Since 1958, the Pilot Bioproduction Facility (PBF) has specialized in manufacturing clinical grade drugs and vaccines to combat disease threats faced by U.S. Service Members. The PBF guarantees quality assurance for vaccines and other drugs to be used in preclinical and human clinical trials. Partnering with the PBF is an asset for any researcher, agency, or company that requires pilot scale production according to Good Manufacturing Practice (GMP). The PBF's experienced staff work closely with clients' principal investigators, and apply GMP and proven management control techniques to ensure projects are completed efficiently.

In the coming months, the PBF will undergo a $50 million renovation to expand its services. The renovations, which are expected to last until the fall of 2018, will enable the PBF to produce up to 20,000 vials per fill and provide vaccines and other drugs for Phase IIb clinical trials.

From biosurveillance conducted in our overseas labs to basic science in our headquarter laboratories, WRAIR's Pilot Bioproduction Facility and Clinical Trials Center can transform research into product development and testing.

Clinical Trials Center

The Clinical Trials Center (CTC), established in 1992, conducts primarily phase I trials for candidate drugs and vaccines intended to prevent and treat a variety of infectious diseases. The CTC's integrated and collaborative platforms enable successful and timely execution of first-in-human product development. The CTC also boasts highly skilled and certified staff who are dedicated to maintaining the highest ethical and quality standards. As part of the WRAIR team, the CTC is fully integrated within a network designed to bring products to market.

Since its inception, the CTC has conducted over 150 clinical trials of drugs and vaccines for a variety of infectious diseases, including malaria, Zika, MERS-CoV, Ebola, Japanese encephalitis, dengue, norovirus, shigella, and many others. The CTC can currently conduct 7-10 clinical trials each year and has the capacity and expertise to pivot quickly in accordance with their clients' needs.

Translational Medicine

WRAIR is the Department of Defense's one-stop shop to combat infectious diseases

When tasked with developing preventive measures, such as vaccines or treatments for an infectious disease, WRAIR can be involved in all stages of research and development, beginning with the initial work in labs producing and testing the finalized product.

From biosurveillance conducted in our overseas labs to basic science in our headquarter laboratories, WRAIR's Pilot Bioproduction Facility and Clinical Trials Center can transform research into product development and testing.

CTC Highlights

- Malaria vaccine and drug studies using controlled human malaria infection model
- First-in-human Ebola vaccine study
- First MERS-CoV vaccine clinical trial
- Zika vaccine Phase I clinical trials

The PBF has produced vaccines for a variety of infectious diseases:

- Zika, dengue, malaria, and HIV
- Enteric diseases (shigella, ETEC, typhoid, cholera)
- Hepatitis A
- Plague
- Japanese encephalitis

Pilot Bioproduction Facility

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Translational Medicine
PBF Services

While under construction, the PBF will provide the following services:
- Product and document storage
- Shipment of products and test articles to clients
- Stability testing of products
- Viral testing
- Quality assurance support

Services provided by the PBF when fully operational:
- Pilot-scale production for Phase I-IIb
- Cell Banking
- Fermentation
- Purification
- Formulation/vialing/freeze-drying
- BSL-2

Comprehensive pre-clinical QC testing
- Protein concentration
- Purity
- Potency
- Identity
- Sterility
- Endotoxin

Types of products produced by the PBF:
- Recombinant subunit vaccines
- Live-attenuated and purified, inactivated viral vaccines
- Live-attenuated and killed whole cell bacterial vaccines
- Inactivated bacterial and viral vaccines
- Skin test antigens
- Therapeutic proteins
- Adjuvants, placebos

For more information, including how to partner with WRAIR, call 301-319-9471 or email
usarmy.detrick.medcom-wrair.mbx.pilot-bio-production-facility@mail.mil

www.wrair.army.mil