October 11, 2022

AGENDA

All times are Eastern (EDT 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)

9:00 – 9:05

Welcome

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

9:05 – 9:10

Keynote

Douglas Throckmorton, MD
Deputy Director for Regulatory Programs
CDER

Your SBIA Hosts for Day One

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

Renu Lal, PharmD
Lcdr, USPHS
DDI | OCOMM | CDER

Nora Lim, PharmD, BCPS
Lt USPHS, Pharmacist
SBIA | DDI | OCOMM | CDER
### CMC Guidance For Development of Products that Contain Nanomaterials

We will discuss the recently finalized Guidance to Industry, "Drug Products, Including Biologicals, that Contain Nanomaterials" and provide feedback for how this can be applied to development of new products that contain nanomaterials.

**Olen Stephens, PhD**  
Chemist  
Office of New Drug Product (ONDP)  
Office of Pharmaceutical Quality (OPO) | CDER

### Nonclinical Perspective on Development of Drug Products Containing Nanomaterials

This presentation aims to provide an overview of nonclinical development for drug products containing nanomaterials and describes how the safety profile of drug products containing nanomaterials is evaluated to advance development for use in clinical trials. Case studies will be presented to provide examples of drug products containing nanomaterials in development, with a FDA perspective regarding the pharmacology and toxicology evaluation of drug product containing nanomaterials intended to treat advanced cancer. Additional resources and information of drug products containing nanomaterials standards and nonclinical safety evaluation guidances will also be discussed.

**Wimolnut Manheng, PhD**  
Toxicologist  
Division of Hematology Oncology Toxicology (DHOT)  
Office of Oncology Drugs (OOD) | CDER

### Q&A Panel

**Olen Stephens and Wimolnut Manheng**

### Development and Characterization of Generic Drug Products Containing Nanomaterials

We will discuss the recently finalized Guidance to Industry, "Drug Products, Including Biologicals, that Contain Nanomaterials" in context to generic drug development and review. In particular we will discuss FDA funded research into the characterization of generic drug products containing nanomaterials, how this research informs FDA’s product-specific guidances for generic drug development, and we will highlight some recently approved generic drug products containing nanomaterials.

**Darby Kozak, PhD**  
Deputy Division Director  
Division of Therapeutic Performance 1 (DTPI)  
Office of Research and Standards (ORS)  
Office of Generic Drugs (OGD) | CDER

### Considerations for the Quality, Safety and Efficacy of Prophylactic Lipid Nanoparticle mRNA Vaccines

**Keith Peden**  
Microbiologist  
Division of Viral Products  
Office of Vaccines Research and Review (OVRR)  
Center for Biologics Evaluation & Research (CBER)
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<tr>
<th>Time</th>
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<tr>
<td>11:45 – 12:05</td>
<td>Q&amp;A Panel</td>
<td>Darby Kozak and Keith Peden</td>
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<td>12:05 – 12:50</td>
<td><strong>LUNCH BREAK</strong></td>
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| 12:50 – 1:20 | **Safety Evaluation of Food Contact Substances Containing Nanomaterials** | Raymond Brinas  
Division of Food Contact Substances  
Office of Food Safety and Applied Nutrition (OFSAN)  
Center for Food Safety and Applied Nutrition (CFSAN) |
| 1:20 – 1:50 | **Nanomaterial Standards Development at FDA**    | Anil Patri, PhD  
FDA Nanocore Director  
OSC | NCTR  
Jiwen Zheng, PhD  
Division of Health Technology 2 C  
Office of Health Technology 2  
Center for Devices and Radiological Health (CDRH) |
| 1:50 – 2:05 PM | **BREAK**                                      |                                                                           |
| 2:05 – 2:35 | **Future of Continuous Manufacturing of Drug Products Containing Nanomaterials** | Xiaoming Xu, PhD  
Office of Testing and Research (OTR)  
OPQ | CDER |
| 2:35 – 3:05 | Q&A Panel                                       | Raymond Brinas, Anil Patri, Jiwen Zheng, and Xiaoming Xu                  |
| 3:05 – 3:10 | **Symposium Closing**                           | Olen Stephens, PhD  
Chemist  
Office of New Drug Product (ONDP)  
Office of Pharmaceutical Quality (OPQ) | CDER |
| 3:10 PM      | **ADJOURN SYMPOSIUM**                           |                                                                           |

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