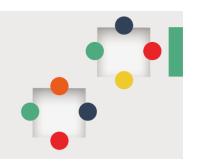
• aaps Workshops

AAPS GUIDANCE FORUM

SEPTEMBER 11-12, 2018 • SILVER SPRING, MD



Agenda

Tuesday, September 11, 2018

Guidance: Drug products, including biological products, that contain nanomaterials

7:30 am – 8:30 am Registration Check-In / Coffee

8:30 am – 8:45 am Welcome and Opening Remarks

Vinod P. Shah, Ph.D., VPS Consulting LLC.

8:45 am – 9:30 am **Regulatory Perspectives – Overview of the Guidance**

Katherine Tyner, U.S. Food & Drug Administration (Invited)

9:30 am – 10:15 am **Industry Perspectives**

Daryl Drummond, Merrimack Pharmaceuticals

10:15 am - 10:30 am Coffee Break

10:30 am – 11:15 am Regulatory Research in Nanomedicine Drug Products

Wenlei Jiang, U.S. Food & Drug Administration

11:15 am – 11:30 am Stakeholder Concerns and Challenges

Vinod P. Shah, Ph.D., VPS Consulting LLC.

11:30 am – 12:30 pm Lunch

12:30 pm – 2:30 pm **Breakout Session**

Scott McNeil, Ph.D., Frederic National Lab

Katherine Tyner, U.S. Food & Drug Administration (Invited)

Sesha Neervannan, Ph.D., Allergan

Wenlei Jiang, U.S. Food & Drug Administration

Jon de Vlieger, Lygature

	Daryl Drammon, Merrimack Pharmaceuticals
2:30 pm – 2:45 pm	Coffee Break
2:45 pm – 3:45 pm	Summary of Breakout Sessions
	Vinod P. Shah, Ph.D., VPS Consulting LLC.
3:45 pm – 4:45 pm	What We Learned: Nanomedicines, Issues, Discussion and Next Steps
	Daan Crommelin, Utrecht University
4:45 pm – 6:00 pm	Networking Reception

Wednesday, September 12, 2018

Guidance: Assay Development and validation for immunogenicity testing of therapeutic protein products.

Registration / Coffee
Welcome and Opening Remarks
Vinod P. Shah, Ph.D., VPS Consulting LLC.
Regulatory Perspectives and Updates
Susan Kirshner, Ph.D., U.S. Food & Drug Administration (Invited)
Industry Perspectives
Boris Gorovits, Ph.D., Pfizer
Coffee Break
Immunogenicity – In House and External Research
Daniela Verthelyi, U.S. Food & Drug Administration (Invited)
Best Practices
Lauren Stevenson, Biogen
Stakeholders Concerns and Challenges
Vinod P. Shah, Ph.D., VPS Consulting LLC.
Lunch
Breakout Session
Vishwanath Devanarayan, Nthrys Biotech Labs
George Gunn, Ph.D., GlaxoSmithKline

	Ronald Bowsher, Ph.D., B2S Life Sciences
	Renuka Pillutla, Ph.D., Bristol-Myers Squibb
	Heather Myler, Ph.D., PPD
	Adrienne Clement-Egan, Ph.D., Janssen R&D
3:15 pm – 3:30 pm	Coffee Break
3:30 pm – 4:15 pm	Summary of Breakout Sessions
3:30 pm – 4:15 pm	Summary of Breakout Sessions Vinod P. Shah, Ph.D., VPS Consulting LLC.
3:30 pm – 4:15 pm 4:15 pm – 4:45 pm	•
	Vinod P. Shah, Ph.D., VPS Consulting LLC.