Version 7 – Updated June 29, 2020

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AGENDA

All times are Eastern (EDT UTC-4)

Tuesday, June 30, 2020

8:55 – 9:00: Administrative Announcements — **Jeff Kelly**

9:00 – 9:05

Welcome

Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

9:05 - 9:15

Keynote Address

ShaAvhrée Buckman-Garner
Director
Office of Translational Sciences (OTS)

Office of Pharmaceutical Quality (OPQ) Session

9:15 - 9:35

Bioanalytical Method Validation: History, Process, and Regulatory Perspectives

Patrick Faustino
Lab Chief
Division of Product Quality Research (DPQR)
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)

Tuesday, June 30, 2020

9:35 - 9:55

Regulated Bioanalysis for Large Molecules

Jinhui Zhang
Chemist
DPQR | OTR | OPQ

9:55 - 10:15

Regulated Bioanalysis for Small Molecules

Diaa Shakleya
Senior Pharmacologist
DPQR | OTR | OPQ

10:15 - 10:30

Q&A for OPQ Session

Patrick Faustino, Jinhui Zhang, Diaa Shakleya

10:30 - 10:40: BREAK

Office of Clinical Pharmacology (OCP) Session

10:40 - 11:00

Drugs and Biologics

Sriram Subramaniam
Senior Clinical Pharmacology Reviewer
Division of Cancer Pharmacology | OCP

11:00 - 11:30

Biosimilars

Salaheldin Hamed
Acting Biosimilars Lead
Division of Cancer Pharmacology | OCP

11:30 - 11:50

Q&A for OCP Session

Salaheldin Hamed, Sriram Subramaniam

11:50 - 12:50 PM: LUNCH BREAK

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Office of Generic Drugs (OGD) Session

12:50 - 1:10 PM

Bioanalysis of Unstable Analytes in Pharmacokinetic Bioequivalence Studies Submitted in ANDAs

Zhen Zhang
Bioequivalence Reviewer
Office of Bioequivalence | OGD

1:10 - 1:30

Common Deficiencies for Study Sample Reanalysis in Pharmacokinetic Bioequivalence Studies Submitted in ANDAs

Tian Ma
Bioequivalence Reviewer
Office of Bioequivalence | OGD

1:30 - 1:50

Bioanalysis of Endogenous Compound in Pharmacokinetic Bioequivalence Studies Submitted in ANDAs

Zhen Zhang
Bioequivalence Reviewer
Office of Bioequivalence | OGD

1:50 - 2:10

Q&A for OGD Session

Zhen Zhang, Tian Ma

2:10 - 2:20: BREAK

Office of Study Integrity and Surveillance Session (OSIS): Understanding OSIS Inspections and Emerging Issues

2:20 – 2:35 PM

Overview of Immunogenicity Inspections

Melkamu Getie-Kebtie
Reviewer
Division of Generic Drug Study Integrity | OSIS

2:35 - 2:50

Considerations on *ex vivo* Conversion of Prodrugs During Bioanalysis

Xiaohan Cai
Reviewer
Division of Generic Drug Study Integrity | OSIS

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2:50 – 3:05

Bioanalysis of the dried blood spot (DBS) by mass spectrometry for the FDA regulated clinical studies

Yiyue (Cynthia) Zhang
Senior Staff Fellow
Division of New Drug Study Integrity | OTS

3:05 - 3:20

What meta-analysis can tell you about the performance of bioanalytical methods

Ruben Ayala
Lead Pharmacologist
Division of New Drug Study Integrity | OTS

3:20 - 3:30

CREST Site Selection Model Overview

Gabriel Davila
Interdisciplinary Scientist
CREST Team | OSIS

3:30 - 3:50

Q&A for OSIS Session

Melkamu Getie-Kebtie, Xiaohan Cai, Cynthia Zhang, Ruben Ayala, Gabriel Davila

3:50 - 4:00: BREAK

4:00 - 5:00

Case Study Session: Bioanalytical Approaches to Mitigate Issues Identified During BE Clinical Site Inspection

Arindam Dasgupta
Deputy Director
Division of New Drug Study Integrity | OTS

5:00 - 5:30

Closing Question and Answer Session

5:30: ADJOURN

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