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# BIOLOGICS MANUFACTURING CENTRE OVERVIEW


**The National Research Council of Canada was mandated by the Government of Canada to establish the new Biologics Manufacturing Centre at our Royalmount site in Montréal, Quebec.**

## PURPOSE

The Biologics Manufacturing Centre will:

- Ensure access to domestic production capacity for vaccines and other biologic products in times of national and global emergencies
- Advance development of the industry in Canada by supporting made-in-Canada vaccines and help accelerate Canadian innovation

## CONSTRUCTION AND FIT-UP COMPLETE

Generally, a new Good Manufacturing Practices (GMP)-compliant biomanufacturing facility can take two years or more to complete.

The construction and interior fit-up of the Biologics Manufacturing Centre was completed after just 10 months. This is one month ahead of schedule.

### Accelerated process

Hiring multiple teams of contractors enabled consecutive work shifts.

The interior fit-up design of the Biologics Manufacturing Centre was completed while the construction of the building shell was taking place.

This accelerated process allowed for a condensed construction schedule, while still addressing all of the many details required to ensure the facility meets GMP compliance.

### Next steps

Although construction and interior fit-up of the Biologics Manufacturing Centre are now both complete, several critical steps remain before actual vaccine production can begin.

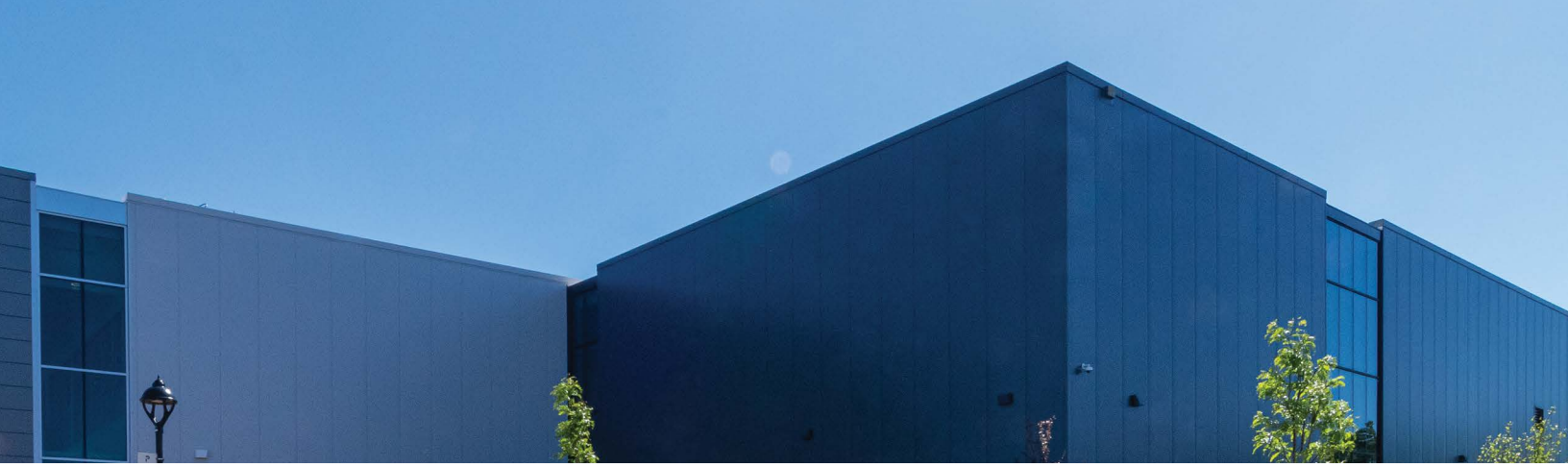
Each of these steps must be customized for the specific vaccine that will be produced:

- **Technology transfer** – to establish the process of making the specific vaccine in the facility
- **Process qualification** – to ensure the process will produce the specific vaccine with precisely the same quality in every dose
- **Health Canada approval** – regulatory checks to ensure the specific vaccine, produced with the specific process, in the specific facility will result in precisely the same quality in every dose

These customized processes and approvals are an essential part of ensuring the vaccines being produced are consistently safe and effective for Canadians to use.

## KEY FEATURES

- Full end-to-end manufacturing capabilities - from scale-up to secondary packaging
- Flexible physical configuration
- Two individual production lines
- GMP-compliant



**Facility characteristics**

- Approximately 5,400 square metres/ 58,000 square feet
- Critical heat, ventilation and air conditioning (HVAC) systems
- Critical purified water and water for injection (WFI) systems
- Large quality control laboratory space
- Cold room storage
- Large warehouse area

**Specialized equipment includes**

- Bioreactors: 50L, 200L, 500L, 2000L
- Chromatography and tangential filtration equipment
- Aseptic filling equipment

## FINANCIAL

**Government of Canada investment**

- $126 million to build the facility
- $20 million per year to cover operating costs

**Status:** On budget

## HUMAN RESOURCES

**Full-time positions expected:** 100

**Full-time positions filled to date:** 60

**Expertise in:** Good Manufacturing Practices, biopharmaceutical/vaccine, cell culture and purification, quality assurance, quality control, manufacturing, supply chain/warehouse, facilities/engineering, manufacturing science, regulatory affairs, and more.

## TYPE OF PRODUCTS

The Biologics Manufacturing Centre will be able to produce cell-based biopharmaceuticals like vaccines and other biologics, including viral vector, protein subunit, virus-like particles, and other recombinant proteins.

## PRODUCTION CAPACITY

The Biologics Manufacturing Centre will have a production capacity of approximately 4000 litres a month.

Based on 500 doses per litre, this would translate into approximately 24 million doses of a vaccine per year.

The number of doses will vary widely depending on the specific vaccine and its manufacturing yield.

## GOOD MANUFACTURING PRACTICES (GMP)

GMP compliance has been an integral part of the Biologics Manufacturing Centre design from the beginning.

GMP regulations ensure that drugs meet the quality standards appropriate to their intended use.

GMP compliance requires that the **people**, **premises**, **processes**, **products**, and **procedures** involved in making a vaccine are doing exactly what they are supposed to do with repeatable precision.

With an end product intended to be administered to people, absolute compliance GMP is required to ensure vaccines produced in the facility are consistent in safety, identity, strength, purity, and quality — every single dose, every single time.

To ensure compliance with GMP regulations, the Health Product Compliance Directorate (HPCD) of Health Canada inspects establishments that fabricate, package or label, distribute, import, wholesale or test drugs. During these inspections, HPCD verifies GMP compliance with Part C, Division 2 of the Food and Drug Regulations.

This is a requirement for issuing a drug establishment licence and to ensure products are safe for human use.

More information on GMP can be found on the Health Canada website.

## CONTACT

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