Influenza Vaccine Manufacturing in Insect Cells

September 18, 2007
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Novavax, Inc. is developing an Influenza Virus-Like Particle (VLP) Vaccine as an alternative to traditional influenza vaccines.

The process uses recombinant baculovirus to infect and express VLPs that contain Hemagglutinin (HA), Neuraminidase (NA), and Matrix (M) Protein.

The proteins self-assemble as particles that resemble influenza virus, but do not contain flu RNA.

The approach has a number of quality and manufacturing advantages to the traditional influenza manufacturing processes.
Influenza Vaccine Manufacturing in Insect Cells

Novavax, Inc.
H5N1 Flu VLP

Influenza Virus

Envelope HA/NA Spikes
Influenza Vaccine Production

Egg-based Flu Vaccine Production:
- Grow, Collect, & Fertilize Eggs
- Infect with Influenza Virus
- Incubate 32 – 37°C
- LS/HS Centrifugation, Diafiltration, Chromatography
- Treat with Formaldehyde (subvirion products treated with detergent)

Mammalian Cell-Culture-based Flu Vaccine Production:
- Thaw vial from WCB
- Grow to Mfg Scale
- Infect with Recombinant Baculovirus
- Incubate 32 – 37°C
- LS/HS Centrifugation, Diafiltration, Chromatography
- Treat with Formaldehyde (subvirion products treated with detergent)
Influenza Vaccine Production

Cell Substrate Preparation → Infect & Incubate → Remove Cells, Purify Virus → Inactivate Virus

Insect Cell Culture:

Thaw vial from WCB → Grow to Mfg Scale

Infect with Influenza Virus → Incubate 22-27°C → MF/DF, Chromatography → baculovirus inactivated
Influenza Vaccine Production

- Upstream Advantages of Insect Cell Culture
  - Simplicity/security of supply chain versus egg-based approach
  - Lower variation of yield compared to using live flu virus
  - Timing of new strain availability
    - No adaptation of new virus strains to cell line
    - Insect process requires only the gene sequence of the strain
    - Product available in about 2 months from identification of sequence
  - Suspension Culture
Influenza Vaccine Production

- Upstream Advantages of Insect Cell Culture
  - Process Yield Higher than Mammalian Cell Culture
  - Avoid use of live influenza virus
    - Eliminate requirement for facility containment
    - No risk of infecting employees
    - No influenza virus RNA
    - No risk of reassorting event with circulating disease
Influenza Vaccine Production

Quality Advantages of Insect Cell Culture

- Strain selection based on risk of circulating disease versus ability to produce
  - Comprise sometimes required to ensure sufficient supply
  - No compromise required with recombinant approach
- Use of native protein conformation
  - No requirement for reassorting, reverse genetics, or adaptation to cell culture system which can alter the viral proteins
  - Lack of live flu virus obviates need for inactivation with formaldehyde, which may also alter influenza proteins
Influenza Vaccine Production

Downstream Advantages of Insect Cell Culture

– Traditional approaches can be used for purifying VLPs from the cell culture harvest
– Novavax, Inc has developed a process using proven technology for pandemic and seasonal flu strains:
  • VLP purity is ~90%
  • Yields are higher than egg-based production (based on mcg HA/L of harvest) and expected to improve during process development
– The use of Insect cells has allowed Novavax, Inc to develop a process that uses disposable equipment and closed systems for product processing
Influenza Vaccine Production
The Disposable Approach
Influenza Vaccine Production

Advantages of Disposable/Closed Manufacturing Approach

- Reduced process equipment complexity
- Reduced facility complexity and cost
- Rapid expansion of capacity
- No change-over cleaning/validation between strains/products
- LEAN manufacturing approach
- Significant reduction in facility/equipment validation (>50%)
- Manufacturing cost structure shifted to variable costs
  - Significant reduction in capital equipment costs (>70%)
  - Supports a regional manufacturing approach
# Comparison of Flu Mfg Technologies

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Egg based</th>
<th>Mammalian Cell Culture</th>
<th>Insect cell culture in disposable technology</th>
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<tbody>
<tr>
<td>Simple/secure of supply chain</td>
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<td>P</td>
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<td>Fast response to new/late strain</td>
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<td>High Yield</td>
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<td>Low Yield Variation</td>
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<td>Low Facility Cost (Containment Level)</td>
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<td>Fast Validation Time</td>
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<td>Ease of scale up (Suspension Culture)</td>
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