

Third HIV Env Manufacturing Workshop
Sponsored by the
Division of AIDS/NIAID/NIH and the Global HIV Vaccine Enterprise
 July 20-21, 2017
 Conference Room 1D13, 5601 Fisher's Lane, Bethesda, MD

DAY 1		
TIME	TOPIC	SPEAKER
8:25 – 8:30	Welcome and Introduction	Jane Halpern, DAIDS
8:30 – 9:30	FUNDER UPDATES NIAID Activities BMGF Activities	Mary Marovich Susan Barnett
	APPROACHES TO ACCELERATE PHASE 1 MANUFACTURING	SESSION CHAIR Jane Halpern, DAIDS
9:30 – 10:10	HIV Env Manufacturing Landscape – Updates and Challenges	Michael Pensiero, DAIDS
10:10 – 10:50	Acceleration of Phase 1 Manufacturing	Fredrick Porter, DHVI
10:50 – 11:20	BREAK	
11:20 – 12:00	Advances in HIV Env Antigen Manufacturing to Improve Timelines and Product Quality/Productivity	Dan Gowetski, VRC, NIAID
12:00 – 12:30	Progress and Future Plans of European AIDS Vaccine Initiative (EAVI)	Dietmar Katinger, Polymun
12:30 – 1:30	LUNCH	
1:30 – 2:30	SHORT UPDATES ON ONGOING PROGRAMS BG505 SOSIP.664 (Antu Dey) eOD-GT68 60 mer (Vadim Tsvetnitsky) 426c.Core-C4b (Rob Kegel) GTH1-656 MPER Peptide Liposome (Vadim Tsvetnitsky)	SESSION CHAIR Yegor Voronin, Enterprise
2:30 – 3:00	BREAK	
	CURRENT CHALLENGES AND TECHNICAL INNOVATIONS	SESSION CHAIR Susan Barnett, Gates Foundation
3:00 – 3:20	Progress in improving HIV Envelope Manufacturing Processes	Phillip Berman, UCSC
3:20 – 3:40	Transient transfection	Michael Pensiero, DAIDS
3:40 – 4:00	Avoiding non-technical pitfalls in CMO selection and contract negotiation	Ericka Sjogren, Fred Hutchinson
4:00 – 5:00	PANEL DISCUSSION	

DAY 2		
TIME	TOPIC	SPEAKER
	PRODUCT DEVELOPMENT FOR EARLY STAGE CLINICAL HIV VACCINE STUDIES	SESSION CHAIR Antu Dey, IAVI
8:30 – 9:10	Introduction – Overview Accelerated Product Development for Phase I/II clinical evaluation – balancing science, time and cost	Antu Dey, IAVI
9:10 – 9.45	Phase I product development at a biotech – managing science, time, cost and risk	Nicholas Vrolijk, Celldex Therapeutics, Inc.
9:45 – 10:20	Phase I product development at CMOs – managing science, time, cost and risk	Abhinav Shukla, KBI Biopharma, Inc.
10:20 – 10:55	Formulating HIV Env as frozen drug product for Phase I testing – Key considerations	Bruce Kerwin, Just Therapeutics
11:00 – 12:00	PANEL DISCUSSION –Best practices, Common findings, Exceptions	
12:00 – 1:00	ADJOURN & CLOSING REMARKS	