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CLINICAL TRIAL MATERIAL FACILITY OVERVIEW

In spring 2020, the Government of Canada invested $44 million for the National Research Council of Canada (NRC) to design, construct, commission, and qualify a GMP-compliant clinical trial material facility to de-risk and accelerate vaccine development at the NRC's Royalmount site in Montréal, Québec.

SPRING - FALL 2020 READINESS FOR A TEMPORARY FACILITY

Renovation work was undertaken to functionalize a temporary facility within the existing NRC building to be ready for potential production of clinical trial materials.

During this time, the NRC:

- Purchased and received equipment for the clinical trial material facility, such as 50-litre and 500-litre bioreactors and aseptic filling equipment.
- Upgraded existing facilities to prepare for a potential need to produce clinical trial materials under GMP conditions.
- Renovated existing larger-scale purification suites to meet enhanced biosafety guidelines.
- Installed aseptic filling equipment in a temporary location.
- Provided GMP training to researchers.
- Hired GMP specialists such as quality assurance personnel.
- Wrote 150+ standard operating protocols related to GMP compliance and quality assurance framework.

WINTER 2020/21 PLANNING A PERMANENT FACILITY

As priorities shifted during the course of the pandemic, the NRC pivoted to planning construction of a new-build **permanent** clinical trial material facility, which will be an essential **long-term sustainable** part of Canada's biomanufacturing capacity.

This shift meant new site assessments and concept designs were needed to initiate construction of an optimal and flexible facility for future production of clinical trial materials.

The aseptic filling equipment was moved to a permanent location in the NRC's Biologics Manufacturing Centre.

Other equipment purchased for the temporary facility such as bioreactors, will be transferred to the new permanent clinical trial material facility once construction is complete.

PERMANENT CLINICAL TRIAL MATERIAL FACILITY

Design and engineering work is now underway for a new permanent GMP-compliant facility.

The new permanent clinical trial material facility will:

- Enable Canadian vaccines and other biologics to advance to clinical trials in Canada.
- Be a product development bridge between vaccine research and development, and vaccine production of late-stage or authorized products in large quantities elsewhere.
- Be a technology transfer hub to complete verification runs and optimize GMP manufacturing processes.
- Be an essential part of the continuum of building Canada's biomanufacturing capacity.

When it is complete, the new facility will be able to produce clinical trial materials of cell-based biologics, including viral vector, protein subunit, virus-like particles, and other recombinant proteins

Building on more than 30 years of experience in biomanufacturing research and development, the addition of the clinical trial material facility will enable the NRC to support three distinct, but complementary, stages of biomanufacturing in Canada:

- vaccine research and development in the existing research labs.
- GMP-compliant production of clinical trial material at the new clinical trial material facility.
- GMP-compliant vaccine production at the Biologics Manufacturing Centre.

The research and development labs, clinical trial material facility and Biologics Manufacturing Centre could operate together or separately, depending on the requirements for each particular project.

PROJECT MILESTONES

Spring 2021 - New concept plan approved and design, engineering and architecture contracts awarded.

Summer 2021 - Select construction management firm, hire GMP consultant, continue procurement.

Fall 2021 - Begin design and construction.

Winter 2021/22 - Complete detailed design and exterior shell.

Summer 2022 - Complete construction.

Winter 2022/23 - Complete interior fit-up, commissioning and qualification.

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