

2nd Env Manufacturing Workshop

Location: NIAID, NIH
5601 Fishers Lane
Rockville, MD 20852

Date: Thursday, September 15, 2016

Organizers: Antu Dey, International AIDS Vaccine Initiative (IAVI)
Stephen Hadley, Bill and Melinda Gates Foundation
Jane Halpern, NIAID, National Institute of Health (NIH)
Shan Lu, University of Massachusetts Medical School
Michael Pensiero, NIAID, National Institute of Health (NIH)
Jerry Sadoff, Janssen Pharmaceutical Companies
Yegor Voronin, Global HIV Vaccine Enterprise

Agenda

8:30 – 8:40	Welcome and Objectives, Yegor Voronin (Global HIV Vaccine Enterprise)
8:40 – 9:15	Overview: Progress since 2015 and the state of the field, Michael Pensiero (NIH)
Session 1: Protein Production	
Chair: Jerry Sadoff (Janssen Pharmaceutical Companies)	
9:15 – 9:50	Choosing the right protein, <i>Hans Langedijk (J&J)</i>
9:50 – 10:25	Expression of native flexibly linked (NFL) HIV Env trimers from stable CHO lines, <i>Antu Dey (IAVI)</i>
10:25 – 10:45	Coffee break
10:45 – 11:20	Evaluation of recombinant prokaryotic lectins for capture of highly glycosylated proteins, <i>Prathima Acharya & Abhinav Shukla (KBI Biopharma Inc.)</i>
11:20 – 11:55	Case study: Considerations for P5 protein manufacturing scale-up, <i>Susan Barnett (GSK)</i>
11:55 – 12:40	Lunch break
Session 2: Formulation Science	
Chair: Stephen Hadley (Bill and Melinda Gates Foundation)	
12:40 – 1:15	Basic framework for formulation, <i>David Volkin (U.Kansas)</i>
1:15 – 1:50	Case study of formulating protein for P5, <i>Antu Dey (IAVI)</i>
1:50 – 2:25	Case study of formulating protein for Janssen program, <i>Thierry-Thien Nguyen (Janssen)</i>
2:25 – 2:40	Coffee break
Session 3: Packaging and Viral Clearance	
Chair: Jane Halpern (NIAID, NIH)	
2:40 – 3:15	Impact of storage conditions and/or storage containers, <i>Roger Asselta (Genesis Pack. Tech.)</i>
3:15 – 3:30	Short talk: Challenges to the vialing of final products, <i>Shan Lu (U. Massachusetts Medical School)</i>
3:30 – 4:05	Viral clearance, <i>Kathy Remington (BioReliance)</i>
4:05 – 4:15	Wrap up