Land O' Lakes 61st Annual Pharmaceutical Analysis Conference
VIRTUAL WORKSHOP

Monday, August 9, 2021

10:00 AM – 12:00 PM ET	**Part 1: Concepts of Patient Centricity**
10:00 am – 10:05 am	Introduction and Welcome (Madhavi Srikoti, Ph.D., Bristol Myers Squibb)
10:05 am – 10:35 am	Session 1: Pharmaceutical Design Aspects for Patient-Centric Approach (Jenn John, Bristol Myers Squibb)
10:35 am – 11:05 am	Session 2: Considerations for Pediatric Formulations (Rachel S. Meyers, Ph.D., Rutgers)
11:05 am – 11:35 am	Session 3: Understanding User Needs for Drug Delivery through Market Research (Kate Hasbro, Design Science)
11:35 am – 11:55 am	Panel Discussion and Q&A
11:55 am – 12:00 pm	Closing Remarks (Madhavi Srikoti, Ph.D., Bristol Myers Squibb)
12:00 PM – 1:00 PM ET	**Poster Presentations and Sponsored Roundtables**
2:00 PM – 4:00 PM ET	**Part 2: Drug Delivery Systems and Unique Products**
2:00 pm – 1:05 pm	Introduction and Welcome (Nathan Whitford, Ph.D., Eurofins Lancaster Laboratories, Inc.)
2:05 pm – 2:35 pm	Session 4: Building an Analytical Toolbox for Lipid Nanoparticle Formulations in Vaccine Development (Tian Lu, Ph.D., Merck)
2:35 pm – 3:05 pm	Session 5: Drug Devices Combination (James Mullis, Ph.D., PPD)
3:05 pm – 3:35 pm	Session 6: Taste Masking Options for Pediatric Formulations (Alex Bachmanov, Ph.D., GSK)
3:35 pm – 3:55 pm	Panel Discussion and Q&A

3:55 pm – 4:00 pm	Closing Remarks (Nathan Whitford, Ph.D., Eurofins Lancaster Laboratories, Inc.)

Tuesday, August 10, 2021

9:00 AM – 9:45 AM ET	**Live Coffee Chats** Testing Methods for Nitrosamines Analysis in Pharmaceuticals & Analytical Challenges (Amanda Guiraldelli, Ph.D., USP)
10:00 AM – 11:30 AM ET	**Part 3: Formulation and Analytical Challenges Part 1**
10:00 am – 10:05 am	Introduction and Welcome (Narayan Variankaval, Ph.D., Merck)
10:05 am – 10:35 am	Session 7: Nitrosamine Impurities: Assessing Risk Leading to Analysis Approaches & Case Studies (Adam Berro, Ph.D., Perrigo)
10:35 am – 11:05 am	Session 8: Formulation Challenges in Early Development Space / Food Effect (Shruthi Varadarajan, Ph.D., Bristol Myers Squibb)
11:05 am – 11:35 am	Session 9: Novel Excipients as Vaccine Adjuvants: Analytical Development and Regulatory Considerations (Tricia Egan, Ph.D., Merck)
11:35 am – 11:55 am	Panel Discussion and Q&A
11:55 am – 12:00 pm	Closing Remarks (Narayan Variankaval, Ph.D., Merck)
12:00 PM – 1:00 PM ET	**Poster Presentations and Sponsored Roundtables**
2:00 PM – 4:00 PM ET	**Part 4: Formulation and Analytical Challenges, Part 2**
2:00 pm – 2:05 pm	Introduction and Welcome (Stefanie Rentfrow, Ph.D., Perrigo)
2:05 pm – 2:35 pm	Session 10: Assessing the Relevance of Solution Phase Stress Testing of Solid Dosage Form Drug Products: A Cross-Industry Benchmarking Study (Todd Zelesky, Ph.D., Pfizer)
2:35 pm – 3:05 pm	Session 11: A Novel Ultra-long Lasting Solid Oral Dosage Formulation: Analytical Strategies and Challenges (Carlos Lee, Ph.D., Lyndra)
3:05 pm – 3:35 pm	Session 12: Drug Product Characterization with Biorelevant Media: Learnings and Possibilities (Arzu Selen, Ph.D., FDA)

3:35 pm – 3:55 pm	Panel Discussion and Q&A
3:55 pm – 4:00 pm	Closing Remarks (Stefanie Rentfrow, Ph.D., Perigo)

Wednesday, August 11, 2021

9:00 AM – 10:00 AM ET	**Live Coffee Chats** Extractable and Leachables (Patricia High, Ph.D.)
10:00 AM – 12:00 PM ET	**Part 5: Container Closure and Packaging Considerations**
10:00 am – 10:05 am	Introduction and Welcome (Tina Morris, Ph.D., AAPS)
10:05 am – 10:35 am	Session 13: Human Factor Studies and User Needs for Packaging Considerations (Robin Littlejohn, Ph.D., MedStar)
10:35 am – 11:05 am	Session 14: Use of ASAP Stability Studies for Packaging Considerations (Paul Gerst, MS., Pfizer)
11:05 am – 11:35 am	Session 15: Compliance with Container Closure Integrity Testing: An Overview (Lauren Levac, Ph.D., PPD)
11:35 am – 11:55 am	Panel Discussion and Q&A
11:55 am – 12:00 pm	Closing Remarks (Tina Morris, Ph.D., AAPS)
12:00 PM – 1:00 PM ET	**Poster Presentations and Sponsored Roundtables**
2:00 PM – 4:00 PM ET	**Part 6: Global Regulatory Considerations**
2:00 pm – 2:05 pm	Introduction and Welcome (Catherine Sheehan, Ph.D., USP)
2:05 pm – 2:35 pm	Session 16: FDA CDRH
2:35 pm – 3:05 pm	Session 17: An Overview of Regulatory Guidances and Compendial Tools (Mrunal Jayawant, Ph.D., USP)
3:05 pm – 3:35 pm	Session 18: ICHQ12 and Life Cycle Management -- What Can We Expect for Implementation (Tina Morris, Ph.D., AAPS)
3:35 pm – 3:55 pm	Panel Discussion and Q&A

3:55 pm – 4:00 pm	Closing Remarks (Catherine Sheehan, Ph.D., USP)