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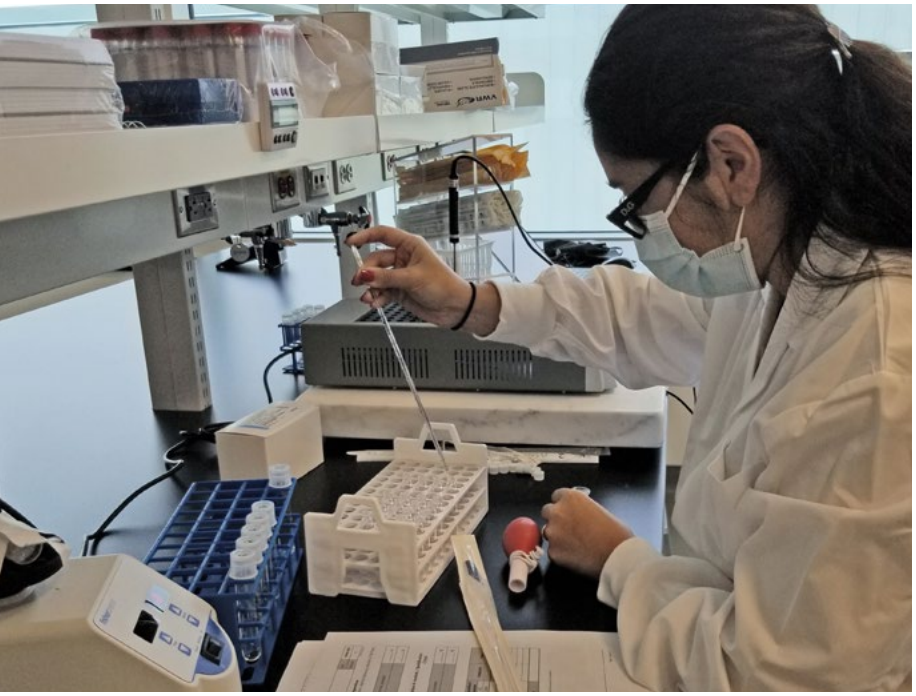
What is commissioning, qualification and validation?



One of the biomanufacturing experts at the NRC's Biologics Manufacturing Centre conducts tests in the quality control lab as part of the commissioning, qualification and validation process.

Before commercial production can begin at the Biologics Manufacturing Centre, the NRC must complete a critical, but also complex and time-consuming process to demonstrate compliance with good manufacturing practices (GMP). One of the GMP requirements is the completion of a process called commissioning, qualification and validation, which is required for all new biomanufacturing facilities in Canada.

GMP compliance is an integral part of the Biologics Manufacturing Centre design. GMP regulations ensure that drugs meet the quality standards appropriate to their intended use.

GMP compliance requires that the people, premises, processes, products and procedures involved in making a vaccine are doing exactly what they are supposed to do with repeatable precision.

With an end product intended to be administered to people, absolute GMP compliance is required to ensure vaccines produced in the facility are consistent in safety, identity, strength, purity and quality—every single dose, every single time.

Essentially, the commissioning, qualification and validation process tests all of the functionality of a facility. It is intended to ensure that each piece of equipment, as well as each room and each system, does exactly what it is supposed to do. As part of this process, the facility itself, as well as all of the rooms and each piece of the new equipment, need to be "qualified" prior to use. All of the qualification work must be completed and documented before being reviewed by Health Canada.

As with any completely new facility with all brand new equipment, minor challenges are expected. As part of the rigorous commissioning, qualification and validation process, all issues need to be formally addressed by the Biologics Manufacturing Centre qualification teams. Similar to an audit, for any issue—big or small— the team will investigate and document the root cause, then propose, evaluate, approve, implement and document the corrective action.

If, at any point during the qualification process, a piece of equipment doesn't operate precisely as it should, or if the testing doesn't provide exactly the expected results, then the qualification process stops. An internal investigation takes place, and once the corrective action is taken and documented, then the qualification steps for that piece of equipment start over again.

Part of the Biologics Manufacturing Centre's extensive heating, ventilation and air conditioning (HVAC) system.

Since June 2021, teams at the NRC have been focused on completing this process for more than 50 rooms and more than 250 pieces of equipment.

In tandem with the qualification process, an important part of demonstrating the facility is compliant with rigorous GMP requirements is to develop an extensive and comprehensive set of standard operating procedures (SOPs) to outline exactly how each piece of equipment, each room, and every process will operate, and exactly how they will be GMP compliant. Teams at the Biologics Manufacturing Centre are developing, reviewing and training on the application of more than 300 SOPs, for everything from how to write a standard operating procedure to how to operate the bioreactor.

The qualification teams at the Biologics Manufacturing Centre have made significant progress in the commissioning, qualification and validation process, including on the testing and documentation required to qualify the clean rooms—areas where the production activities will take place.

Once all the steps in the commissioning, qualification and validation process are completed, Health Canada will do the necessary inspections before granting the NRC a drug establishment licence for the Biologics Manufacturing Centre. This is required for all Canadian drug production facilities.

The commissioning, qualification and validation of the Biologics Manufacturing Centre is happening in parallel with the technology transfer for a subunit COVID-19 vaccine developed and owned by Novavax Inc., which is expected to be the first vaccine that will be produced at the new facility. These 2 complex processes are happening concurrently due to the unique circumstances of the COVID-19 pandemic.

Read the 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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