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, Ph.D., Lygature-NBCD Working Group
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.

7:30 am – 8:30 am  Registration / 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 and Updates**
Susan Kirshner, Ph.D., U.S. Food & Drug Administration (Invited)

9:30 am – 10:15 am  **Industry Perspectives**
Boris Gorovits, Ph.D., Pfizer

10:15 am – 10:30 am  Coffee Break

10:30 am – 11:15 am  **Immunogenicity – In House and External Research**
Daniela Verthelyi, U.S. Food & Drug Administration (Invited)

11:15 am – 12:00 pm  **Best Practices**
Renuka Pillutla, Bristol-Myers Squibb

12:00 pm – 12:15 pm  **Stakeholders Concerns and Challenges**
Vinod P. Shah, Ph.D., VPS Consulting LLC.

12:15 pm – 1:15 pm  Lunch

1:15 pm – 3:15 pm  **Breakout Session**
Viswanath Devanarayan, Charles River Laboratories
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