



From Cell Culture to Clinics Across the Globe

Vaccine Program Manufactures High-Impact Products for Studies Worldwide

The world needs treatments and vaccines for multiple frightening infectious diseases. Although scientists are diligently evaluating experimental compounds in large trials, this often requires massive quantities of such products.

The Vaccine Clinical Materials Program (VCMP) at the Frederick National Laboratory helps fill this gap. As part of a partnership with the National Institutes of Allergy and Infectious Diseases (NIAID) Vaccine Research Center, it operates the Vaccine Pilot Plant, a state-of-the-art facility that complies with the FDA's current Good Manufacturing Practice standards, where its staff manufactures treatments and vaccines and ships them to study sites around the world.

Ebola Treatment Goes to Africa

The team has put thousands of vials of a new antibody therapy, mAb114, in the hands of clinical staff battling an Ebola outbreak in the Democratic Republic of Congo.

The antibody was one of four treatments studied in the Pamoja Tulinde Maisha (PALM) trial, where it and another product—Regeneron Pharmaceuticals' REGN-EB3—dramatically increased patients' survival. Approximately 66 percent of patients who received mAb114 survived, and the number was even higher—89 percent—among those who had low levels of the virus.

Prior to PALM, average survival during the outbreak was approximately 30 percent. The results from the two treatments were so promising that PALM's principal investigators discontinued the others so all patients could receive either mAb114 or REGN-EB3.

The VCMP manufactured two large batches of liquid mAb114 for PALM in just over a month while simultaneously making products for other trials. The 10,642 vials of antibody were enough to treat approximately 1,600 patients—more than had enrolled at the time.

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On top of that, the team stored, maintained, and shipped 800 vials of freeze-dried powder mAb114 that was manufactured by an outside contractor. The effort included extensive testing to show the FDA that the liquid and powder formulations were of equally high quality.

"All manufacturing steps and most in-process and release testing is performed in-house at the Pilot Plant: We have the ability to make starting cell banks, produce drug substance (bulk), and fill vialled drug product. It's not typical that this range of capabilities are co-located in a one-stop shop," said VCMP Director David Lindsay, Ph.D.

Massive Campaign Makes HIV Antibody

While mAb114 is a testament to the VCMP's short-term production ability, the team is equally adept at larger efforts.

Over five years, they churned out 38 batches of VRC01, an investigational anti-HIV antibody, in parallel with other projects. The batches were converted into more than 150,000 vials of drug product, a quantity that equated to 82.6 kilograms (182.1 pounds)—as much as an adult human.

Reaching and maintaining that level of manufacturing required detailed planning and troubleshooting. The VCMP

dedicated its largest production suite, a 2,000-liter bioreactor, exclusively to manufacturing VRC01 during the project. The expert staff leveraged the Pilot Plant's resources to consistently meet a clinical schedule with tight deadlines.

"It took a cross-functional effort at VCMP and a strong collaborative partnership with NIAID's Vaccine Research Center to make this a reality."

"We have unique capabilities and the ability to respond to and meet increasing clinical demand while balancing [competing] priorities."



David Lindsay, Ph.D.

David Lindsay leads the Vaccine Clinical Materials Program at the Frederick National Laboratory.



Clinicians are using VRC01 in the Antibody-Mediated Prevention study, a series of international clinical trials that opened in 2016 and seek to answer fundamental questions about preventing HIV. The trials enrolled adult men and women who were at high risk for HIV infection but did not have HIV upon enrolling. The goal is to study VRC01-based infusions and determine whether they can protect participants from acquiring HIV for several weeks.

So far, VRC01 has been administered to 4,625 participants at 47 sites across 11 countries.

The manufacturing was a team effort, says Lindsay, and it exemplifies VCMP's capacity and capability to enable trials and infectious disease research worldwide.

Collaborate with the Frederick National Laboratory

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