

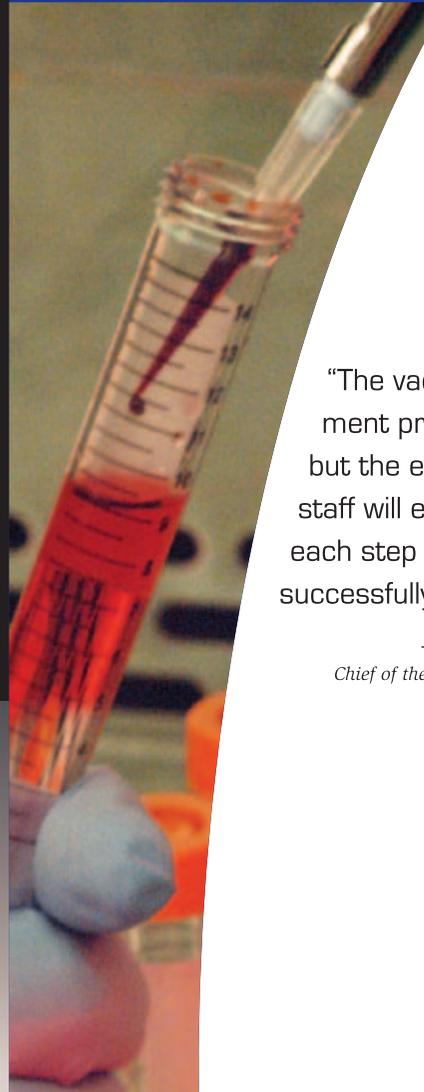
PBF Successes

In the facility's distinguished history, the PBF has received awards and accolades for its role in developing vaccines for diseases like hepatitis A and meningitis. More recently the facility has played a key role in the development of vaccines for dengue fever, malaria, adenovirus, Japanese encephalitis, and shigellosis. Several of these experimental vaccines have progressed to advanced clinical testing and licensing.



Types of products:

- Recombinant subunit vaccines
- Live-attenuated viral vaccines
- Live-attenuated bacterial vaccines
- Inactivated bacterial and viral vaccines
- Skin test antigens
- Therapeutic proteins
- Adjuvants, placebos



"The vaccine development process is complex but the experienced PBF staff will ensure that each step is completed successfully."

— Dr. Kenneth Eckels
Chief of the Pilot Bioproduction Facility



**Walter Reed Army
Institute of Research
Pilot Bioproduction Facility**

503 Robert Grant Avenue
Building 501
Silver Spring, MD 20910-7500

Main Number: (301) 319-9152
Fax Number: (301) 319-9360

Pilot Bioproduction Facility

Vaccines and Biologics

Products for Phase 1-2 Clinical Trials

Pre-clinical Testing



**Walter Reed Army
Institute of Research (WRAIR)**

In partnership with
Clinical Research Management, Inc.

Overview

The Pilot Bioproduction Facility (PBF) located at WRAIR offers manufacturing of clinical grade material for clients in the public and private sectors. The PBF follows all federal regulations that apply to biological products and has special expertise in the development and production of vaccines for the prevention of a variety of infectious diseases.

Established in 1958 as the Department of Biologics Research, the PBF has specialized in developing vaccines for DOD mission-related disease threats. More recently projects for public and private partners have been accomplished through inter-agency and cooperative agreements.

Services

Pilot-scale production for Phase 1/2

- Cell Seed/Bank Production
- Fermentation
- Purification
- Formulation/Vialing/Freeze-drying
- BSL-2

Comprehensive pre-clinical QC testing

- Protein concentration
- Purity
- Potency
- Identity
 - Sterility
 - Endotoxin

The Birth of a Vaccine



“Research Grade Starting Material” submitted



Master and Working Cell Banks are manufactured



Fermentation: Bacterial strain is grown to high densities



Purification: Cell paste is purified into a bulk vaccine



Formulation and Fill: Bulk vaccine is formulated and dispensed into vials.

The PBF guarantees quality assurance during the entire process: compliance, cleanliness, and safety are top priorities. Experienced staff and modern equipment assure the integrity of vaccines.

Classified-air cleanrooms from Class 100,000 to 100 are used for seed preparation, fermentation, purification, and filling.

At the end of this process, the vaccine is tested for safety, potency, and identity, and then is released for use in approved human clinical studies.

Partnering to Bring Vaccines to Market

Forming a partnership with the Pilot Bioproduction Facility (PBF) is an asset for any researcher, agency, or pharmaceutical company with a requirement for pilot-scale GMP production. The experienced staff works closely with a client’s principal investigators to facilitate smooth and efficient projects. The application of GMP and GLP along with proven management control techniques, ensure that all vaccine products are manufactured, monitored, and tested according to specifications during each development phase. Reliable scheduling of production allows timely regulatory approval and planning for clinical trials. Together, researchers, manufacturers, and the PBF can produce vaccines efficiently and within authorized funding allocations.

Partners

WRAIR

NMRC

NIH

USAID

GlaxoSmithKline

Nabi

PATH Vaccine Solutions

Aeras

Universities