CSU's BioMARC Wins HIV Vaccine Manufacturing Project

March 2018

BioMARC, a non-profit biologics contract development and manufacturing organization (CDMO) owned and operated by Colorado State University (CSU), has won a large new contract with Sumagen Co., Ltd, a Seoul, South Korea based global biotechnology company to scale up their manufacturing process for an innovative new HIV vaccine candidate. The key task of this new contract is to continue development work by bringing the manufacturing process to full scale volume. Tasks already successfully achieved in the previous contracts between Sumagen Co., Ltd and BioMARC are process technical transfer, creation of a working virus bank, stability testing of the working virus bank, process development, and a pilot manufacturing run of the HIV vaccine. Soon work will start on verification and qualification of analytical methods associated with the production, and preparation for a full-scale cGMP manufacturing production run with associated fill/finish of drug product to be used in upcoming human clinical trials. Sumagen Co., Ltd stated, "We are pleased to continue our development program with BioMARC on this important vaccine and we look forward to a productive partnership with the BioMARC team."

HIV is a disease that has had significant impact on global health for over 3 decades and continues to be an issue today. Since the first cases of HIV were reported in 1981, approximately 1.8 million people in the United States alone have been infected. According to the CDC, HIV disease continues to be a serious health issue for many parts of the world. Worldwide, there were about 1.8 million new cases of HIV in 2016. About 36.7 million people were living with HIV around the world in 2016. An estimated 1 million people died from AIDS-related illnesses in 2016.

"There are very few places with the capabilities and infrastructure to tackle a project of this scientific complexity with such important biosafety considerations," BioMARC Director John H. Wyckoff III, PhD noted. BioMARC offers the unique combination of full cGMP compliant manufacturing within a high containment environment, suitable to handle large volumes of live virus that require biosafety level 3 (BSL-3) containment. The innovative strategy for this vaccine candidate represents the leading edge of what is occurring in biotechnology research and development today. When a new drug candidate transitions from the research stage into higher volume manufacturing, there are a number of technical and regulatory issues that can arise. This is where BioMARC can apply its expertise to help move vaccine candidates further down the path towards testing and potential approval. "Our whole team has been and continues to be very excited to work on a project with such great potential to address a human health problem of this magnitude," added Wyckoff.

BioMARC is part of CSU's Infectious Disease Research Center (IDRC) at the Foothills Campus, where professors and students can work near life science startup companies who rent lab and office space at the Research Innovation Center (RIC) facility. IDRC Executive Director, Professor Raymond Goodrich commented, "This project is a great example of CSU's continuing commitment to the original land grant mission around research and extension. We serve our communities, state, nation and global healthcare communities by applying scientific expertise and world-class infrastructure to address some of the most important unsolved problems in the field of biotechnology and infectious diseases."

About BioMARC

BioMARC is a not-for-profit biologics CDMO owned and operated by CSU serving biopharma companies and government agencies. We specialize in high containment to safely handle BSL-2 and BSL-3, CDC Tier 1 select agents, and spore-forming microorganisms. Project process development and manufacturing are performed under phase-appropriate cGMP conditions for production of pre-clinical, clinical and commercial biologics products. Services include process and method development, cell and virus banking, bulk drug manufacturing, stability, and aseptic/viral fill finish. Projects involve vaccines, therapeutics, and diagnostic reagents in an FDA- and CDC-inspected state-of-the-art facility.

Contact Information

John H. Wyckoff III, PhD
Director BioMARC
BioMARC-Director@colostate.edu
(970) 491-8799

Sandy Brown
Contracts Supervisor
sandra.brown@colostate.edu
(970) 492-4385