



**Strengthening Canada's biomanufacturing capacity and life sciences sector through regulatory modernization**

CAPRA 2025 Biologics and Biosimilar Symposium  
March 28, 2025, Toronto

Ron Boch, Ph.D.

# Who We Are

BIOTECanada is the national association representing the broad spectrum of Canada's biotech constituents including emerging and established companies in health, agriculture and industrial sectors, as well as academic and research institutions and other related organizations including investors and financial institutions.

- Fully industry-funded
- 220+ members

# Health Biotechnologies

## **Oligonucleotide delivery:**

Ability to deliver oligonucleotides into cells (e.g. lipid nanoparticles).

## **Cell therapies:**

Genetically modified cells, stem cells to treat diseases

## **3D bioprinting:**

Printing of biological tissues and organs, for drug discovery, tissue engineering, and organ transplantation.

## **Gene editing:**

Techniques like CRISPR to enable precise editing of DNA for gene therapy.

## **Protein and peptide therapeutics, radiopharmaceuticals**

Antibodies, next-generation radioconjugates

## **Personalized medicine:**

Tailored treatments based on an individual's genetic makeup through genomics and molecular biology.

# BIOTECanada Mission Statement

Leading the advancement of a globally competitive  
Canadian biotechnology ecosystem.

# Strategic Objectives

1. Increase Canadian biotechnology innovation, research and commercialization.
2. Establish a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology.
3. Establish Canada and Canadian biotechnology as a destination for investment capital.

# National Biotechnology Accord



# HEALTH BASED COMMITTEES & WORKING GROUPS

## Health Advisory Board

Engages leading decision makers on critical issues to ensure innovative life-saving biotechnology treatments are developed in Canada and are available to Canadians. The Health Advisory Board acts through a series of subcommittees to address regulatory, product access intellectual property and industrial development issues that affect the entire biotechnology health-sector from start-up to multi-national.

## Health Advisory Board Working Groups

- **Biologics Regulatory Affairs Group**
- Market Access Working Group
- Next Generation and Orphan Working Group

## Vaccine Industry Committee

Committee members are the leading vaccine manufacturers serving the Canadian market and early-stage Canadian companies developing advance vaccine for Canada, advocates for equitable access to vaccines for all Canadians, and promotes the value of immunization as one of the most cost-effective health interventions available.

## Emerging Companies Advisory Board

CEO advisory board serves the needs of small to medium size member companies, most of which do not yet have major products approved or on the market. It addresses issues affecting smaller companies and facilitates the development of BIOTECanada's programs and policy positions to enhance the development of these companies.

# Biologics Regulatory Affairs Group (BRAG)

**Ambition for Canada is to be a best-in-class jurisdiction attracting new biotech innovations to Canada:**

- Engagement with Health Canada for biologic medicines
- Impact regulatory modernization initiatives
- Improve regulatory performance

# Canada's Biomanufacturing and Life Sciences Strategy

- Canada must continue to ensure it has a best-in-class regulatory system, world-class expertise, and infrastructure for clinical trials through sustained improvements of Canada's regulatory system and the creation of a new Clinical Trial Fund (CTF). These enabling elements are fundamental supports that form the backbone of health innovations, which will attract the best companies and researchers to set up and do their work here in Canada.

[https://ised-isde.canada.ca/site/biomanufacturing/sites/default/files/attachments/1098\\_01\\_21\\_Biomanufacturing\\_Strategy\\_EN\\_WEB.pdf](https://ised-isde.canada.ca/site/biomanufacturing/sites/default/files/attachments/1098_01_21_Biomanufacturing_Strategy_EN_WEB.pdf)

# Ambitious Regulatory Leadership

- Canada's ambition is to be a world leading regulator for new game-changing technologies such as mRNA, cell and gene therapies, gene editing, radiopharmaceuticals and artificial intelligence (AI).
- Health Canada significantly updated and increased the cost recovery fees charged to companies to address the volume of work as well as added complexity from globalization, technological advancement and more sophisticated data and systems.

## **BIOTECanada 2025 Federal Prebudget Recommendation:**

“Health Canada must be resourced to deliver services and expedite the execution on modernizing regulations to remain internationally competitive, meet performance standards, and follow through on Canada's ambition to create a regulatory environment that is “Best in Class” to attract global biotech companies as investors/partners in the ecosystem and as providers of next generation of therapeutics for Canadians.”

<https://www.biotech.ca/news/2025-pre-budget-submission/>

# Thank you

ron.boch@biotech.ca

## Q&A