

# A Canadian Success Story in the Making

Developing a National Pipeline of Highly-Qualified Personnel (HQP) for Biotherapeutic Manufacturing

Adam Shane, Academic Chair

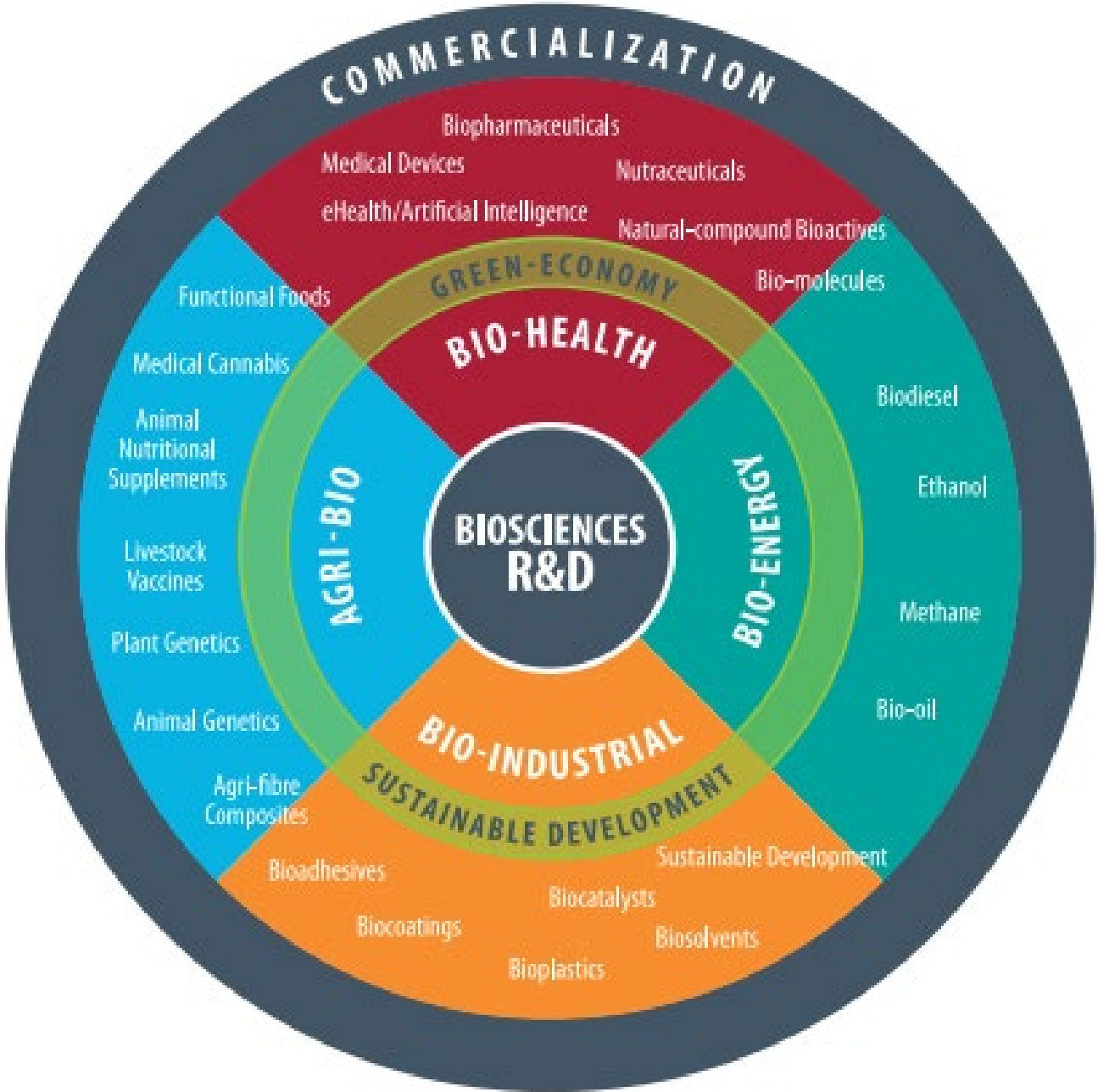


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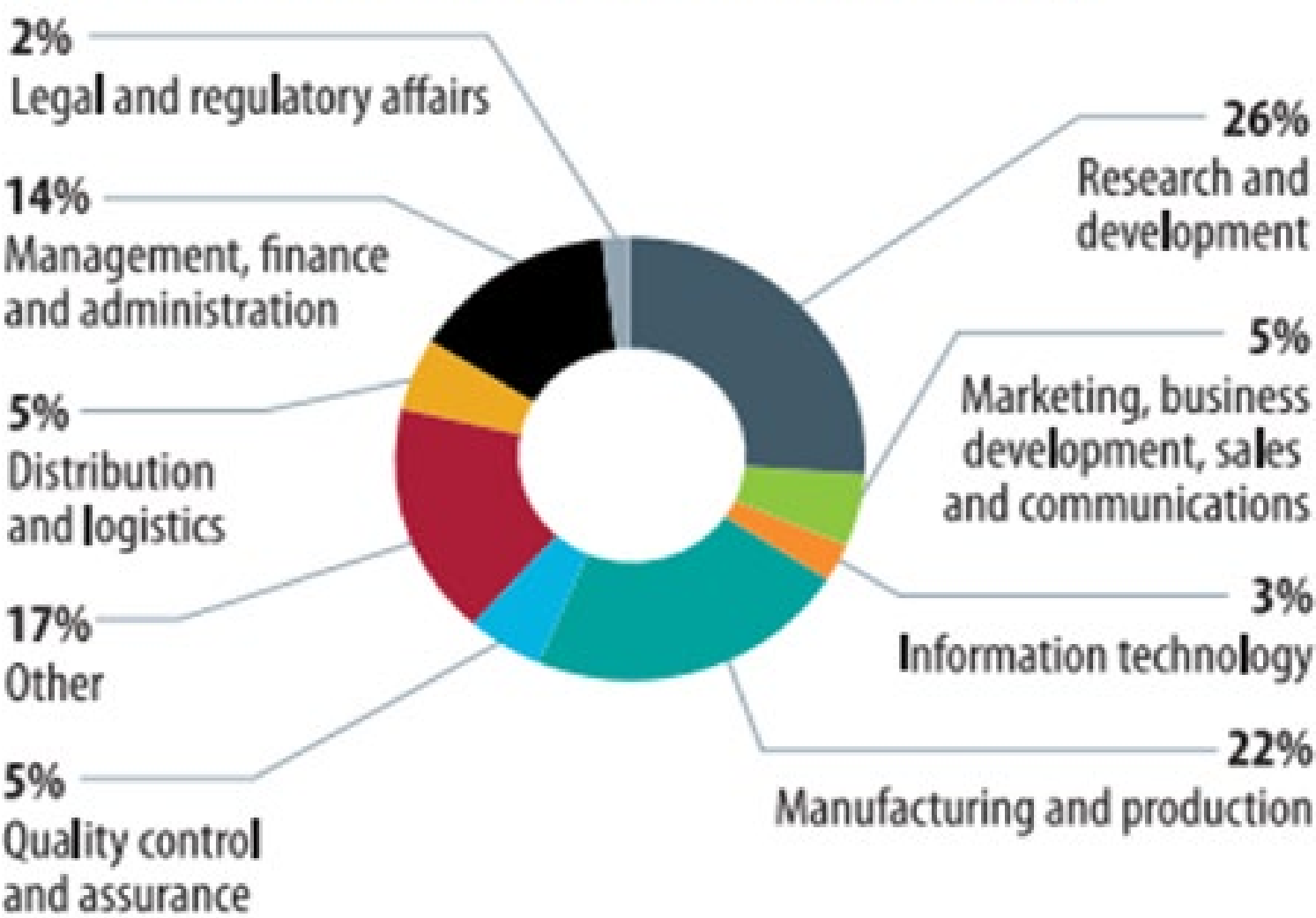


Adam Shane

# Understanding Canada's Bio-Economy



Job functions cover a wide range



Reference: BioTalent Canada's report "Close-up on the Bio-economy – National Report" (Oct 2021)

# Understanding Canada's Bio-Economy

## Hiring Demands Will Outpace Supply (2021-2029)

- Not enough workers to meet the labour need of 65,000 additional workers by 2029.
- Some of the most severe shortages are expected in bio-manufacturing and processing.
- More international students are needed.
- Need to raise awareness of different bio-economy careers.
- Opportunity to seek talent from under-represented groups.

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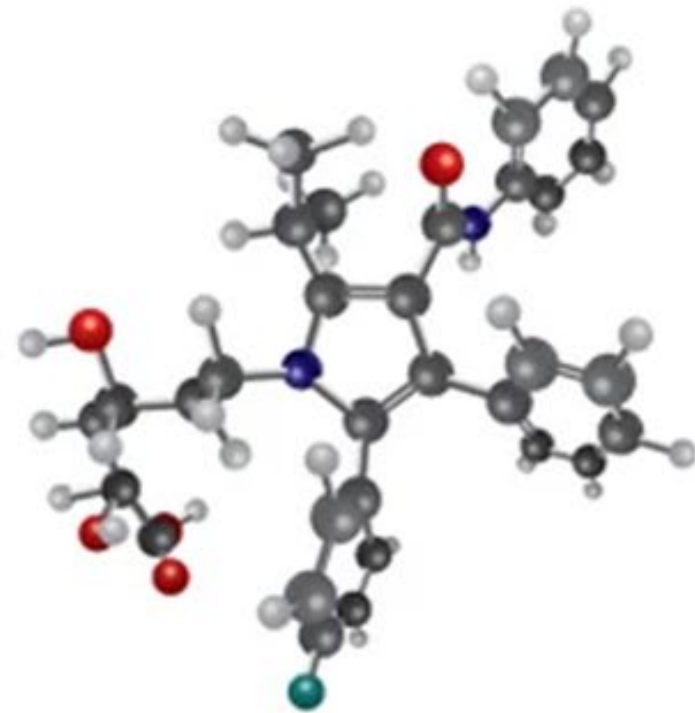
**Employers may be able to fill only 25% of bio-manufacturing and processing job openings by 2029.**

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Reference: BioTalent Canada's report "Close-up on the Bio-economy – National Report" (Oct 2021)

# Traditional vs Biological Therapeutics

Traditional Drug



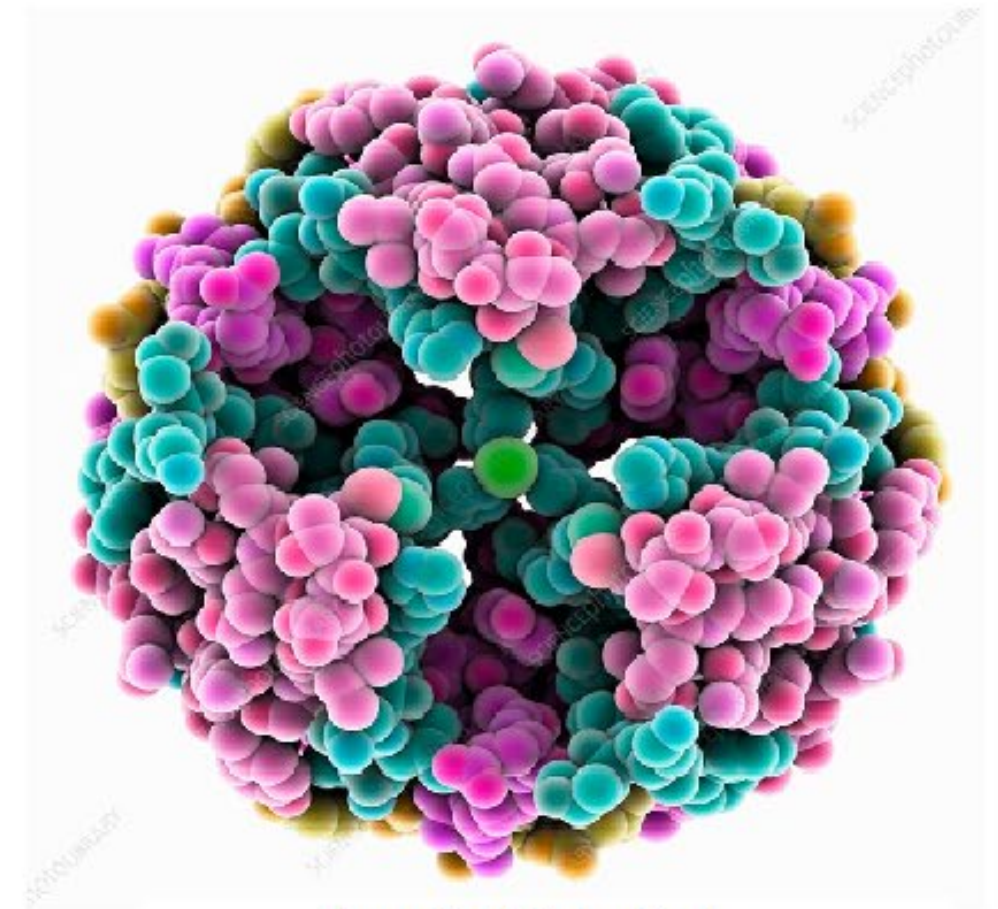
**Lipitor (hypercholesterolemia)**  
molecular weight = 559 daltons

Biologic



**Herceptin (breast cancer)**  
molecular weight = 185,000 daltons

Biologic



**Insulin (diabetes)**  
molecular weight = 5808 daltons



# 10 Top-Selling Biologics in Canada (2018)

Originator biologic (medicine)	Sales (\$million)	Share of biologic sales	Share of pharmaceutical sales
Remicade (infliximab)	\$1,081	14.1%	<b>4.2%</b>
Humira (adalimumab)	\$800	10.4%	3.1%
Eylea (aflibercept)	\$493	6.4%	1.9%
Stelara (ustekinumab)	\$338	4.4%	1.3%
Lucentis (ranibizumab)	\$317	4.1%	1.2%
Enbrel (etanercept)	\$291	3.8%	1.1%
Lantus (insulin glargine)	\$273	3.5%	1.1%
Rituxan (rituximab)	\$266	3.5%	1.0%
Keytruda (pembrolizumab)	\$202	2.6%	0.8%
Herceptin (trastuzumab)	\$186	2.4%	0.7%
<b>Total</b>	<b>\$5,534</b>	<b>55.2%</b>	<b>16.6%</b>

<https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/biologics-part1-market-trends.html>

# Biologics are a High-Growth Segment of Drug Sales

Sales of biologic medicines in Canada, 2011 to 2020

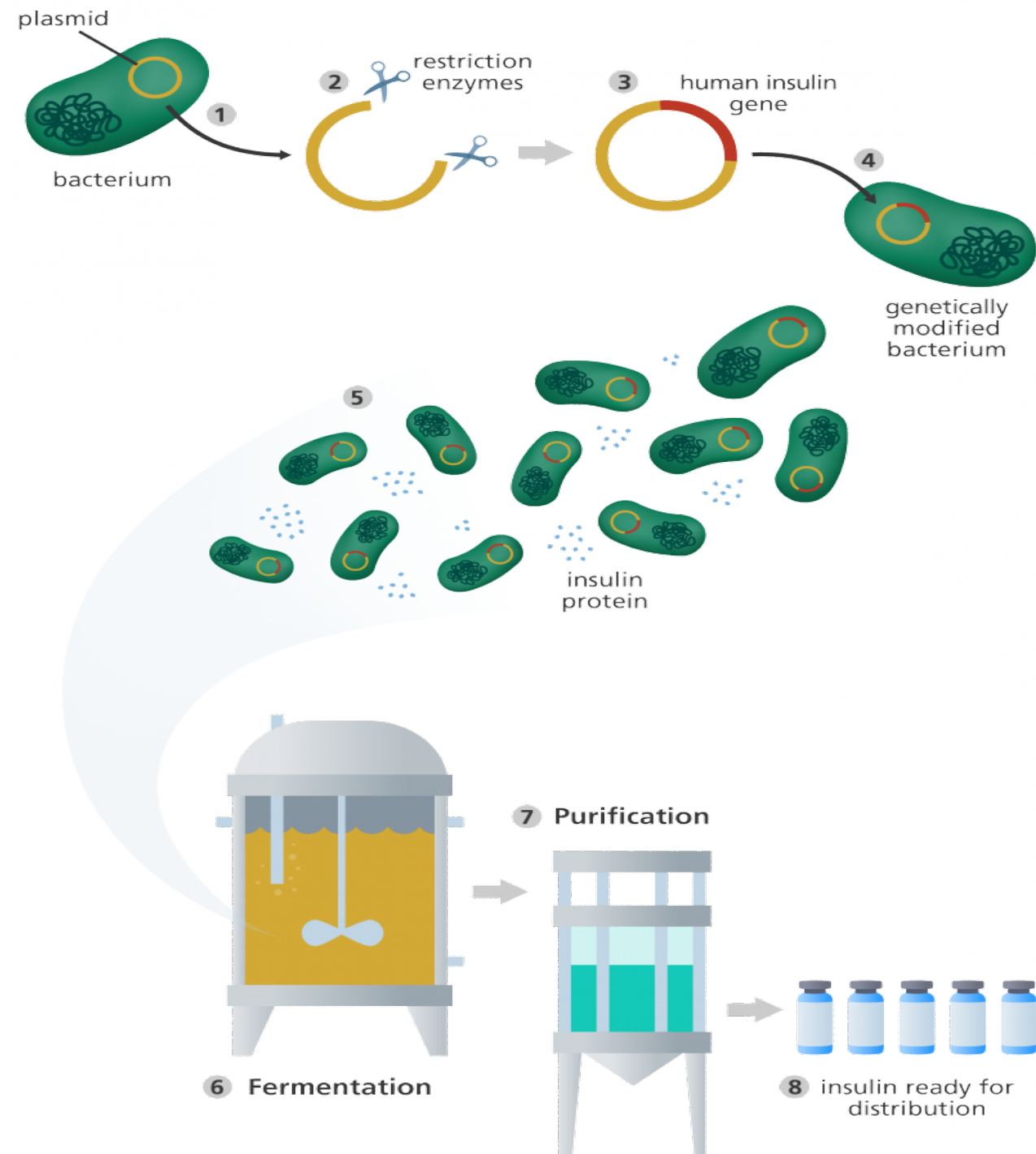


# Canadian History Moment – Discovery of Insulin





# How is Human Insulin Medication Produced Today?



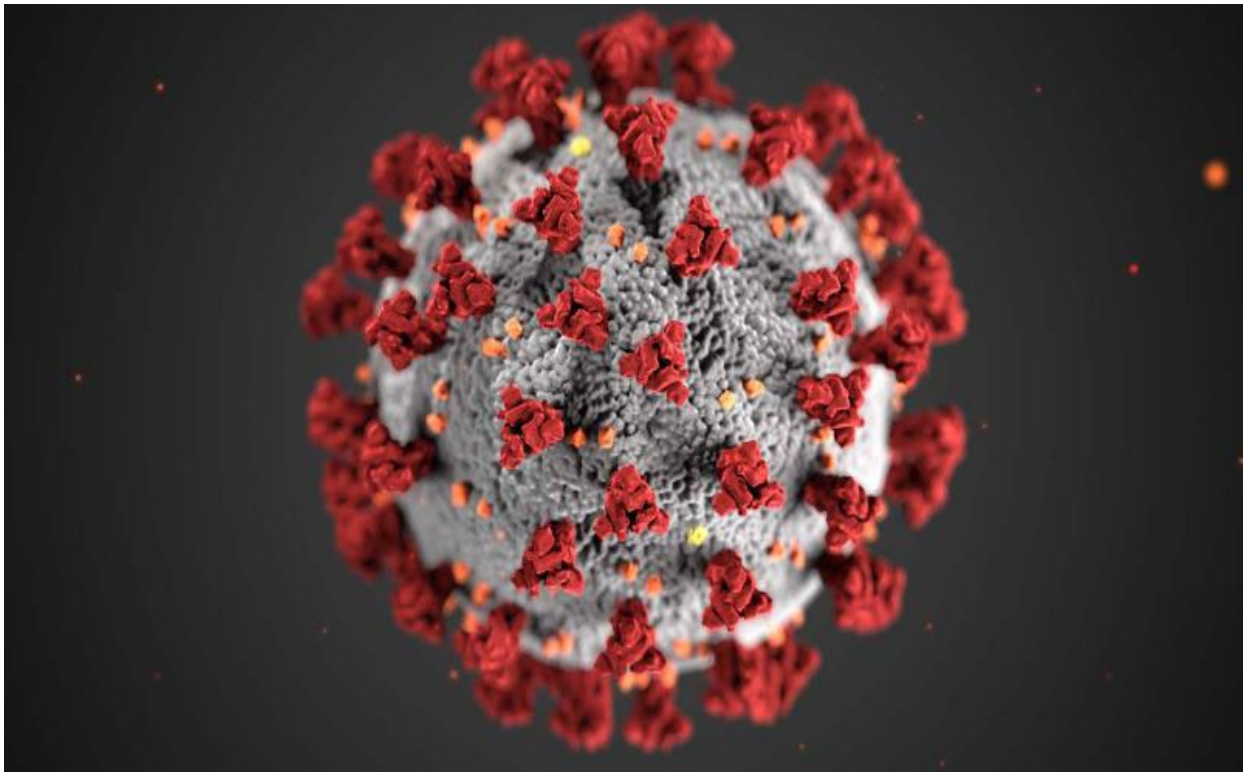


# Global Insulin Manufacturing and Supply Chain

Country		Total quantity of retail insulin exported from country from 2000–2013, kg
Argentina		34 008
Bangladesh		25 620
China		212 941
Egypt		32 218
El Salvador		1313
India		21 787 848
Mexico		1 085 850
Poland		793 462
Russian Federation		27 839
United Arab Emirates		114 050
Countries where 'big three' produce insulin	Denmark <sup>†</sup>	40 106 504
	France <sup>‡</sup>	45 747 289
	USA <sup>‡</sup>	20 960 897
	Germany <sup>†</sup>	12 899 410

Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6593686/>

# What Happens if Supply Chains are Disrupted?



Major Sectors : Food and Beverages, Bio-Pharmaceutical

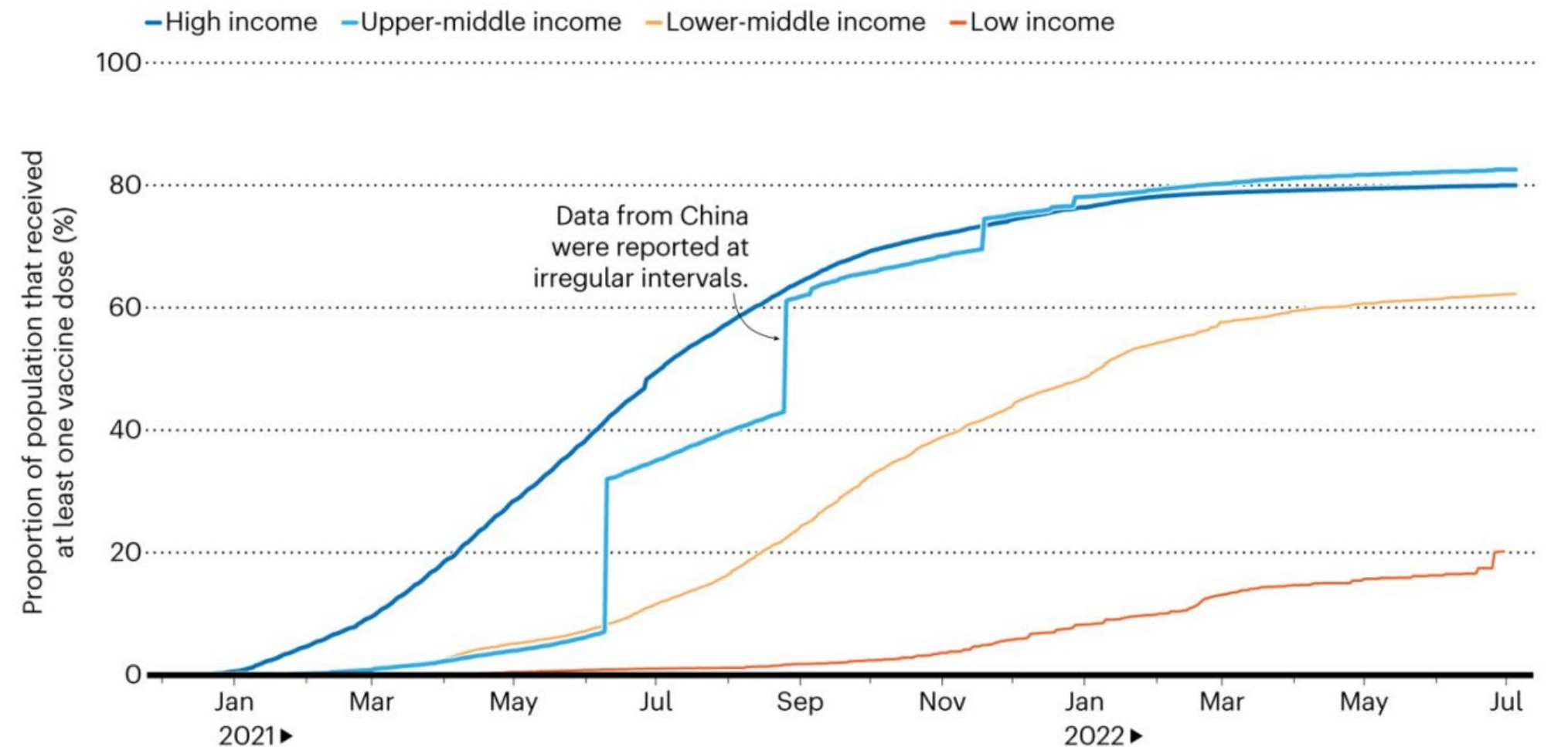
## The Cold chain logistics infrastructure



# Global Demand for COVID-19 Vaccines

- Vaccine equity and universal access?
- Manufacturing capacity limits? Infrastructure? HQP?
- Intellectual property rights/patents?

**nature**



<https://www.nature.com/immersive/d41586-022-01898-3/index.html>



# What is CanPRIME?

## CanPRIME 1.0 Partners (2019)

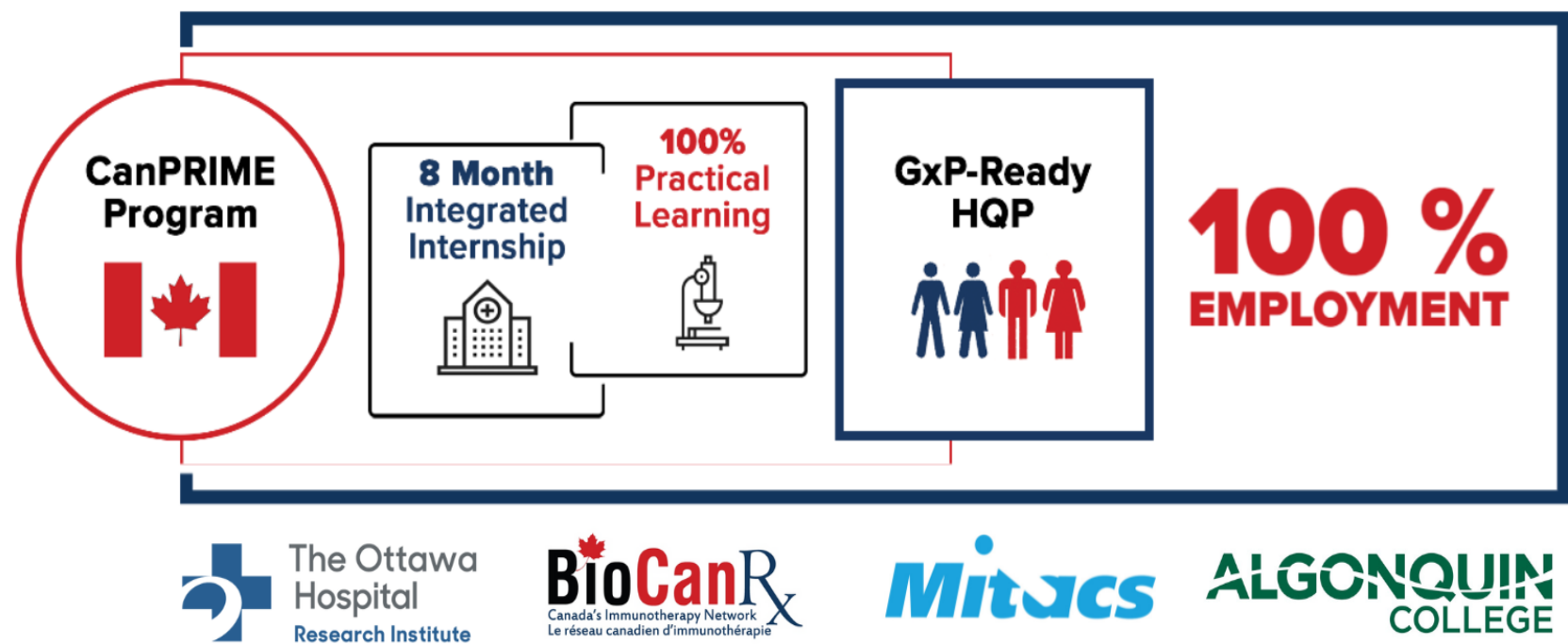


Image by BioCanRx

## Biomanufacturing Centre Ottawa

Over the last 15 years, BMC has manufactured:

- Viral immunotherapies for cancer
- Mesenchymal stem / stromal cells
- CAR-T therapy (cells plus lentivirus)
- Genetically engineered endothelial progenitor cells
- Adeno Associated Viruses for gene therapy
- Vaccines for COVID-19

# CanPRIME Student Testimonials

“I have been working at BMC since January [2020] and it has been fantastic, unforgettable so far. What I have learned working there has been amazing. With the background I have from Algonquin College and the Biotechnology program, everything comes together and they give you every opportunity to learn through CanPRIME. It’s sort of a surreal job because we are contributing, we are part of the team as students.”

**- Britany Donis, Algonquin College Biotechnology-CanPRIME co-op student**

“As a student finishing their studies, preparing to enter the professional world was a daunting task. With partnerships like CanPRIME bridging the gap, those dream jobs I’ve heard about suddenly became more real than ever.”

**- Reuben Benedict, Past CanPRIME Intern**

“CanPRIME gave me the opportunity to develop some very unique and in-demand skills. It feels pretty special to come to work and know that I’m contributing to making potentially life-saving therapies.”

**- Lean Barbeau, Past CanPRIME Intern**

# CanPRIME Quotes

“This partnership between CanPRIME and Mitacs is one of many examples of Ontario researchers working together with industry in order to bolster our province’s biotherapeutic sector. Not only will this partnership help train Ontario students with critical, in-demand skills, but it will also help make Ontario better prepared to deal with urgent healthcare threats.”

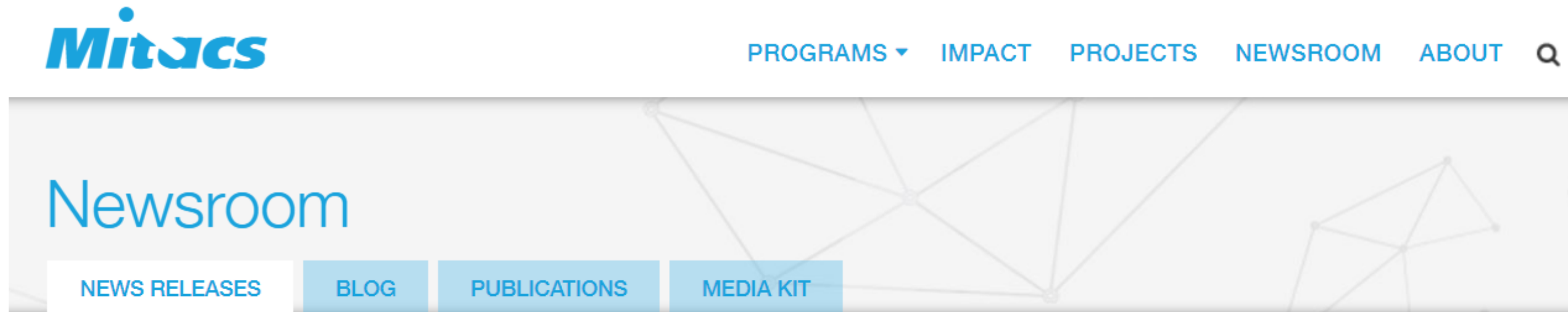
**- Ross Romano - Minister of Colleges and Universities (Ontario)**

“Canada’s competitive advantage is our talented and skilled workforce, and at no time has that been more important than in the face of the COVID-19 pandemic. Through partnerships, like this one between Mitacs and CanPRIME, the Government of Canada is not only supporting the advancement of science and research, but also helping the next generation of researchers to build a healthy, more resilient, and more prosperous country for everyone.”

**- Honourable Navdeep Bains - Minister of Innovation, Science and Industry**



# CanPRIME 2.0 = National Expansion



## Unique Hands-on Training Program in Biotherapeutics Manufacturing Expanding Across Canada

09/23/2022

### **Mitacs and BioCanRx partner to meet the need for highly skilled biotherapeutics manufacturing workforce**

**Vancouver, B.C.** – Mitacs, in partnership with BioCanRx, has developed CanPRIME 2.0 — a national, first-of-its-kind initiative that will enable standardized, hands-on training to work in a biomanufacturing environment. The Canadian biomanufacturing sector is growing rapidly. But despite an influx in physical capacity, the highly qualified personnel (HQP) who are instrumental to the success of these facilities are in short supply with few formal mechanisms in place to train more. CanPRIME 2.0 addresses this crucial need.



Source: <https://www.mitacs.ca/en/newsroom/news-release/unique-hands-training-program-biotherapeutics-manufacturing-expanding-across>

# CanPRIME 2.0 Partner Expansion



# Federal Support for Biomanufacturing in Canada

- **Canada's Biomanufacturing and Life Sciences Strategy** was announced in August 2021
- Two main objectives:
  1. Grow a strong, competitive domestic life sciences sector with cutting edge biomanufacturing capabilities
  2. Ensure preparedness for future pandemics or other health emergencies
- Includes over \$2.2 billion in federal funding across 7 years (multi-staged)

<https://ised-isde.canada.ca/site/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy>



# Federal Support for Future Pandemic Preparedness



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ARTICLE

## Launch of integrated funding competition to strengthen Canada's biomanufacturing ecosystem

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MARCH 2, 2023

**\$570 million for proposals associated with new biomedical research hubs**

- Funded through Canada Biomedical Research Fund (CBRF) and Biosciences Research Infrastructure (BRIF)
- Stage 1 = \$10 million
- Stage 2 = \$570 million
  - \$360 million (BRIF)
  - \$210 million (CBRF)

Source: <https://www.innovation.ca/news/CBRF-BRIF-competition-launch-March-2023>

# 5 New Canadian Research Hubs

- **The CBRF PRAIRIE Hub: Protecting Canada by Building on Excellence in Pandemic Preparedness.** Led by the University of Alberta. Accelerating the development and commercialization of vaccine, antiviral and diagnostic countermeasures for potential pandemic pathogens.
- **Canada's Immuno-Engineering and Biomanufacturing Hub: Engineering Immunity for Pandemic Response.** Led by The University of British Columbia. Helping develop next-generation immune-based therapeutics that can be manufactured domestically using the latest innovations in biomanufacturing in response to pandemics.
- **Eastern Canada Pandemic Preparedness Hub (ECaPPH).** Led by the Université de Montréal. Increasing the agility, connectivity and growth of the biomanufacturing and life sciences sector to ensure that Canada is prepared for future pandemics and public health crises.
- **Canadian Pandemic Preparedness Hub (CP2H).** Led by the University of Ottawa and McMaster University. Catalyzing research and biomanufacturing innovations to help Canada produce vaccines, therapeutics and diagnostics ahead of future pandemics.
- **Canadian Hub for Health Intelligence & Innovation in Infectious Diseases (HI3).** Led by the University of Toronto. Advancing the concept of “personalized and precise medicine” to influence the development of vaccines, therapeutics and other public health interventions.

# CP<sub>2</sub>H Hubs

McMaster, University of Ottawa join forces to prepare Canada for future pandemics



Canada's Global Nexus for Pandemics and Biological Threats is central to the hub and will play a critical role in its success, said Gerry Wright, executive director.

MARCH 2, 2023

“CP<sub>2</sub>H will bolster pandemic preparedness infrastructure by linking academia with companies to develop transformative technologies. This will not only support pandemic readiness but also promote novel therapeutics and biomanufacturing capacity and support job creation and retention in a highly competitive market. This involves the creation of a trans-Canadian cooperative of Good Manufacturing Practice (GMP) biomanufacturing facilities with complementary expertise to support clinical trials and grow capacity at multiple sites across Canada”

<https://www.uottawa.ca/research-innovation/news-all/university-ottawa-mcmaster-university-join-forces-prepare-canada-future-pandemics>



# Made-in-Canada Vaccine Manufacturing

HEALTH

## Moderna's Patricia Gauthier is preparing Canada for the next pandemic

The company's first Canadian general manager is laying the groundwork for the country to become a leader in vaccine production

By Christina Frangou  
June 9, 2022



(Photography by Wade Hudson)

In November of 2020, Patricia Gauthier walked away from her post as head of vaccine business at pharmaceutical giant GSK to become the general manager—and first employee—of Moderna Canada, a subsidiary of a decade-old U.S. biotech company that had yet to bring a product to market.

## U of T receives \$35 million to modernize high containment facility



The Toronto High Containment Facility houses the largest containment level 3 lab in Ontario, where researchers can study high risk pathogens such as SARS CoV 2, HIV and the bacteria that causes tuberculosis (photo by Nathan Cypris)

The University of Toronto has received \$35 million in critical research infrastructure funding from the federal government to revitalize the Toronto High Containment Facility (THCF), an investment that positions the facility to play a significant role in addressing future pandemic and health threats in Ontario and Canada.

November 16, 2022

By Betty Zou

<https://macleans.ca/society/health/modernas-patricia-gauthier-is-preparing-for-the-next-pandemic/>

<https://www.utoronto.ca/news/u-t-receives-35-million-modernize-high-containment-facility>

# New Biomanufacturing Infrastructure in Canada

## New Biologics vaccine manufacturing centre completed in 10 months

DCN-JOC News Services June 23, 2021



NRC — Construction of Montreal's new Biologics Manufacturing Centre took only 10 months, half the timeline of similar facilities.

<https://canada.constructconnect.com/dcn/news/projects/2021/06/new-biologics-vaccine-manufacturing-centre-completed-in-10-months>



# Made-in-Canada Vaccine Manufacturing

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Drug manufacturing facility gets green light thanks to federal dollars

Canadian Critical Drug Initiative will commercialize new drug discoveries and prevent future shortages by producing homegrown supply.

March 17, 2023 By Gillian Rutherford

Alberta's burgeoning biomanufacturing and life sciences industry got an \$80.5-million boost in federal funding today, putting it at the centre of efforts to commercialize new discoveries and give Canadians a reliable national supply of life-saving drugs, including antivirals.

The announcement gives the green light for the Canadian Critical Drug Initiative (CCDI) — a partnership between the not-for-profit Applied Pharmaceutical Innovation (API) and the University of Alberta's Li Ka Shing Applied Virology Institute (LKSIVI) — to create an integrated research, development and manufacturing cluster in Edmonton.

<https://news.gov.bc.ca/releases/2023JEDI0022-000540>

<https://www.ualberta.ca/folio/2023/03/drug-manufacturing-facility-gets-green-light-thanks-to-federal-dollars.html>

# Made-in-Canada Vaccine Manufacturing

## PEI BioAccelerator to grow biomanufacturing capacity for Canada

A \$50-million government investment in major infrastructure in PE will support Canada's rapidly expanding bioscience industry.

March 1, 2023 By PEI BioAlliance



The Governments of Canada and Prince Edward Island today announced a \$50 million investment in the BioAccelerator on Feb. 10, 2023. Photo: PEI BioAlliance.

<https://peibioalliance.com/news/new-bioaccelerator-to-grow-biomanufacturing-capacity-for-canada/>



# Established Online Training at Algonquin College

## **Jan to Aug 2021**

- Algonquin College developed an online, industry-aligned (BioCanRx) course in Good Manufacturing Practices (GMP)

## **Sep 2021 – Pilot #1**

- 35 registrants (mix of AC Biotech graduates and BioCanRx mid-career employees)

## **Sep 2022 - Pilot #2**

- 50 registrants (national audience with a broader background including Biotech, Regulatory Affairs, Environmental Regulation, Medical Devices, Cannabis Testing)

## **Sep 2023 - National Launch**

- Hoping to host 100-200 registrants per intake

# (Possible) Program Development at Algonquin

- Graduate Certificate in GMP with emphasis on biomanufacturing
- 8-month (650hrs) graduate-level program + 4-month co-op (optional)
- First graduate-level program in Canada fully-devoted to GMP/biomanufacturing
- Awaiting CBRF funding support



# (Possible) Infrastructure Expansion at Algonquin

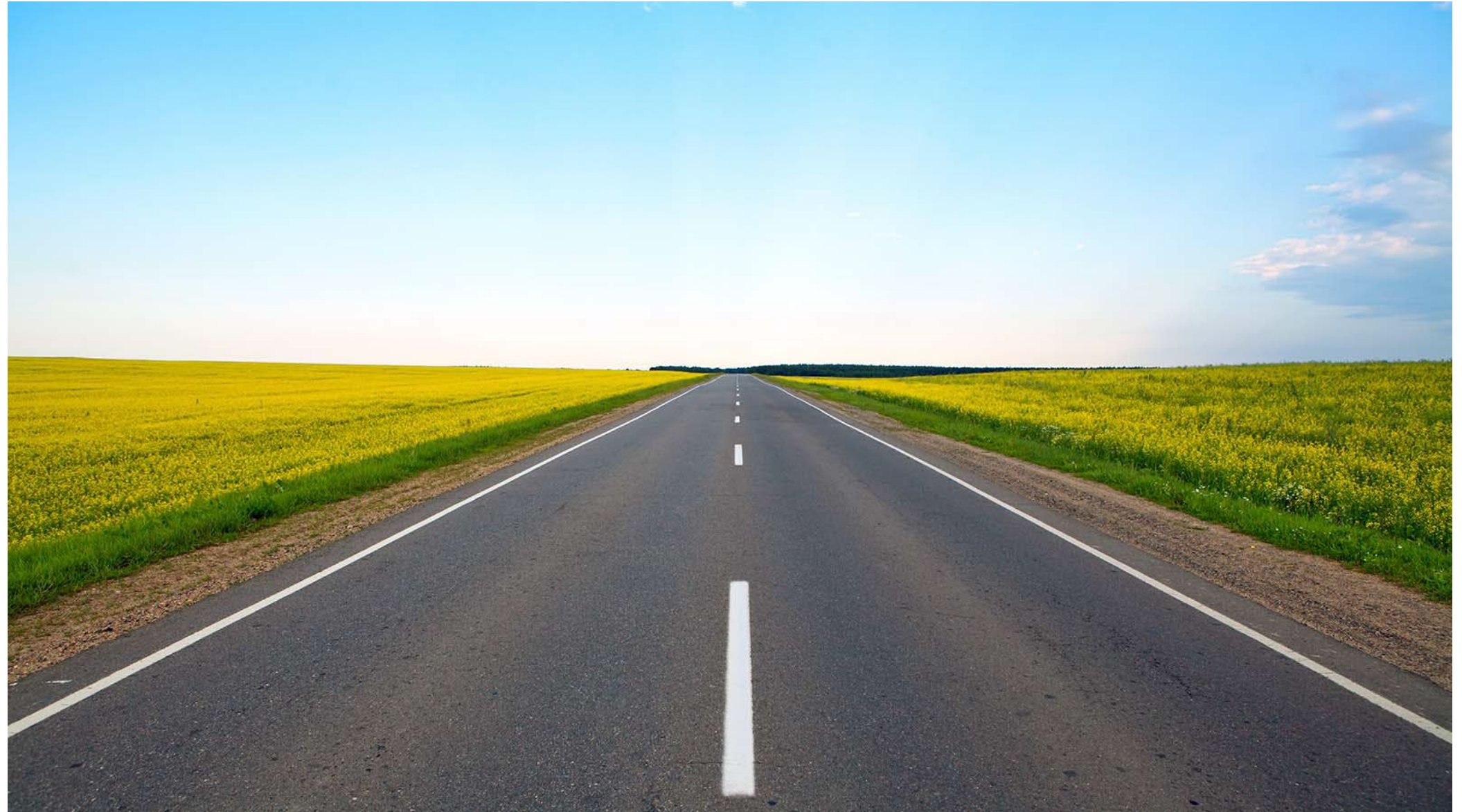
- Proposed new 8,000 sq. ft. set of biotech/GMP labs
- Students can gain practical, hands-on experience in GMP/GLP
- Support a suite of life sciences programming, including biotechnology and GMP/GLP
- Awaiting BRIF funding support





# What is the Role of Canadian Polytechnics in Biomanufacturing in Canada?

- Training programs?
- National collaboration & standardized curriculum with regional influences?
- Infrastructure network?
- Applied research?
- Raising awareness of bio-economy careers?





# Thanks for Listening – Let's Connect!

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**Adam Shane**

