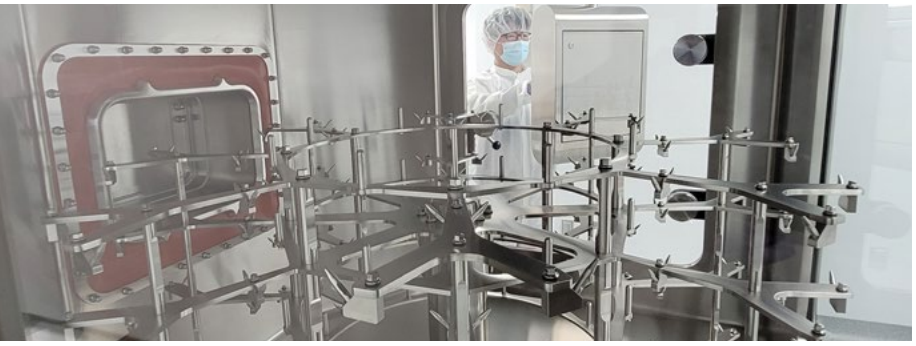
NRC·CNRC

What is inside the Biologics Manufacturing Centre?



A look inside the aseptic filling equipment that will be used for filling sterile vials with vaccine produced at the Biologics Manufacturing Centre.

The NRC is focused on completing the complex commissioning, qualification and validation process for more than 50 rooms and more than 250 pieces of equipment at the Biologics Manufacturing Centre. What is the purpose of some of those 50 rooms? What does the equipment do, exactly? Let's take a closer look at what is inside this new facility.

Production suites

Vaccines produced at the Biologics Manufacturing Centre will be made from billions of microscopic cells, which produce antigens—the part of the vaccine that triggers a body's immune response.

Biomanufacturing experts grow the cells in large bioreactors, where conditions like temperature and oxygen levels can be tightly controlled to provide optimal conditions. As the cells multiply during the production process, the cell culture is transferred to successively larger bioreactors.

This cell growth (also called cell culture) in the production suites is part of the first stage of vaccine production, called upstream processing.

The Biologics Manufacturing Centre has 4 bioreactors in 2 separate production suites, also called clean rooms. The bioreactors vary in size from 50 litres to 2000 litres.

The NRC is completing the testing and documentation required for both production suites, and for all the equipment inside, as part of the ongoing commissioning, qualification and validation process.

The 2000-litre bioreactor is the largest in the Biologics Manufacturing Centre. It holds roughly the equivalent of 12 standard bathtubs.

Downstream processing rooms

The cell mixture coming from the bioreactor must be separated and purified before it can be used for a vaccine. The complex separation and purification process is called downstream processing.

There are many steps in downstream processing. For example, chromatography and tangential flow filtration equipment are used to purify the drug substance, which is the medically active—and most important—ingredient of the vaccine.

Fill and finish areas

Once the vaccine has gone through all the steps in production, it is transported to the filling suite, where it is put into sterile vials using specialized machinery called aseptic filling equipment. (Aseptic is a technical term for sterile.)

Each vial is carefully inspected in inspection booths, then labelled and packaged in the packaging room, and stored in the warehouse until they can be shipped to their next destination. The 8400-square-foot warehouse is also used to receive and store critical vaccine-making supplies.

The Biologics Manufacturing Centre has cold rooms that can store materials between 2 and 8 degrees Celsius, as well as ultra-cold freezers for storage below -60 degrees Celsius!

A biomanufacturing expert at the Biologics Manufacturing Centre works on chromatography equipment as part of the qualification process to ready the facility for vaccine production.

Utilities

There are also many systems constantly running in the background of the Biologics Manufacturing Centre to enable the vaccine production processes to run smoothly, with the absolute sterility required for good manufacturing practices (GMP) compliance, and to ensure that the end product is safe for human use.

Some of these important utilities include complex water purification and water-for-injection systems, and a heat, ventilation and air conditioning system spanning almost the full length of one floor of the facility.

The largest ingredient in most vaccines is very pure water, so water systems are an important part of the equipment at the Biologics Manufacturing Centre.

Quality control laboratory

Compliance with GMP is an integral part of each and every step of vaccine production at the Biologics Manufacturing Centre. GMP compliance and quality assurance protocols are essential to ensuring the products produced in the Biologics Manufacturing Centre will be safe for human use.

Ongoing quality assurance and quality control, including constant testing and verification, ensure GMP compliance, supported by solid documentation at each step in the process. This testing and verification takes place throughout the production process in the quality control lab.

The quality control lab also plays a role in the commissioning, qualification and validation process. For example, quality control experts test microbiology samples from the production suites, and water samples from the water purification systems, using equipment in the quality control lab.

Before the quality control lab can be used to test samples, all the equipment in the quality control lab itself must first be qualified!

This is only a sample of some of the 50 rooms and 250 pieces of equipment currently going through the commissioning, qualification and validation process at the Biologics Manufacturing Centre. Each room and each individual piece of equipment—as well as the overall facility—must be tested, documented and reviewed before Health Canada can issue a drug establishment licence for the Biologics Manufacturing Centre. Qualification teams continue to make progress through this complex undertaking.

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

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canada.ca/nrc-biologics-manufacturing-centre

Paper: Cat. No. NR16-385/2022E • ISBN 978-0-660-43361-5
PDF: Cat. No. NR16-385/2022E-PDF • ISBN 978-0-660-43360-8
05·2022 • Également disponible en français