

# WRAIR Pilot Bioproduction Facility (PBF)

## FREQUENTLY ASKED QUESTIONS

### What are the PBF's capabilities/services?

- Seed preparation
- Fermentation
- Purification
- Formulation
- Filling
- Lyophilization
- cGMP production for phase 1 & 2 Clinical Trials
- Pre-clinical testing
- Validation
- BSL-2
- Biologics
- Vaccines
- QC Testing
- Sterility
- Identity
- Protein concentration
- Potency
- Scale-up consultation
- Assay development and qualification
- 100% vial inspections
- Extensive Environmental monitoring
- Adapt to many processes
- Non-GMP runs (development runs)

### What does the PBF have to offer?

Efficient, fast, and economical cGMP productions  
Scale up, multi-use facility  
Versatility  
Class 100,000 to 100 clean rooms  
30, 60, 300 liter fermentation tanks  
Water for injection (WFI) usage  
Aseptic Filling  
Yearly fill validations  
Full gowning in clean rooms  
Qualified operators with years of experience  
Quarterly preventive maintenance  
HEPA clean room certification 2x/year  
Long term product storage  
Alarm system for freezers and clean rooms



### What are the PBF manufacturing capacities?

300 liters of fermentation broth; 2,000 vials of finished product.

### How long will it take the PBF to produce a clinical grade product?

After the tech transfer is completed it usually takes less than a year to make a product from start to finish.

### Can the PBF handle any portion of a manufacturing process?

The PBF can work with BSL-2 organisms. The PBF can handle any step of a manufacturing process from seed banking to filling.

### How often is the facility audited?

The facility is audited on a regular basis by various customers; on average 4—8 customer audits per year. A Type V Facility Master File is filed with the FDA.

### What products can the PBF manufacture?

- Skin test agents
- Adjuvants
- Microspheres
- Therapeutic proteins
- Placebos
- Complexes/Conjugations
- Recombinant subunit vaccines
- Live-attenuated viral vaccines
- Live-attenuated bacterial vaccines
- Inactivated bacterial and viral vaccines



### How does private industry deal with a government facility?

The PBF uses CRADAs and Inner Agency Agreements (IAAs). Contact the PBF Chief, Kenneth Eckels at (301) 319-9233 for more information.

### Who are PBF's customers?

WRAIR and government agency researchers and industrial partners throughout the world .

### Who do I contact for further questions?

WRAIR Pilot Bioproduction Facility:  
Kenneth Eckels, Chief, (301) 319-9233  
Rick Millward, Deputy Chief, (301) 319-9322

### How many people are employed at the PBF?

35 (currently)

### How can I arrange a tour of the PBF?

Contact Ken Eckels at (301) 319-9233

### What is the relationship between the PBF and Clinical Research Management (CRM)?

CRM has a government contract with WRAIR to supply the PBF with personnel to work at the facility.

#### THE PBF MISSION

The PBF mission is research, development, production, and testing of vaccines for human use. The PBF at Forest Glen is a multi-use facility designed and operated for production of vaccines in compliance with current Good Manufacturing (cGMP) regulations. Compliance with cGMP ensures that products prepared in the facility will be safe, potent, and reproducible. Vaccines are produced that will protect soldiers against diseases they might encounter in areas of deployment. These include vaccines to prevent shigellosis and other diarrheal infections, dengue, malaria, meningitis, and HIV.



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