



# FLU CELL CULTURE FOR PANDEMIC PREPAREDNESS

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Patrick Bastek, Ph.D.

Senior Director, Technical Development

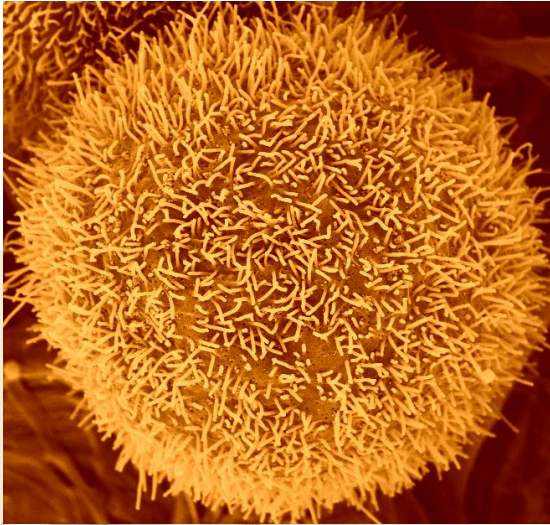
# Holly Springs Mission

*In Holly Springs our Mission is to manufacture life saving, preventive vaccines. At the core of this Mission is our commitment to the US Government to produce 200 million doses of pandemic flu vaccine to protect the US population within 6 months of a declared pandemic.*

*Seasonal is our business. Pandemic is our purpose.*



# Flu Cell Culture Manufacturing Technology



- 15 years of experience in developing FCC technology for flu vaccines
- Robust, consistent, and reproducible means of vaccine production<sup>1</sup>
- Potential reduction of lead time by weeks – Critical in the event of a pandemic
- No reliance on hens or roosters, especially important in an avian flu outbreak
- Produced in a closed bio-reactor system with readily available and standardized ingredients fully independent from animal-derived components
- Reduced risk of introduction of exogenous or endogenous adventitious agents<sup>1</sup>
- Enables Class III biosafety standards

<sup>1</sup> WHO 2007. Initiative for Vaccine Research. Use of Cell Lines for the Production of Influenza Virus Vaccines: An Appraisal of Technical, Manufacturing, and Regulatory Considerations

# Holly Springs Facility

- **Production Facility**

- Highly automated, state of the art technology and construction
- >486,000 ft<sup>2</sup> of finished space
- ~500 Seqirus employees on site
- Named International Society of Pharmaceutical Engineering (ISPE) Facility of the Year in 2013

- **Capabilities**

- Bulk Flu Cell Culture (FCC) production
- MF59 production
- Formulation, Aseptic Filling, Inspection, and Packaging
- Technical Development (TD) laboratories and small-scale production facilities to support development opportunities

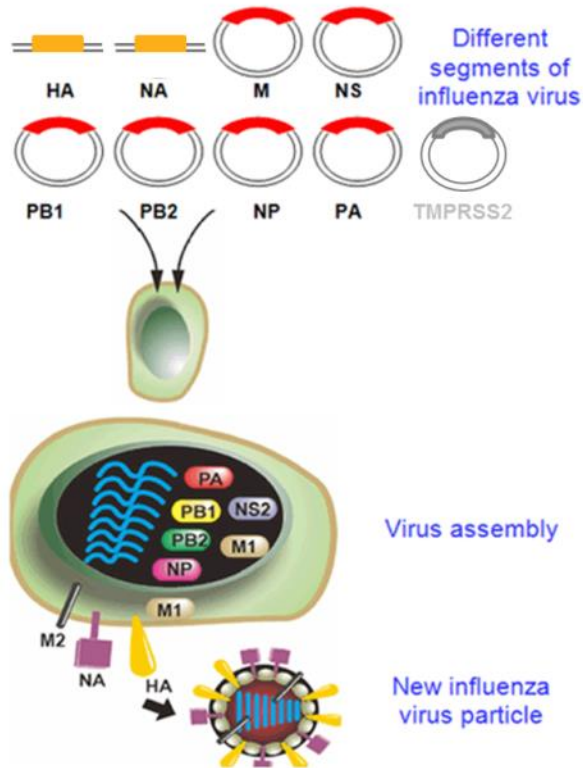
# Seqirus / HHS Partnership

## Holly Springs, North Carolina



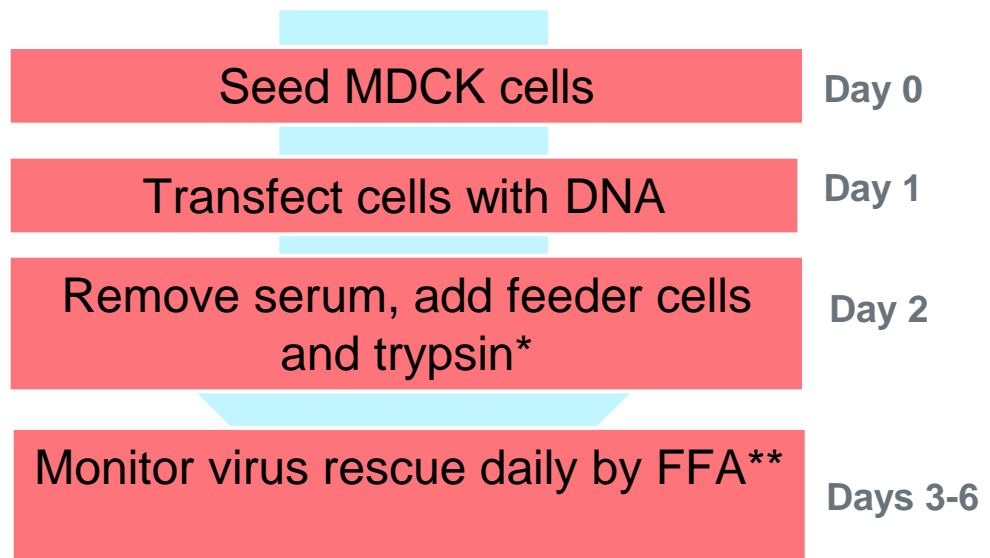
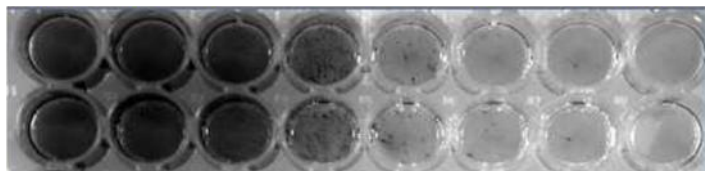
- Facility on US soil was a “must”
- Strategic advantages to building in Holly Springs
  - Experienced and relevant talent base
  - Best supporting education infrastructure
  - Low operating costs
- Collaboration between US Department of Health and Human Services (HHS) and Biomedical Advanced Research and Development Authority (BARDA)
- Have seasonal, pre-pandemic, and pandemic vaccine capability
- The facility represents a significant financial commitment for Seqirus and HHS
- We also have one of three Advanced Development and Manufacturing contracts
  - Provides enhanced medical counter measures, product development capabilities, and ensuring domestic vaccine manufacturing surge capacity

# Established robust process to rescue influenza virus using synthetic gene segments in vaccine-approved MDCKs



Virus titration →

Undil 10<sup>-1</sup> 10<sup>-2</sup> 10<sup>-3</sup> 10<sup>-4</sup> 10<sup>-5</sup> 10<sup>-6</sup> no virus



**Confirmed rescues = 4 - 7 days**

\* Replenish trypsin concentration every 48h if rescues take longer than 3 days.

\*\* focus-formation assay; based on immunological staining of viral nucleoprotein in infected cells

# H7N9 – Unprecedented Rapid Response to Novel Threat

*Risk-taking facilitated by long-standing trust and partnership*

**Mar 31: 1<sup>st</sup>**  
H7N9 Cases  
Reported

