

Researchers developing compound for cream that may block HIV transmission

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A UNL researcher in the Biological Process Development Facility. Credit: Greg Nathan

Scientists at the University of Nebraska-Lincoln College of Engineering's Biological Process Development Facility have successfully produced a drug compound with potential to block HIV transmission in women.

The compound features the 5P12-Rantes molecule, discovered by scientists at the Mintaka Foundation in Switzerland to block HIV transmission by preventing the virus from attaching to human cells. Mintaka has contracted with the UNL facility to develop the manufacturing method for the compound.

The UNL facility in Othmer Hall has delivered its first batch of the compound to the nonprofit research organization for formulation as a vaginal cream for use in clinical trials in South America. The facility landed the \$3.8 million contract in 2010 from Mintaka to develop this biological production process for the microbicide.

The successful production run also confirms that the manufacturing process developed at the BPDF is ready to be transferred to a large-scale manufacturing facility, said Scott Johnson, Good Manufacturing Practices coordinator for the UNL facility.

Robin Offord, Mintaka's executive director, said his organization is "happy with the robust nature of the process developed at BPDF.

"Properly validated GMP (Good Manufacturing Practices) production is key to Mintaka's plans to empower women and girls in developing countries with a means of protection from HIV/AIDS," he said.

"Already, we have successfully transferred the technology to our collaborating institution in South Africa with excellent pilot scale results."

The BPDF's role in this phase of development illustrates the complexity of bringing drugs to clinical trial, officials said.

Good Manufacturing Practices are the strict guidelines imposed by the Food and Drug Administration for the development and manufacture of all pharmaceuticals, with rigorous procedures to test and validate every

aspect of the development and production process.

UNL's BPDF meets those requirements, following strict quality control standards and scrutiny for the pharmaceutical industry, including long-term environmental and water quality testing.

Johnson said the facility works closely with its clients to develop processes that will produce material suitable for use in [clinical trials](#).

"A client will present us with a gene product they want expressed," he said. "We develop and optimize that process, then scale it up and move the finalized process to our GMP facility for production."

The successful production of 5P12-Rantes was the first to be completed in the BPDF's recently commissioned GMP plant in Othmer Hall. The GMP plant was the first in the nation to be established on a university campus.

Provided by University of Nebraska-Lincoln

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