



## Agenda

### Tuesday, September 11, 2018

**Guidance:** [Drug products, including biological products, that contain nanomaterials](#)

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|---------------------|--|
| 7:30 am – 8:30 am   | Registration Check-In / Coffee   |
| 8:30 am – 8:45 am   | <b>Welcome and Opening Remarks</b><br>Vinod P. Shah, Ph.D., VPS Consulting LLC.  |
| 8:45 am – 9:30 am   | <b>Regulatory Perspectives – Overview of the Guidance</b><br>Katherine Tyner, U.S. Food & Drug Administration ( <i>Invited</i> )   |
| 9:30 am – 10:15 am  | <b>Industry Perspectives</b><br>Daryl Drummond, Merrimack Pharmaceuticals  |
| 10:15 am – 10:30 am | Coffee Break   |
| 10:30 am – 11:15 am | <b>Regulatory Research in Nanomedicine Drug Products</b><br>Wenlei Jiang, U.S. Food & Drug Administration  |
| 11:15 am – 11:30 am | <b>Stakeholder Concerns and Challenges</b><br>Vinod P. Shah, Ph.D., VPS Consulting LLC.  |
| 11:30 am – 12:30 pm | Lunch  |
| 12:30 pm – 2:30 pm  | <b>Breakout Session</b><br>Scott McNeil, Ph.D., Frederic National Lab<br>Katherine Tyner, U.S. Food & Drug Administration ( <i>Invited</i> )<br>Sesha Neervannan, Ph.D., Allergan<br>Wenlei Jiang, U.S. Food & Drug Administration<br>Jon de Vlieger, Lygature |

	Daryl Drammon, Merrimack Pharmaceuticals
2:30 pm – 2:45 pm	Coffee Break
2:45 pm – 3:45 pm	<b>Summary of Breakout Sessions</b>
	Vinod P. Shah, Ph.D., VPS Consulting LLC.
3:45 pm – 4:45 pm	<b>What We Learned: Nanomedicines, Issues, Discussion and Next Steps</b>
	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.](#)

7:30 am – 8:30 am	Registration / Coffee
8:30 am – 8:45 am	<b>Welcome and Opening Remarks</b>
	Vinod P. Shah, Ph.D., VPS Consulting LLC.
8:45 am – 9:30 am	<b>Regulatory Perspectives and Updates</b>
	Susan Kirshner, Ph.D., U.S. Food & Drug Administration ( <i>Invited</i> )
9:30 am – 10:15 am	<b>Industry Perspectives</b>
	Boris Gorovits, Ph.D., Pfizer
10:15 am – 10:30 am	Coffee Break
10:30 am – 11:15 am	<b>Immunogenicity – In House and External Research</b>
	Daniela Verthelyi, U.S. Food & Drug Administration ( <i>Invited</i> )
11:15 am – 12:00 pm	<b>Best Practices</b>
	Lauren Stevenson, Biogen
12:00 pm – 12:15 pm	<b>Stakeholders Concerns and Challenges</b>
	Vinod P. Shah, Ph.D., VPS Consulting LLC.
12:15 pm – 1:15 pm	Lunch
1:15 pm – 3:15 pm	<b>Breakout Session</b>
	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**

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

4:15 pm – 4:45 pm

**Wrap Up & What We Learned**

Binodh DeSilva, Ph.D., Bristol-Myers Squibb

4:45 pm – 5:00 pm

**Closing Remarks**