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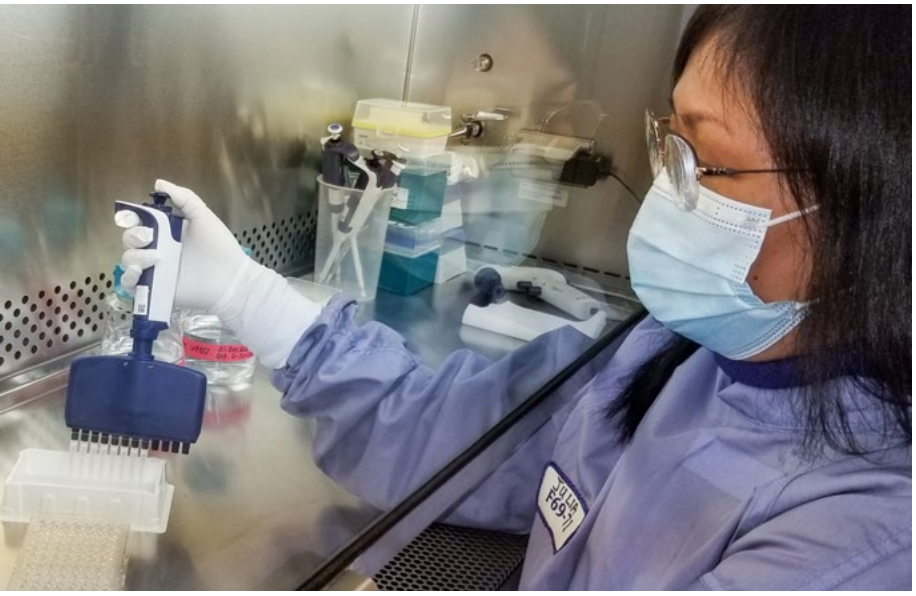
Technology transfer – It's not about downloading files



A scientist from the NRC Human Health Therapeutics Research Centre doing analysis of the concentration and potency of a vaccine during technology transfer.

Every biomanufacturing project is unique. As a biomanufacturing facility, the Biologics Manufacturing Centre will collaborate with different vaccine and biologics development organizations, on a contractual basis, to manufacture their regulatory-approved vaccines or biologics for large-scale production.

As part of these collaborations, a detailed process must take place to transfer the vaccine production process to the facility—this is called a technology transfer. The name makes it sound like a quick process of plugging in a flash drive, downloading a few "how to" guides, and you're good to start making vaccines. In reality, it's a much more complex process.

During the technology transfer, experts at the biomanufacturing facility learn the step-by-step process of how to make the specific vaccine. It takes into account the equipment at the specific facility where the vaccine is being produced, understanding the raw materials and consumables that will be required, and transferring all of the quality control tests.

The technology transfer process includes identifying the product-specific materials and equipment that will be used within the facility. Each material, every piece of equipment and each step in the process are methodically outlined and documented.

Even for technical experts with decades of experience, each technology transfer is essentially starting from scratch every time. Before production can start, teams go through an extensive and methodical learning process to ensure they know everything there is to know about how to make the specific vaccine in the specific facility with complete accuracy—every single time.

During the technology transfer process, test batches are produced and used to demonstrate that the transferred production process will yield an end result that is precisely what is expected by the vaccine sponsor.

Multiple layers of qualification protocols are built into the technology transfer process. These are essential to ensuring the products produced in the Biologics Manufacturing Centre will be safe for human use.

Experts at the NRC are currently preparing the new Biologics Manufacturing Centre to produce its first product—a subunit COVID-19 vaccine developed by Novavax, Inc.

Biomanufacturing experts with the Human Health Therapeutics Research Centre work with the chromatography system, used for purification during downstream processing in vaccine production. This is one of the many steps in the production process for a specific vaccine that experts learn during technology transfer.

Teams from the NRC and Novavax have been working together since March 2021 on the technology transfer for the Novavax COVID-19 vaccine. While that seems like a really long time, it is actually happening at an accelerated pace, especially as the teams are preparing to produce a new vaccine, in a new facility.

In fact, the technology transfer process began in parallel with construction of the Biologics Manufacturing Centre. With extensive experience in vaccine development, including technology transfer, and housed right next door on the NRC's Royalmount site, the NRC's biomanufacturing experts from the Human Health Therapeutics Research Centre were perfectly positioned to take on the first phase of the technology transfer for production of the Novavax COVID-19 vaccine at the Biologics Manufacturing Centre. This enabled the NRC to start working on the tech transfer before the new facility was ready to use for this purpose.

The NRC has now completed technology transfer batches for the Novavax vaccine at smaller scale, which confirmed that the exact process to produce the vaccine can be transferred successfully to the Biologics Manufacturing Centre. The next step in the process will be to scale up the production process and produce technology transfer batches at larger scale. This phase of the technology transfer will happen inside the new facility once the commissioning, qualification and validation process has been completed and all necessary materials have been received, tested and released. The processes are happening in parallel due to the unique circumstances of the COVID-19 pandemic.

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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