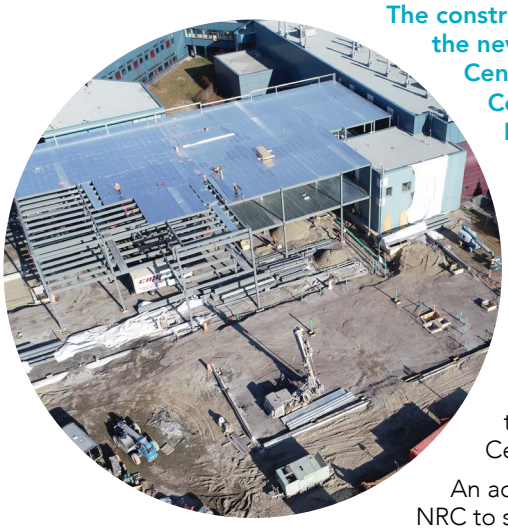
NRC·CNRC

BIOLOGICS MANUFACTURING CENTRE MILESTONES



The construction and interior fit-up of the new Biologics Manufacturing Centre on the National Research Council of Canada's (NRC) Royalmount site in Montréal is now complete, less than one year after breaking ground, and one month ahead of schedule. This and other critical milestones are outlined below.

AUGUST 2020

Design and construction of the Biologics Manufacturing Centre began.

An accelerated pace allowed the NRC to significantly condense the schedule, while still addressing all of the many details required to ensure the facility is Good Manufacturing Practices (GMP) compliant.

DECEMBER 2020

The **exterior shell** of the Biologics Manufacturing Centre was completed, less than six months after breaking ground.

Completing this milestone on schedule allowed the interior construction to take place and the fit-up to start during the remaining winter months, and the overall condensed construction schedule to be maintained.

The **interior fit-up** began, with long-lead equipment ordered and beginning to arrive on site.

FEBRUARY 2021

The Government of Canada signed a memorandum of understanding in February to pursue options to produce Novavax, Inc.'s COVID-19 vaccine candidate in the Biologics Manufacturing Centre. In March, the NRC **signed a collaboration agreement** with Novavax to enable the related technology transfer to begin in early April.

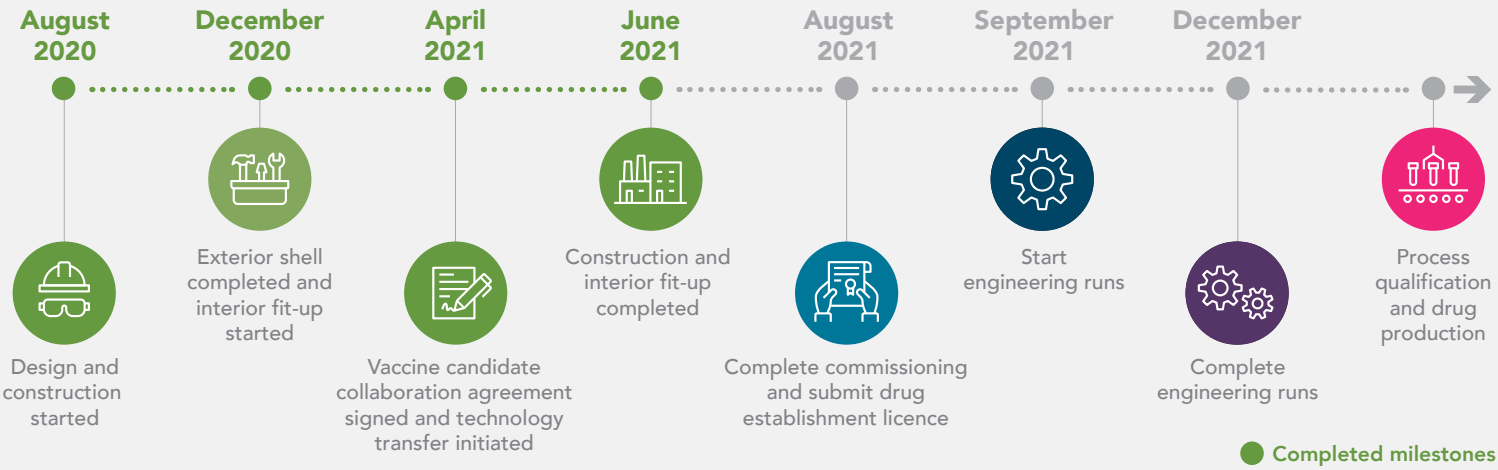
APRIL 2021

The **technology transfer** is a critical step before a product can be manufactured in the Biologics Manufacturing Centre. It must be customized for each specific product that is produced in the facility.

The technology transfer establishes the step-by-step process of making a specific vaccine in the facility, including identifying the product-specific materials and equipment to be used within the facility.

These details are methodically outlined, tested and documented multiple times, to ensure the process will consistently produce the intended product.

In parallel with the technology transfer process, a manufacturing agreement will be established between the Biologics Manufacturing Centre and the vaccine sponsor before full-scale vaccine production can take place.



JUNE 2021

The construction and all interior fit-up for the Biologics Manufacturing Centre was completed in only 10 months, which is one month ahead of schedule. Generally, a GMP-compliant biomanufacturing facility can take two years or more to complete.

This includes the exterior and interior construction, and the receipt and installation of equipment to be ready for commissioning, and GMP qualification and validation.

Preparation is in progress for the following critical milestones in the commissioning, qualification and initial operations of the Biologics Manufacturing Centre.

AUGUST 2021

Commissioning is expected to be complete.

The commissioning of a facility, equipment, or system for operation under GMP regulations involves qualification (the process of determining that all operations, including the facility, utilities, systems and equipment, are suited for their intended purpose). For this facility, that purpose is the production of vaccines for human use.

Application for drug establishment licence is expected to be complete.

Once the commissioning is complete, the Biologics Manufacturing Centre will apply for a drug establishment licence from Health Canada. As a Canadian drug production facility, this licence is required to demonstrate compliance with Good Manufacturing Practices.

DECEMBER 2021

Engineering runs are expected to be complete.

Engineering runs are used to demonstrate full-scale manufacturing in the environment under which the vaccine will be produced, including equipment and processes.

These test runs confirm that the full-scale process will produce the vaccine in accordance with the required specifications and quality characteristics as defined by the vaccine sponsor.

EARLY 2022

Process qualification is expected to be complete

The Biologics Manufacturing Centre will produce process qualification batches, which demonstrate consistent and reliable production of the vaccine using the established process under GMP conditions.

These batches will be tested extensively to ensure the process has resulted in precisely the same quality in every batch and can be approved by Health Canada for human use.

The results of these batches, with the supporting analysis and documentation, will then be submitted by the vaccine sponsor for regulatory approval by Health Canada.

These necessary quality assurance processes and regulatory approvals ensure vaccines produced in Canada are consistently safe and effective for human use. They are complex and can take several months to complete.

The timing for the release and distribution of the vaccine is dependent on when the vaccine sponsor receives regulatory approval.

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