

BIOLOGICS MANUFACTURING CENTRE AND CLINICAL TRIAL MATERIAL FACILITY KEY FACTS

There are two separate construction projects underway at the NRC's Royalmount site in Montréal that will help support Canada's biomanufacturing production capacity.

The **Biologics Manufacturing Centre** is a new biomanufacturing facility to manufacture vaccines and other biologics for large-scale human use.

Its first priority will be to produce safe and effective COVID-19 vaccines, therapeutics, and other biologics for Canada. The Biologics Manufacturing Centre will also ensure that large quantities of other

vaccines and biologics can be safely manufactured in Canada in the future.

The **clinical trial material facility** is intended to manufacture vaccine and other biologic materials **for clinical trials**. The NRC is completing the final design and engineering work for this permanent GMP-compliant clinical trial material facility. When complete, this facility will support vaccine development at the clinical trial stage.

As a combined capability across the value chain of biologics research, development and production, the Biologics Manufacturing Centre and the clinical trial material facility will strengthen overall biomanufacturing capacity and pandemic readiness in Canada.

The table below explains further the similarities and the differences between the two facilities.

	Biologics Manufacturing Centre	Clinical Trial Material Facility
Funding / Purpose	\$126M to design, construct, commission and qualify a new GMP-compliant end-to-end biomanufacturing facility to produce vaccines and other biologics	\$44M to design, construct, commission and qualify a GMP-compliant permanent clinical trial material facility to de-risk and accelerate vaccine development
Location	On the NRC's Royalmount site in Montréal	On the NRC's Royalmount site in Montréal
Planned Operations	Manufacturing vaccine and other biologics for large-scale human use	Manufacturing vaccine and other biologics materials for clinical trials



	Biologics Manufacturing Centre	Clinical Trial Material Facility
Status	Construction and interior design complete, installation of critical equipment underway	Equipment procured, staff training and procedures underway, completing final design and engineering work
Construction scope	Construction includes: <ul style="list-style-type: none"> • Physical building construction • Interior design and fit-up 	Construction will include: <ul style="list-style-type: none"> • Physical building construction • Interior design and fit-up
Expected completion of construction	Completed June 2021	Summer 2022
Technology transfer	A customized approach for technology transfer, revalidation, and product-specific Health Canada approval will be needed before actual vaccine production can begin	
Vaccine type	Cell-based biologics – i.e. viral vector, protein subunit, virus-like particle based vaccine doses	Cell-based biologics – i.e. viral vector, protein subunit, virus-like particle based materials for clinical trials
Manufacturing capacity	Bioreactor capacity of approximately 4000 litres per month	Bioreactor capacity of approximately 500 litres per month
Number of doses	<p>The number of doses will vary widely depending on the type of vaccine, the manufacturing platform and process as well as its yield</p> <p>Based on information of general yields available for other products, a conservative estimate is 500 doses/L/month.</p> <p>This could translate to approximately 2 million vaccine doses per month</p>	<p>This could translate to up to 250,000 doses per month of vaccine materials for clinical trials</p>

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