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** *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)** *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**	

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