

How do you build a new facility and start using it at the same time?



The Biologics Manufacturing Centre in Montréal, Québec.

Imagine being asked to build a brand new house. While your new house is still under construction, you need to plan and produce a very special dinner for a few thousand people. You need to plan the menu—before knowing whether the fridge, stove, cookware, flatware and all the necessary ingredients will be delivered in time. You need to make sure everything works properly when it does arrive. You will be preparing new recipes, in a new house, with new equipment for the first time. And you need to do it as quickly as possible. Your meal needs to be approved by a very important food critic before it can be served. Many other people are trying to make a similar meal at the same time. And some of the critical ingredients have limited availability anywhere in the world.

Now, imagine what has been happening at the NRC's Biologics Manufacturing Centre since August 2020, as teams progress through the highly regulated processes required to establish a new biomanufacturing facility, and prepare it to make a new vaccine—a situation that is many times more complex, even more challenging, and which requires extraordinary attention to detail.

Building a specialized biomanufacturing facility and getting it commissioned and licensed for drug production is an enormous, complex, labour-intensive and time-consuming undertaking.

Completing the technology transfer for a new vaccine is also a methodical, labour-intensive, and time-consuming undertaking.

In normal times, building and commissioning the facility, and completing the technology transfer are done in a sequenced manner. But these aren't normal times. Due to the unique circumstances of the COVID-19 pandemic, the NRC was authorized to complete both processes at the same time.

The NRC was given this mandate because we have more than 30 years of experience in vaccine research and development at our Human Health Therapeutics Research Centre, along with a history of solving science-based challenges in emergency situations.

However, the NRC's focus has always been research and development, and the shift to vaccine production required building a new team with the required expertise. The NRC has hired more than 80 specialized biomanufacturing experts over the past year, with expertise in good manufacturing practices (GMP), biopharmaceutical/vaccines, cell culture and purification, quality assurance, quality control, manufacturing, supply chain / warehouse, facilities/engineering, manufacturing science, and regulatory affairs.



A biomufacturing expert at the Biologics Manufacturing Centre prepares the 2,000 L bioreactor for the commissioning, qualification and validation process.

The NRC's teams have been working diligently over many months to overcome pandemic-related challenges. As of January 10, 2022, the NRC has successfully secured the majority of materials required to prepare for the commissioning, qualification and validation process, the technology transfer, and the initial vaccine production, with plans in place to procure the remaining materials.

In addition to hiring staff and procuring materials, since construction of the Biologics Manufacturing Centre was completed in June 2021, the facility has been a steady hub of activity, as dedicated teams work to complete the detailed process of commissioning, qualification and validation of the facility, which is required for all drug production facilities in Canada.

At the same time, the NRC is working on the technology transfer required to produce the first vaccine in the facility, a subunit COVID-19 vaccine developed and owned by Novavax, Inc.

Back to building a house, once it is ready, all the appliances are in and working, you've mastered your recipe and the food critic likes it—now you're ready for your big event. Similarly, once commissioned, the Biologics Manufacturing Centre will be ready for commercial production and for future emergencies.

Read other stories in this series to learn more:
<https://nrc.canada.ca/en/research-development/nrc-facilities/readying-biologics-manufacturing-centre>

●●● Contact

Media Relations,
National Research Council of Canada
1-855-282-1637 (toll free in Canada only)
1-613-991-1431 (elsewhere in North America)
001-613-991-1431 (international)
media@nrc-cnrc.gc.ca

canada.ca/nrc-biologics-manufacturing-centre

© 2022 Her Majesty the Queen in Right of Canada,
as represented by the National Research Council of Canada.
Paper: Cat. No. NR16-390/2022E • ISBN 978-0-660-43405-6
PDF: Cat. No. NR16-390/2022E-PDF • ISBN 978-0-660-43404-9
05/2022 • Également disponible en français