

CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

# 2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials

FDA U.S. FOOD & DRUG  
ADMINISTRATION

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**OCTOBER 11**

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## 2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials

For files and resources, please visit

[The Event Page on SBIAevents.com](https://www.fda.gov/CDERSBIA)

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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

#### Opening Remarks

**Anil Patri, PhD**

*FDA Nanocore Director*

*Office of Scientific Coordination (OSC)*

*National Center for Toxicological Research (NCTR)*

**Namandjé N. Bumpus, PharmD**

*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**

## 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**