BARDA International Influenza Vaccine Manufacturing Capacity Building Program

Julie Schafer
Influenza Division
Biomedical Advanced Research and Development Authority (BARDA)
Objectives:

- Protect people by reducing the global risk of influenza
- Develop and sustain influenza vaccine manufacturing capabilities and capacity for pandemic readiness
- Promote international investment, diplomacy and partnerships
- Achieve sustainable influenza vaccine production capacity worldwide by leveraging BARDA’s unique resources

Approach:

- Expanding global vaccine manufacturing capacity
- Ensuring a skilled workforce that knows how to make cGMP quality vaccine
- Provide in-country technical implementation assistance
BARDA Multifaceted Approach

Manufacturing, Technical, Analytical Infrastructure = WHO

Clinical Trial & CMC Development = PATH

Technology Transfer of Adjuvant = UNIL & IDRI

Direct Technical Support = USU & NCSU/BTEC

Regulatory & Clinical Support

Trajectory for the Future

- Advance clinical development of influenza vaccine by at least ten developing country vaccine manufacturers
- Licensure of influenza vaccine by at least nine developing country vaccine manufacturers
- Enhance technical skills and best practices through training in advanced manufacturing and in-country technical support
- Production capability for 500M doses of pandemic vaccine in 2016
BARDA International Initiative: Current Priorities

• Cooperative agreement with PATH for expansion of targeted clinical trial and manufacturing technical support

• Cooperative agreement with WHO for continued support of GAP for Influenza Vaccines

• Continuation, and evolution, of Biomanufacturing Training Program

• Continued interest in supporting development of adjuvants for use in influenza vaccines

Goal is licensure of influenza vaccines