FIP/USP/AAPS Workshop on
Nanomedicines—Technical and Regulatory Perspectives
March 20–22, 2017
USP Meetings Center, Rockville, MD USA

Final Agenda

DAY ONE: Monday, March 20, 2017

8:00 – 8:30 a.m.	**Registration & Coffee**
8:30 a.m.	**Welcome**
8:30 – 9:00 a.m.	**Nanotechnology - Common Language for Nomenclature, Standards (ISO, ASTM) and Data Reporting** Fred Klaessig, Ph.D., *Manager, Pennsylvania Bio Nano Systems, LLC*
9:00 – 9:30 a.m.	**Non-Biological Complex Drugs: Regulatory Challenges** Daan Crommelin, Ph.D., *Emeritus Professor in Biopharmaceutics, Utrecht University*
9:30 – 10:00 a.m.	**Quality Considerations and Regulatory Perspectives for Drug Products Containing Nanomaterials: FDA Perspective** Katherine Tyner, Ph.D., *USP Government Liaison, JS – Nanotechnology Expert Subcommittee* *Associate Director of Science (acting), Office of Pharmaceutical Quality Science, CDER, U.S. Food and Drug Administration*
10:00 – 10:20 a.m.	**Morning Break**
10:20 – 10:50 a.m.	**Quality Considerations and Regulatory Perspectives for Drug Products Containing Nanomaterials: European Perspective** René Thürmer, Ph.D., *USP Volunteer, Member, Glatiramer Expert Panel* *Deputy Head-Unit Pharmaceutical Biotechnology, BfArM - Federal Institute for Drugs and Medical Devices, Germany*
10:50 – 11:20 a.m.	**Perspectives on the Start-Up of EU-NCL** Susanne Bremer-Hoffman, Ph.D., *Senior Scientific Officer, European Commission*
11:20 – 11:50 a.m.	**USP Perspectives for Drug Products Containing Nanomaterials** Anthony Hickey, Ph.D., *USP Volunteer, Chair, JS – Nanotechnology Expert Subcommittee* *Distinguished RTI Fellow, Research Triangle Institute*
11:50 a.m. – 12:20 p.m.	**Q&A**

12:20 – 1:10 p.m.	**Lunch** USP Museum Open
1:10 – 1:40 p.m.	**Immunological Characterization of Nanotechnology-Based Formulations: Challenges and Considerations** Marina Dobrovolskaia, Ph.D., MBA, PMP, *Head of Immunology Section, Nanotechnology Characterization Lab, Leidos Biomedical Research Inc.*
1:40 – 2:10 p.m.	**Development of In vitro Release Procedure for Complex Nanotechnology Products** Ye Zhang, Ph.D., *Center for Drug Evaluation and Research, U.S. Food & Drug Administration*
2:10 – 2:30 p.m.	**Afternoon Break**
2:30 – 3:00 p.m.	**Challenges in the Release Testing of Next-Generation Nanomedicines** Matthias G. Wacker, Ph.D., *Head of Department, Pharmaceutical Technology and Nanosciences, Fraunhofer-Institute for Molecular Biology and Applied Ecology, Germany*
3:00 – 3:30 p.m.	**Use of Mononuclear Phagocyte Platforms to Characterize Nanomaterials, Nanoparticles and Colloids** William Zamboni, Pharm.D., Ph.D.**,** *Associate Professor**,** Eshelman School of Pharmacy, University of North Carolina at Chapel Hill*
3:30 – 4:00 p.m.	**Analytical Aspects** Scott McNeil, Ph.D., *Director, Nanotechnology Characterization Laboratory, National Cancer Institute/NIH*
4:00 – 4:30 p.m.	**Q&A**
4:30 – 5:15 p.m.	**Networking Reception** Shuttle to Bethesda North Marriott will depart at 5:15 p.m.

DAY TWO: Tuesday, March 21, 2017

8:00 – 8:30 a.m.	**Registration & Coffee**
8:30 – 9:00 a.m.	**Development of In vitro Release Procedure for Small Molecules and Biologics** Ajit Narang, Ph.D., *Senior Scientist, SMPS, Genentech, Inc.*
9:00 – 9:30 a.m.	**Systematic Engineering of Critical Nanoparticle Design Parameters as a Strategy for Developing Predictive Nanoscale-QSAR for Nanomedicines** Donald Tomalia, Ph.D., *CEO/Founder*, *NanoSynthons, LLC*

9:30 – 10:00 a.m.	**Characterization of Nanomedicine Drug Product Critical Quality Attributes** Jim Nolan, *Director, Nanomedicine Development & Manufacturing, Pfizer, Inc.*
10:00 – 10:20 a.m.	**Morning Break**
10:20 – 10:50 a.m.	**Characterization of Nanomaterials – Best Practices and Databases** Martin Fritts, Ph.D., *Research Associate*, *National Institute of Standards and Technology/NCI*
10:50 – 11:35 a.m.	**Characterization of Nanomaterials** Christie Sayes, Ph.D., *Associate Professor of Environmental Science, Baylor University*
11:35 a.m. – 12:05 p.m.	**Complementary Technologies for Characterization of Particles in the Nano/Colloidal Range** Aaron B. Krueger, Ph.D., *Scientist II, KBI Biopharma, Inc.*
12:05 – 12:35 p.m.	**Q&A**
12:35 – 1:25 p.m.	**Lunch** USP Museum Open
1:25 – 1:55 p.m.	**The Use of Zeta Potential for the Characterization of Nanomaterials** Alan Rawle, Ph.D., *Applications Manager, Malvern Instruments*
1:55 – 2:25 p.m.	**In Situ Spectroscopy with Nanoparticles** Alexis Guillot, Ph.D., *Scientist, PHAST GmbH*
2:25 – 2:55 p.m.	**Industrial Perspective on Nanomedicine Characterization Strategies** Don Parsons, Ph.D., *USP Volunteer, Member, Chemical Medicines Monographs 3 Expert Committee* *Head, Drug Product Process Science, Moderna Therapeutics*
2:55 – 3:15 p.m.	**Afternoon Break**
3:15 – 3:45 p.m.	**Characterization of Liposomes** Daan Crommelin, Ph.D., *Emeritus Professor in Biopharmaceutics, Utrecht University*
3:45 – 4:15 p.m.	**Oligonucleotide Lipid Nanoparticles: Development, Process Optimization and Specification Setting** Andrew Latham, Ph.D., *Principal Scientist, Merck Research Laboratories*
4:15 – 4:45 p.m.	**The Importance of Multi-Dimensional Characterization in the Pharmaceutical Development and Control of siRNA Nanoparticle Drug Product** Jingtao Zhang, Ph.D., *Principal Scientist, Merck*

4:45 – 5:15 p.m.	**Q&A** Shuttle to Bethesda North Marriott will depart at 5:15 p.m.

DAY THREE: Wednesday, March 22, 2017

8:00 – 8:30 a.m.	**Registration & Coffee**
8:30 – 9:00 a.m.	**Biocompatible Nanoparticles for Targeted Delivery** Sylvia Wagner, Ph.D., *Head of Department, Bioprocessing & Bioanalytics, Fraunhofer Institute for Biomedical Engineering*
9:00 – 9:30 a.m.	**Biomaterials for Polymeric Particulate Delivery Systems: Technical and Regulatory Considerations** Sudhir Chakravarthi, Ph.D., *Research Investigator II, Bristol-Myers Squibb*
9:30 – 10:00 a.m.	**Particle Size and Shape Characterization: Current and Emerging Techniques** Mario Hubert, Ph.D., *USP Volunteer, Member, General Chapters-Physical Analysis 2015 Expert Committee* *Principal Scientist, Bristol-Myers Squibb*
10:00 – 10:20 a.m.	**Morning Break**
10:20 – 10:50 a.m.	**Impact of Drug Nanocrystal Aggregation in Oral Dosage Forms** Ecevit Bilgili, Ph.D., *Associate Professor of Chemical Engineering, New Jersey Institute of Technology*
10:50 – 11:20 a.m.	**Current and Emerging Techniques** Tao Lu Lowe, Ph.D., *Associate Professor, Biomedical Engineering, University of Tennessee Health Science Center*
11:20 – 11:50 a.m.	**End of Life for Nanomedicines** Christie Sayes, Ph.D., *Associate Professor of Environmental Science, Baylor University*
11:50 a.m. – 12:20 p.m.	**Scientific and Regulatory Considerations on Particle Size Analysis of Nanomaterials** Zhigang Sun, Ph.D., *USP Government Liaison, General Chapters-Physical Analysis 2015 Expert Committee* *Branch Chief (Acting), Office of Process and Facilities, OPQ, CDER* *U.S. Food & Drug Administration*
12:20 – 12:50 p.m.	**Q&A**
12:50 – 1:05 p.m.	**Workshop Report / Closing Remarks** Margareth Marques, Ph.D., *USP Principal Scientific Liaison, General Chapters*
1:05 p.m.	**Workshop Concludes/Lunch** Boxed lunches will be available