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What's not inside the Biologics Manufacturing Centre? Dust, dirt and other contaminants.

A member of the Biologics Manufacturing Centre's production team cleaning equipment.

It's logical to assume that a facility that is compliant with good manufacturing practices (GMP) would need to be clean. But just how clean does it really need to be? Squeaky doesn't even come close to describing how clean the Biologics Manufacturing Centre facility really is.

Sanitation is one of the key requirements of the Biologics Manufacturing Centre's commissioning, qualification and validation process. Once Health Canada issues a drug establishment licence, cleaning the facility becomes an ongoing process and an integral part of GMP-compliant operations to ensure the products produced in the facility are safe and free from environmental contamination.

It's a big job

A surface area of approximately 38,000 square feet (3517 m^2) inside the Biologics Manufacturing Centre must be cleaned to consistently meet stringent GMP regulations. That equals the square footage of about 19 average Canadian houses!

The surface area only includes the floors, walls and ceilings. All the equipment, and all the furnishings including work surfaces, tables and carts also need to be cleaned to GMP standards.

Cleaning and sanitizing a biomanufacturing facility is a big job that requires a solid plan, specific tools, properly trained people, and a lot of time!

The plan

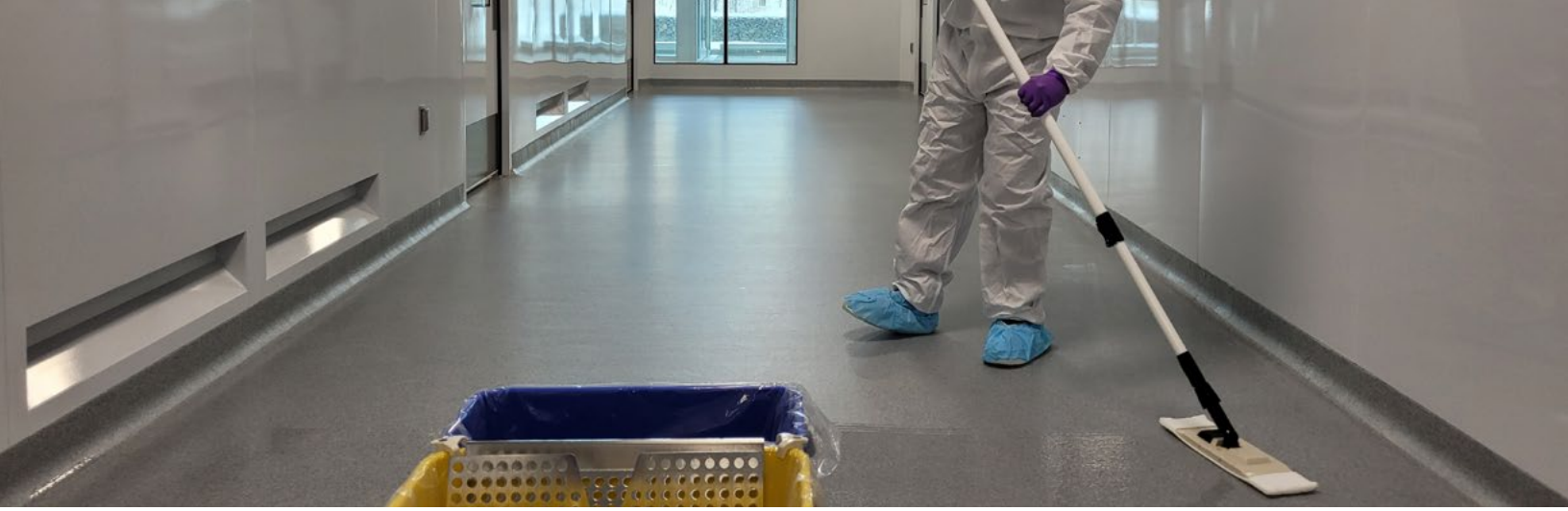
To achieve GMP-compliance, the Biologics Manufacturing Centre must have and execute a detailed sanitation program, including different grades of cleaning required in various areas of the facility.

For example, rooms like the cafeteria, office space and meeting rooms are unclassified, meaning they need to be cleaned like normal office areas with standard janitorial practices.

The areas where the vaccine is made, like the production suites and fill-and-finish areas, are considered higher-grade cleanrooms. They are classified according to limits of particulates in the air and must be cleaned using defined procedures with selected cleaning and sanitizing agents.

The air inside the facility is also purified and free of bacteria. The higher-grade areas use HEPA-filtered, pressure-balanced air-handling systems with air locks designed to keep the inside air pure and within the approved limits of particulates. This environment is constantly monitored to ensure it conforms to acceptable limits.

As an early part of the commissioning, qualification and validation process, the Biologics Manufacturing Centre's sanitation program was finalized in August 2021 and implementation of the program began soon after.



Cleaning is an important part of getting and maintaining GMP compliance for the Biologics Manufacturing Centre.

The right tools

To develop the sanitation program, experts at the Biologics Manufacturing Centre researched, analyzed and selected specific chemical reagents, particular tools and well-defined procedures to sanitize the facility.

Even the water to clean the facility is special—it's the purified water from the water-for-injection system.

Properly trained people

The Biologics Manufacturing Centre has hired a professional cleaning and sanitization company to clean the floors and ceilings. The production team is responsible for cleaning the equipment and their work surfaces.

Experts held workshops to train personnel on cleaning procedures, including how to use the reagents and tools, and how to implement the approved cleaning procedures. This included training on the physical techniques, such as the pull method for ceilings and walls (overlapping strokes starting from top to bottom), and the overlapping S method for the floors (side to side).

A lot of time

An expert at the Biologics Manufacturing Centre wearing a sterile coverall, hairnet, and gloves, before entering a clean area of the facility.

Collectively, the team spends approximately 13.5 hours cleaning the Biologics Manufacturing Centre every single day. In addition to the daily cleaning, there are monthly and annual deep cleans, which each require about 60 dedicated hours.

And then there's the triple clean—named after the 3 applications of reagents, used in a particular sequence with a defined contact time. A triple clean is required every time there is a major shutdown of the facility, after construction or renovations, or if there are issues with maintaining the specified particulate limits for the room.

Taking approximately 147 hours, a triple clean is an important step in transitioning a facility from the construction stage to GMP-compliant status. A triple clean took place at the Biologics Manufacturing Centre after construction was completed in June 2021.

Keeping out the particulates

In addition to the specialized cleaning and sanitation program, keeping the facility GMP-compliant also involves limiting the potential for particulates to get into the clean areas at all.

The cleanliness of the production suites is maintained by ensuring everyone who enters is wearing cleanroom apparel, which prevents particulates from outside being carried into the clean rooms. This includes changing from street clothes into clean laundered scrubs, a sterile coverall, a hairnet, gloves, dedicated shoes and shoe covers.

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

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