

# Biologics Development Module Fact Sheet

## WHAT IS NBAF?

The National Bio and Agro-Defense Facility, or NBAF, located in Manhattan, KS is a national asset operated by the U.S. Department of Agriculture that will help protect the nation’s agriculture, farmers and citizens against the threat and potential impact of serious animal diseases. Equipped with a next-generation facility and situated in proximity to the highest concentration of animal health organizations in the world, NBAF is in a unique position to do diagnostics and training, as well as research and development of veterinary countermeasures — such as vaccines and antivirals — for foreign, emerging and zoonotic diseases in large livestock within the safety and security of this next-generation facility.

## WHAT IS THE BIOLOGICS DEVELOPMENT MODULE?

The Biologics Development Module, or BDM, is a unique proof-of-concept production facility inside NBAF’s secure campus. It is designed to enhance and expedite the transition of innovations from research to commercially-viable countermeasures like vaccines and diagnostics.

The BDM lab space exists outside of NBAF’s main biosafety level-3 and -4 lab spaces operating as a BSL-2 lab space. Within NBAF’s secure campus and with access to facility safety support systems, some portions of the BDM have the capacity to scale up to function as a BSL-3 production space if needed.

## WHY IS THE BDM IMPORTANT?

The transition of research from discovery through proof-of-concept, process optimization, and product licensure carries a significant risk of failure to get a return on investment for industry partners. This is especially true in limited market areas such as transboundary and emerging veterinary pathogens.

Through a project development plan, the BDM will help industry partners see the potential in new discoveries developed through NBAF’s research and de-risk those potential projects so industry stakeholders can understand their return on investment.



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## WHAT IS THE FOCUS OF THE BDM?

The BDM will focus its efforts on:

- Transitioning NBAF research projects into development projects
- Performing proof-of concept studies for safety and efficacy
- Scaling up processes
- Developing analytical tools to support projects.

By reducing the risk undertaken by industry partners, the BDM team hopes to enhance the number of veterinary medical countermeasures available on the market to meet emerging threats to American agriculture.

## HOW WILL THE BDM SUPPORT INDUSTRY?

The BDM will create opportunities for partnerships and collaborations between NBAF scientists and private pharmaceutical and animal health companies to develop new vaccines, biotherapeutics, diagnostics, and pathogen detection products. The BDM will perform the scientific work needed to confirm product efficacy and establish datasets needed for product licensure.

The BDM and its team at NBAF are equipped to perform science at all stages of product development from biological research to manufacturing capabilities. This allows them to undertake whatever work is needed for product development.

As a component of NBAF, the BDM has the capability to plan and facilitate animal studies in cattle, swine, goats and sheep to generate both proof-of concept data as well as the data required for regulatory submissions. The science done within the BDM will reduce the risk for industry partners in getting a veterinary product to licensure and allow for better realization of research discoveries applications.

## HOW MANY USDA EMPLOYEES WILL WORK IN THE BDM?

The BDM will have roughly 10 fulltime employees with diverse skillsets and experiences. In addition to fulltime USDA employees, the BDM can bring in support employees from partner organizations to assist in product development and transition when needed.

## HOW DO NBAF AND THE BDM ENGAGE WITH EXTERNAL PARTNERS?

External partners that have projects fitting within NBAF's mission of protecting the food supply will have access to the BDM's expertise. The BDM will use a diverse toolbox of agreements to facilitate the transition of research to a final product. These agreements will allow the BDM to lower input costs through cost-sharing agreements, meet regulatory requirements for pre-license work, and establish clear pathways to products for research projects.

Anyone interested in learning more about NBAF or the BDM can send questions to [nbaf@usda.gov](mailto:nbaf@usda.gov). Watch [USAJobs](#) and follow NBAF on [Twitter](#) and [LinkedIn](#) for regular updates.

