Version 3 – Updated September 11, 2022

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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

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9:10 – 9:40

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 (OPQ) |CDER

9:40 – 10:10

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

10:10 – 10:30

Q&A Panel

Olen Stephens and **Wimolnut Manheng**

10:30 – 10:45: BREAK

10:45 – 11:15

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

11:15 – 11:45

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)

All times shown are Eastern (EDT UTC-5)

11:45 – 12:05

Q&A Panel

Darby Kozak and **Keith Peden**

12:05 – 12:50: LUNCH BREAK

12:50 – 1:20

Safety Evaluation of Food Contact Substances Containing Nanomaterials

In this presentation, we will discuss FDA's food contact notification (FCN) program and how the safety of a food contact substance (FCS) is evaluated. In addition, we will discuss the guidance document on significant manufacturing changes and its relevance to FCSs that contain nanomaterials, as well as provide considerations when assessing the safety of FCSs that contain 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

The talk will highlight the need and opportunity in advancing manufacturing technology of drug products, with a special focus on those containing nanomaterials such as liposomes and lipid nanoparticles

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: ADJOURM SYMPOSIUM

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