Version 4 – Updated August 28, 2023

2023 NanoDay Symposium:
Continuous Manufacturing of Nanomaterials

For files and resources, please visit
The Event Page on SBIAevents.com
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October 11, 2023
AGENDA

All times are Eastern (UTC-4)
View Start Time on World Clock

8:50 – 9:00

Administrative Overview

Brenda Stodart, PharmD, MS, BCGP, RAC
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

9:00 – 9:10

Welcome and Opening Remarks

Anil Patri, PhD
FDA Nanocore Director
Office of Scientific Coordination (OSC)
National Center for Toxicological Research (NCTR)

Namandjé N. Bumpus, PhD
FDA Chief Scientist
Office of the Chief Scientist (OCS)
Office of the Commissioner (OC) | FDA

9:10 – 9:20

Nanotechnology Meets Continuous Manufacturing: Learning from the Future

Introduction to the Symposium

Xiaoming Xu, PhD
Division Director, Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ) | CDER

Your SBIA Hosts for Day One

Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS
DDI | OCOMM | CDER

Session 1: Benefit and Lessons on Continuous Manufacturing

9:20 – 9:50

CDER's Perspective on the Continuous Manufacturing Journey: Past, Present, and Future

Introduction of CM to drug product, lesson learned from approving CM products, and what may be applied to nanomaterials

Thomas O'Connor, PhD
Deputy Office Director, OTR
OPQ | CDER

9:50 – 10:35

Continuous Manufacturing Platform for Lipid and Polymer-based Nanoparticle Therapeutics

Research grant on CM platform for liposomes and lipid nanoparticles

Antonio Costa, PhD
University of Connecticut

10:35 – 10:45: BREAK

10:45 – 11:30

An Integrated Platform for Continuous RNA Nanoparticle Formulation and Drying

Research grant on spray drying of lipid nanoparticle vaccine through flash nanoprecipitation

Kurt Ristroph, PhD
Purdue University

11:30 – 12:15

Q&A Panel

Thomas O'Connor, Antonio Costa, Kurt Ristroph, and **Xiaoming Xu**

12:15 – 12:45: LUNCH BREAK

All times shown are Eastern (UTC-4)

Session 2: Regulatory Considerations and Outreach

12:45 – 1:10

Quality Considerations and Controls for Drug Products Containing Nanomaterials – Where are We and How We Get Here

Regulatory perspective on assessment of drug products containing nanomaterials, example may include liposome formulation, lipid nanoparticles, and future consideration of platform technology

Hailing Zhang, PhD
Branch Chief
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

1:10 – 1:35

Advanced Separations and Detection in Assessment of Quality for Drug Products Containing Nanomaterials

Research perspective on characterization, with a focus on emerging technologies that may benefit the product development and process control

William Smith, PhD
Research Scientist, OTR
OPQ | CDER

1:35 – 2:05

Regulatory Science Programs and Outreach

Discussion on regulatory science program and different mechanisms that FDA works with academia/industry partners, with a focus on nanotechnology

Tina Morrison, PhD
Director
Office of Regulatory Science and Innovation (ORSI)
OCS | OC

2:05 – 2:45

Q&A Panel

Hailing Zhang, William Smith, Tina Morrison, Anil Patri, and

Olen Stephens, PhD
Chemist
Office of New Drug Product (ONDP)
OPQ |CDER

2:45 – 2:50

Symposium Closing

Olen Stephens, PhD

2:50 PM: ADJOURN SYMPOSIUM

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