# HIV ENV MANUFACTURING WORKSHOP

**A workshop sponsored by the**
**Division of AIDS/NIAID/NIH and the Global HIV Vaccine Enterprise**

**June 11, 2015 8:30 a.m. to 4:30 p.m.**
**June 12, 2015 8:30 a.m. to 12:30 p.m.**
**Conference Room 1D13, 5601 Fisher's Lane, Bethesda, MD**

**Goals and objectives:**

- *To provide an update on the status of manufacturing of HIV ENV antigens for planned clinical evaluations*
- *To exchange information and experiences encountered when transitioning form production of ENV proteins in the research setting to production as investigational clinical products.*
- *To discuss and identify pathways and strategies for improving the model for clinical manufacturing of ENV Proteins*

**DAY ONE**

| | | |
|---|---|---|
| 8:30–8:35 | **Welcome and Introduction** | Jane Halpern |
| 8:40–9:10 | HIV ENV Vaccine Manufacturing Landscape: Challenges and Paths Forward | Michael Pensiero |
| 9:10–9:45 | Unique Challenges Associated with the Production of Viral Glycoproteins | Dick Schwartz |
| 9:45-10:15 | Strategies on Improving the AIDSVAX® Vaccine | Phil Berman |
| 10:15–10:30 | **BREAK** | |

**Session 1 – Technical Challenges and Case Studies of HIV ENV Candidates (moderator Phil Berman)**

| | | |
|---|---|---|
| 10:30-11:15 | gp140 Clade C production in the Per.C6 platform: A collaboration between BIDMC, DAIDS and Janssen | Iedo Beeksma |
| 11:15-12:00 | Cell Line Selection and Purification Strategies | Shan Lu |
| 12:00-1:00 | **LUNCH** | |
| 1:00-1:45 | Development of a manufacturing process for clinical production of gp120 based envelope proteins | Abhinav Shukla |
| 1:45-2:30 | Production of HIV ENV proteins for P5 Clinical Studies | Fred Porter |
| 2:30-3:30 (moderators) | Session 1 Panel Discussion | Phil Berman / Yegor Veronin |
| **3:30-3:45** | **BREAK** | |

*Conference attendees and/or presenters are responsible for meals and/or light refreshments on their own and at their own cost. Government staff and/or Government contractors may not be involved in the provision or facilitation of food and/or light refreshments for conference attendees and/or presenters.*

| | | |
|---|---|---|
| **3:45-5:00** | **Session 2 – Strategies for Increasing the HIV Env Vaccine Pipeline**<br>*Technical Approaches* | |
| 3:45-4:20 | Characterizing non-native forms of Env and assessing strategies to remove them | Heather Desaire |
| 4:20-5:00 | Use of MAbs for Env Purification: Principles and Experiences | John Moore |
| 5:00 | **WRAP-UP / QUESTIONS** | |
| | **END DAY ONE** | |
| | **DAY 2** | |
| 8:30–8:35 | Introduction | Tina Tong |
| **8:35–12:30** | **Session 2 (Continued)**<br>*Technical Approaches (Continued)* | |
| 8:35-9:00 | Transient Transfection | Jeff Pullen |
| 9:00-9:30 | Use of STEP™ Technology for HIV ENV production | Chris Yallop |
| 9:30-10:00 | Technologies Applied to the Development of Full Length Single Chain | Tim Fouts |
| 10:00-10:15 | **BREAK** | |
| **10:15-10:45** | **Q&A/ Discussion Session** | |
| | *Programmatic Approaches and Shared Learning Efficiencies* | |
| 10:45-11:00 | DAIDS Process and Analytic Cores Overview | Jane Halpern |
| 11:00-11:20 | Vaccine Product Development Center at IAVI | Tom Hassell |
| | *Regulatory Considerations* | |
| 11:20-11:30 | Update on FDA Feedback | Jane Halpern |
| 11:30-11:50 | Strategies for Facilitating Regulatory Pathways | Tanya Kersten |
| 12:00-12:30 | **Q&A / Wrap up** | |

*Conference attendees and/or presenters are responsible for meals and/or light refreshments on their own and at their own cost. Government staff and/or Government contractors may not be involved in the provision or facilitation of food and/or light refreshments for conference attendees and/or presenters.*