will provide individuals the opportunity to explore the type of skills and behaviours required to work in a cleanroom environment through a simulated experience. Such an experience can help those considering a career in biomanufacturing make a more informed decision on whether they could tolerate working under such strict conditions. In addition, the digital nature of such a tool would allow for greater country-wide access. Students and those looking to upskill, reskill or change their career pathways can practice and refine their cleanroom skills in a digital space, be tested and certified without having to travel for training or access a physical cleanroom.

7.1.2 Labour market attachment

What interventions best help workers develop stronger labour market attachment (e.g., pre-employment, wrap-around supports)?

The development of a practical assessment framework, skills standards and a VR digital cleanroom will help to develop a qualified diverse talent pool.

The practical assessment framework for cleanroom certification was designed by industry experts and employers using recognized standards to assess and certify proficiency in cleanroom skills. The standardization will help reduce bias in skills testing and reduce skills mismatches. The practical assessment framework can serve as part of a curriculum within bioscience programs and for training, upskilling or reskilling workers. Once developed, a VR digital cleanroom will also help make training more accessible and help to develop stronger labour market attachment for underrepresented groups and vulnerable populations.

7.1.3 Employment transformation

What do workers and jobseekers need to know to better manage their careers into the 4th Industrial Revolution, the Green Economy, or other major transformation affecting employment in Canada?

Workers and jobseekers with cleanroom training and assessment are sought after for biomanufacturing positions.

Many jobseekers look for an edge that will help them develop their professional portfolio and secure a position. Participating biomanufacturers stated that they would be more likely to hire an individual with

cleanroom training over someone with no cleanroom experience. Once implemented, BioTalent Canada's practical assessment framework for cleanroom certification can help to increase the number of individuals with the skills and experience required for biomanufacturing positions. Continued marketing will increase awareness of the practical assessment framework and development of a VR digital cleanroom will increase access to cleanroom training. This will help workers and job seekers to better manage their careers by providing greater options for training and access to biomanufacturing opportunities.

7.2 SME Adaptability

7.1.4 Reducing skills mismatches

What approaches or tools are best at helping SME employers to assess and recognize skills in the labour market, and under what conditions can their use reduce or eliminate skills mismatches?

BioTalent Canada's practical assessment framework for certification in a biomanufacturing cleanroom was designed to help assess the extent to which an individual has acquired standard cleanroom skills.

Employers will more readily recognize the cleanroom skill sets of candidates that have undergone the practical assessment. SMEs will also be able to use this assessment with their employees and candidates looking to enter the biomanufacturing field. In addition to establishing an individual's cleanroom competency it will also help to identify areas where additional training is required.

7.1.5 Supporting investment in training

How do Canadian SMEs make decisions regarding investing in skills and HR development, and what behaviours or systems are associated with high levels of SME investment in training, use of high-performance HR practices, etc.?

Involving SMEs in the development of the assessment certification framework, skills standards and a VR digital cleanroom helps to encourage investment in training.

Participating biomanufacturers stated that having a practical assessment framework developed with their input gave them trust in the finished product and they would be more inclined to incorporate the framework and related tools into their training strategies. This would include using a VR digital cleanroom to train employees or sending them for training to learn standard cleanroom skills. However, they cautioned that such programs would need to be available to them under considerations of cost and access.

As mentioned, the majority of biomanufacturing employers currently take on the responsibility to train their employees to work in cleanrooms due to the lack of cleanroom training programs. However, such training must be done when production is idle or in other non-cleanroom spaces. Many SMEs do not have the capacity or budget to invest in a cleanroom solely for training or to send employees long distances to receive cleanroom training.

Having a practical assessment framework, including access to a VR digital cleanroom, has the potential to be more cost effective and efficient than current efforts to train for cleanroom skills. For example, hiring candidates that have undergone the practical assessment means that employers do not have to spend as much time training for the basic skills and can focus on the training specific to their manufacturing processes. New candidates with cleanroom training present less risk for employers as they are less likely to quit after training because the cleanroom environment was not what they were expecting. Implementing a VR digital cleanroom for training workers requires less physical space and does not interfere with production lines.

7.1.6 Scaling up and supporting sustainability

How can approaches that effectively address SME barriers to investing in training and adopting better HR management practices be scaled up to become sustainable or self-sustaining?

BioTalent Canada has developed partnerships with industry employers, trainers and experts to help ensure scalability and sustainability of a practical assessment for cleanroom certification.

BioTalent Canada has developed partnerships with close to 80 industry associations, employers, trainers and post secondary institutions from which they seek input and feedback when developing programs and services to support the bioeconomy. These partnerships enhance the adoption and scalability of initiatives including the practical assessment for cleanroom certification and the development of a VR digital cleanroom. Engaging industry in the development of these tools to address SME barriers and meet demands for a qualified biomanufacturing workforce, helps to ensure sustainable resources moving forward.

8. Suggestions, Recommendations and Implications

BioTalent Canada has demonstrated that it is developing the tools and programs that will help to meet industry demand for qualified talent in biomanufacturing roles. A series of suggestions and recommendations emerged as ways to help the practical assessment framework move to implementation and encourage the development of a VR digital cleanroom. The evaluation concludes with implications for the funding of this and other similar projects.

8.1 Stakeholder Suggestions

Industry partners and employers interviewed were supportive of the practical assessment framework, agreeing that once implemented it will help reduce bias in skills testing, skills mismatches and improve employers ability to assess workers' skills. They also expressed support for a VR digital cleanroom for training purposes, but had reservations on the extent to which cleanroom readiness could be accurately assessed through a digital environment. They offered a few suggestions for BioTalent Canada's consideration as they continue their work.

- **Continue to solicit feedback from industry experts.** Participating industry partners and employers agreed that input from industry helps to build tools, services and programs that industry will use. Interviewees suggested that the assessment framework continue to be vetted by industry experts and employers during another series of focus groups. They further suggested that focus groups should be held across the country to engage feedback from a wider audience.
- **Continue to raise industry awareness and support for the practical assessment framework and the National Skills Standard for Cleanroom Readiness.** A few interviewees observed that endorsement from large Canadian biomanufacturers would go a long way to instilling trust in and acceptance of the practical assessment framework among the small and medium biomanufacturing employers. These enterprises may be more inclined to trust the validity of the practical assessment framework and invest in it if large Canadian and global companies were seen as endorsing the practical assessment framework.
- **Provide support for employers, employees and those looking to enter the field of biomanufacturing to access cleanroom training.** Participating employers expressed concern over the costs to send employees long distances for cleanroom training versus costs of in-house physical training including investing in VR digital cleanroom training. Likewise, graduates of high school, college or university programs are rarely exposed to cleanroom environment during their studies and may not have the funds to seek out such training on their own. Thus, the emphasis is placed on employers to train their workers in basic cleanroom skills and behaviour. Interviewees suggested that providing some form of funding, subsidy or other incentive would encourage them to invest in VR digital and/or in-person training focused on basic cleanroom skills.

8.2 Recommendations

With the evaluation findings in mind, the following are recommended:

Recommendation 1: Conduct a series of pilot tests with the practical assessment framework. Although the framework has been conceptually designed with the input of biomanufacturers and industry experts, pilot tests are needed to learn how well the framework assesses cleanroom skills and competencies in practice under different scenarios, demonstrates reduced bias, and underscore the benefits of the assessment. Results from the pilots can be used to make adjustments to the framework. The updated framework can be shared with employers and industry experts to solicit another round of feedback to ensure that the pilot refinements are in line with industry needs.

Recommendation 2: Explore the development of a VR digital cleanroom for training basic cleanroom skills and behaviour. The development of an asset map to identify the equipment and materials needed to assess cleanroom skills forms the inventory from which a VR digital cleanroom can be developed. A consultation process similar to that used to develop the practical assessment framework could be implemented to help further the development of a VR digital cleanroom for training cleanroom workers. This would also have the benefit of developing industry trust and support for a VR digital cleanroom.

Recommendation 3: Continue the marketing campaign and knowledge mobilization events to help increase support and awareness of the practical assessment framework and the National Skills Standard for Cleanroom Readiness. Creating awareness of the practical assessment framework and National Skills Standards for Cleanroom Readiness will help build industry support and acceptance. Results from the aforementioned pilots could also be shared with employers and industry experts to build industry confidence in the framework as a reliable assessment instrument.

8.3 Implications for FSC and Other Funding Organizations

Funding that supports innovation can help meet demand for skilled talent and support SME investment in training.

BioTalent Canada identified and responded to industry demand for skilled biomanufacturing talent through the development of a tool that will help employers assess and recognize skills in the labour market using industry developed testing standards. Additional support is needed to bring the practical assessment framework to implementation. Once developed, support is needed to help ensure training providers and employers have access to such a tool.

The development of a VR digital cleanroom will also help workers develop stronger labour market attachment through access to cleanroom training. A VR digital cleanroom can also reduce barriers to employers investing in training; however, such a tool must be economically feasible compared to in-person training for employers to invest. Funding that supports these types of innovations can help address the demand for skilled talent in Canada's biomanufacturing industry and other growing sectors.

Encouraging partnerships among labour market organizations, employers, industry trainers, and postsecondary institutions will help build a pipeline of qualified talent.

BioTalent Canada has demonstrated its ability to bring together employers and industry subject matter experts, including those who deliver cleanroom training, to design and develop practical solutions to meet demand for a skilled biomanufacturing workforce. However, more could be done to ensure graduates of training and academic programs have exposure to cleanroom environments as part of their training. There is potential for the practical assessment framework, skills standard, and VR digital cleanrooms to be included in industry training and academic programs that focus on preparing individuals to work in biomanufacturing positions. Consideration should be given to supporting the development of partnerships among labour market organizations such as BioTalent Canada and biomanufacturing employers, industry trainers, and postsecondary institutions. This could help encourage the adoption of tools developed by and for the biomanufacturing industry.

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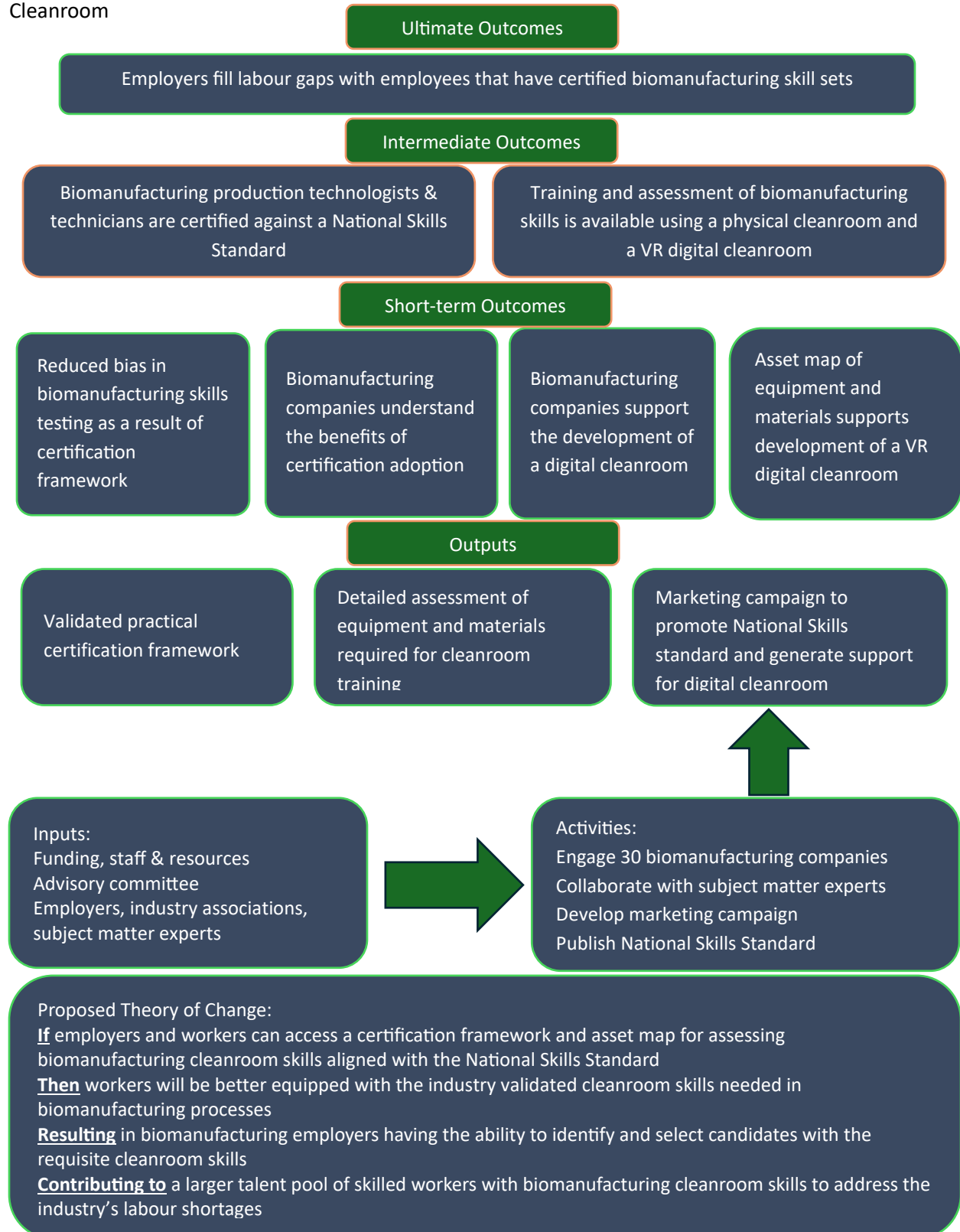
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Appendix B: Logic Model & Theory of Change

Logic Model for BioTalent Canada’s Practical Assessment for Certification in a Biomanufacturing Cleanroom



Appendix C: Evaluation Matrix

The following evaluation matrix details the evaluation questions, sub-questions, key metrics and data collection methods and sources.

Figure C.1 Practical Assessment for Cleanroom Certification With Asset Map Project Evaluation Matrix

Evaluation Questions	Sub-questions	Literature, data, document review	Survey	Interviews	Tracking analytics
Project question 1: To what extent does a practical assessment framework for cleanroom certification help to build a pipeline of qualified talent for biomanufacturing?	a. Is there a need for a certification assessment program to build a pipeline of qualified talent for biomanufacturing? b. Do certification assessment programs for biomanufacturing cleanrooms already exist in the market? c. How does a practical assessment framework help workers develop cleanroom skills d. How does a practical assessment framework provide workers and jobseekers knowledge to better manage their careers? e. How will the practical assessment framework improve SME adaptability? f. How will the practical assessment framework reduce bias in skills testing? g. How will the practical assessment framework improve SME ability to assess and recognize skills and reduce skills mismatches?	x	x	x	
Project question 2: To what extent does the design of the assessment framework ensure EDI&R and accessibility is	a. How does embedding EDI&R and accessibility into the design of the assessment framework help attract diverse workers to the industry? b. How does embedding EDI&R and accessibility into the design of the assessment framework provide workers and jobseekers knowledge to better manage their careers?	x	x	x	

<p>imbedded in the practical assessment and the associated tools to attract a diverse talent pool?</p>	<p>c. How does embedding EDI&R and accessibility into the design of the assessment framework help employers to invest in skills and HR development?</p>				
<p>Project question 3: What is the level of stakeholder satisfaction with the development of a practical assessment framework including feedback from industry partners, employers, trainers?</p>	<p>a. Are biomanufacturing companies willing to work with BioTalent towards completing a certification program in sterile cleanroom environments? b. Are biomanufacturing companies willing invest in a certification program in sterile cleanroom environments?</p>	<p>x</p>	<p>x</p>	<p>x</p>	
<p>Project question 4: To what extent do biomanufacturing companies support the development of a physical and VR digital cleanroom?</p>	<p>a. To what extent is there a need for a VR digital twin cleanroom? b. Do VR digital twin cleanrooms already exist in the market? c. How will a virtual cleanroom help workers develop cleanroom skills? d. How will a virtual cleanroom provide workers and jobseekers knowledge to better manage their careers? e. How will a virtual cleanroom improve SME ability to assess and recognize skills and reduce skills mismatches? f. How will a virtual cleanroom increase employer investment in skills and HR development? g. What is the impact of industry consultations on the scalability of VR digital twin cleanrooms? h. What is the impact of industry consultations on the effectiveness of VR digital twin cleanrooms in biomanufacturing training?</p>	<p>x</p>	<p>x</p>	<p>x</p>	<p>x</p>

<p>Project question 5: To what extent did feedback from employers and subject matter experts lead to the development of an inventory of the digital assets required to design a VR digital virtual cleanroom?</p>	<p>a. Are the tools required to make assessments in a digital cleanroom the same as in a physical cleanroom? b. What adjustments need to be made to ensure the certification can be done in both physical and virtual settings? c. Will an inventory of digital cleanroom assets improve SME ability to assess and recognize skills and reduce skills mismatches?</p>	x	x	x	x
<p>Project question 6: To what extent did/does BioTalent Canada’s marketing campaign help to increase awareness and support among the biomanufacturing industry for a practical assessment framework for cleanroom certification?</p>	<p>a. How did/does BioTalent’s marketing campaign help to increase support among the biomanufacturing industry for a physical and virtual digital cleanroom? b. How does BioTalent Canada’s marketing campaign provide workers and jobseekers knowledge to better manage their careers? c. How does BioTalent Canada’s marketing campaign increase employer investment in skills and HR development related to cleanroom skills?</p>	x	x	x	x

Appendix D: Data Collection Instruments

Survey of Participating Employers and Industry Experts

Thank you for participating in BioTalent Canada's focus group on developing a practical assessment for certification in a biomanufacturing cleanroom! Malatest, an independent third-party evaluator, is supporting BioTalent Canada to understand how events like this help people and employers succeed in biomanufacturing. The findings of this survey will be used to assess the extent to which BioTalent Canada's development of a practical assessment framework and efforts to build support for a virtual cleanroom help to meet the training and assessment needs of biomanufacturing employers and workers. The survey will take approximately 5 to 7 minutes depending on your responses.

To thank you for your time to share your experiences with us, the first 50 eligible individuals will be offered a \$25 gift certificate for completing the survey. For complete eligibility rules, please click here.

To complete this survey over the phone or to ask questions about this research, e-mail fscevaluations@malatest.com or call us toll-free at 1-855-688-1131.

More about this study:

BioTalent Canada's *Practical Assessment for Certification in a Biomanufacturing Cleanroom with Asset Map*, project is funded by the Future Skills Centre. The Future Skills Centre has contracted R.A. Malatest & Associates, an external and independent research firm, to conduct an evaluation in collaboration with BioTalent Canada. During this evaluation, Malatest will hear from biomanufacturing employers and other industry professionals participating in BioTalent Canada's project activities.

Your participation is voluntary. Your information will be kept private. The results will be summarized in aggregate only. No individuals will be reported. Your responses will be protected *as per* [Canada's Privacy Act](#). Management of the information collected through this study will be compliant with Government of Canada's [Policy on Service and Digital](#). For Malatest's privacy policy, please visit: <https://www.malatest.com/privacy-policy/>.

Q1. In participating in BioTalent Canada's focus group, which kind of organization are you representing?

1. A biomanufacturing employer
2. A post-secondary or training institution
3. An industry association
4. A not-for-profit organization other than an industry association
5. A government ministry
6. Another group (please specify)
7. Prefer not to answer

Q2. How did you first learn about BioTalent Canada's development of an assessment for biomanufacturing cleanroom certification?

1. Through an invitation to participate in the development of a practical assessment framework
2. From a BioTalent Canada newsletter or press release
3. From the BioTalent Canada website
4. From my association's website
5. Through participation in an information session or in person event
6. Through an invitation from a BioTalent Canada team member
7. Other, please specify
8. Prefer not to answer

Q3. Please indicate your level of agreement with the following statements:

A practical assessment program for certification in a biomanufacturing cleanroom will help SME adaptability by....	Strongly Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Some what Agree	Strongly Agree	Don't know
Q3_a. Reducing bias in skills testing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
Q3_b. Reducing skills mismatches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
[if Q1=employer, industry association] Q3_c. Improving employers' ability to assess workers' skills	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
Q3_d. Helping ensure the sector's workforce have the required skills to work in cleanroom environments	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
[if Q1=employer, industry association] Q3_e. Encouraging employers to invest in cleanroom training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
Q3_f. Building a pipeline of qualified talent for biomanufacturing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

[if Q1=employer]

Q4. How likely would your organization invest in a practical assessment program for certification in a biomanufacturing cleanroom?

1. Not at all likely
- 2.
3. Somewhat likely
- 4.

- 5. Very likely
- 6. Unsure
- 99. Prefer not to answer.

Q5. Please indicate your level of agreement with the following statements:

A virtual reality digital cleanroom will....	Strongly Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Strongly Agree	Don't know
Q5_a. Enhance access to training for employees and workers looking to acquire cleanroom skills	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
[if Q1=employer, industry association] Q5_b. Improve employers' ability to assess workers' skills	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Q5_c. Help ensure the sector's workforce have the required skills to work in cleanroom environments	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
[if Q1=employer, industry association] Q5_d. Encourage employers to invest in cleanroom training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Q5_e. Build a pipeline of qualified talent for biomanufacturing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Q6. To what extent does your organization support the development of a virtual digital cleanroom for training biomanufacturing workers?

- 1. Does not support
- 2.
- 3. Somewhat supportive
- 4.
- 5. Very supportive
- 99. Prefer not to answer.

Q7. Did you participate in BioTalent Canada's focus group to establish the certification assessment framework?

1. Yes
2. No → Skip next Q

[Ask if participated in focus group]

Q8. Many organizations have created policies to support inclusion, diversity, equity, accessibility and reconciliation to build workplace resiliency and to meet current and future workforce needs. Please indicate your level of agreement with the following statements:

Supporting these aims into the assessment framework will	Strongly Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Strongly Agree	Don't know
Q8_a. Help attract diverse workers to the industry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Q8_b. Help employers to invest in skills and workforce development	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Q8_c. Provide workers and jobseekers knowledge to better manage their careers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Q10. Thank you for taking the time to fill out this questionnaire. Would you like to receive a \$25 gift card to thank you for your time to share your experiences?

If yes, you will receive an email by **Giftbit** directly within the next few weeks (you can enter your email address at the end of the survey). *Gift cards offered by Giftbit include (but are not limited to): Starbucks, Amazon, Uber, and more.*

1. Yes
2. No

Q11. Malatest is seeking individuals for one-on-one interviews with biomanufacturing companies in the coming weeks. The purpose of these interviews is to better understand how BioTalent Canada's development of a practical assessment framework and efforts to build support for a virtual cleanroom help to meet the training and assessment needs of biomanufacturing employers and workers. Those that are selected to participate in an interview will be offered a \$25 honorarium after completing the interview to thank them for their time and sharing their experiences. Would you like to be interviewed by Malatest in the coming weeks?

1. Yes
2. No

QCCONTACT_INFO. [If Q10 and/or Q11 = 1]

- First name (mandatory)

- Last name (optional)
- Email (mandatory)
- Confirm email address (mandatory)
- Phone (optional)

Thank you for taking the time to complete this survey!

Master interview guide
BioTalent Canada Project lead, staff and partners

BioTalent Canada Interview Guide	
<p>BioTalent Canada’s project, to develop a practical assessment for certification in a biomanufacturing cleanroom with asset map has been funded by The Future Skills Centre. The Future Skills Centre has contracted R.A. Malatest & Associates, an external and independent research firm, to conduct an evaluation of funded activities in collaboration with BioTalent Canada.</p> <p>The purpose of this interview is to collect information for the evaluation including:</p> <ul style="list-style-type: none"> • Perceptions on the development of an assessment certification framework. • Level of support for a virtual cleanroom. • Extent BioTalent Canada helps employers assess and recognize skills in the labour market. • Extent BioTalent Canada helps employers address barriers to investing in skills training and HR development. <p>The interview will take approximately 30-45 minutes depending on your answers.</p>	
Confidentiality, Anonymity and Privacy:	<p>No one other than Malatest researchers will have access to any <u>identifying information</u> from this interview. Your responses to interview questions will be <u>anonymized</u> (that is, reported without your name or any identifying information attached). In some cases, we may use anonymized quotations that exemplify a trend among interviewees’ responses; in this case, we will make sure that the quote does not contain any information that could be used to identify you. All identifying data will be destroyed by Malatest when the report provided to FSC and BioTalent Canada is finalized. Note that the evaluation report or portions of the report may be made available to the public in which case all responses will be anonymized.</p> <p>Your responses will be protected <i>as per</i> Canada’s Privacy Act. The information you provide will not be used for any purposes except those described above. Management of the information collected through this study will be compliant with Government of Canada’s Policy on Service and Digital. For Malatest’s privacy policy, please visit: https://www.malatest.com/Privacy.htm.</p>
Informed Consent:	<p>Your participation is <u>voluntary</u>, and you may end participation at any time. You can also skip any question that you do not want to answer, or that is not applicable to you.</p> <p>With your permission, we will audio record this interview, for Malatest’s notetaking and quality assurance purposes only. This recording will be destroyed once the interview notes have been verified and completed. Do I have your <u>permission to audio record</u> the interview?</p>
Questions:	<p>If you have any questions about this interview or this project, please feel free to contact April Balunda, Senior Research Analyst, R.A. Malatest & Associates Ltd., via email at a.balunda@malatest.com.</p>

This master interview guide has been developed for the following:

- BioTalent Canada staff
- Employers (participants responding to survey who have agreed to be interviewed)
- Key project partners

Each question has been labeled by stakeholder. This master guide will be split into individual guides prior to conducting interviews.

A. Background information

Ask all

1. Can you tell me about yourself:
 - a. What are your typical roles and responsibilities?

Employers

2. What are the specific occupational demands and skills needs for your company?
 - a. What are some of the challenges to reskilling/upskilling employees and acquiring individuals with the required skills for your company?

Key project partners, staff

What are the specific occupational demands and skills needs for the biotech industry and biomanufacturing?

- a. What are some of the challenges employers face when reskilling/upskilling employees and acquiring individuals with the required skills?

B. Development of assessment certification framework

Employers, key project partners, staff

1. From your perspective, what are some of the benefits of having a certification framework for assessing cleanroom skills?
 - a. To what extent will such a framework reduce bias in skills testing or skill mismatches?
 - b. To what extent will such a framework ensure the sector's workforce have the required skills to work in cleanroom environments?
 - c. To what extent will such a framework help build a pipeline of qualified talent for biomanufacturing?
 - d. To what extent will such a framework encourage employers to invest in cleanroom training?
 - e. Are there any other benefits a certification framework for assessing cleanroom skills?

Employers, key project partners, staff

2. What do you foresee as some of the challenges to implementing a certification framework for assessing cleanroom skills?
 - a. Can you suggest how these challenges might be mitigated?

Employers, key project partners, staff

3. To what extent are/will employers and industry associations support this framework?

Key project partners, staff

4. In what ways will a certification framework for assessing cleanroom skills impact current training programs for the sector?

C. Establishing support for a virtual cleanroom

Employers, key project partners, staff

1. From your perspective, what are some of the benefits of having a virtual cleanroom?
 - a. To what extent will a virtual cleanroom reduce bias in skills testing or skill mismatches?
 - b. To what extent will a virtual cleanroom ensure the sector's workforce have the required skills to work in cleanroom environments?
 - c. To what extent will a virtual cleanroom help build a pipeline of qualified talent for biomanufacturing?
 - d. To what extent will a virtual cleanroom encourage employers to invest in cleanroom training?
 - e. Are there any other benefits of a virtual cleanroom?

Employers, key project partners, staff

2. What do you foresee as some of the challenges to implementing a virtual cleanroom?
 - a. Can you suggest how these challenges might be mitigated?

Employers, key project partners, staff

3. To what extent are/will employers and industry associations support a virtual cleanroom?

Employers, key project partners, staff

4. What would be some of the key elements of assets needed for designing a virtual cleanroom?

Key project partners, staff

5. In what ways will a virtual cleanroom impact current training programs for the sector?

D. Partnerships

Project partners

1. How would you describe your partnership with BioTalent Canada?
 - a. What worked well?
 - b. What are the benefits of working with BioTalent Canada?

Project partners

2. What, if any, were some of the challenges of working with BioTalent Canada?
 - a. How were these challenges mitigated?
 - b. Were there any areas that you felt could be improved or done differently?

E. Project Activities*BioTalent Canada staff*

1. From your perspective how effective were the knowledge mobilization activities, for this round of FSC funding?
 - a. What worked well?
 - b. What, if any, were some of the challenges encountered by you or your team?
 - c. How were these challenges mitigated?
 - d. Were there any areas that you felt could be improved or done differently?

F. Wrap up*Ask all*

2. Do you have anything else to add, or any questions for me?

Thank you for your time!