Version 5 – Updated February 8, 2022

CDER BIMO GCP Compliance and Enforcement

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AGENDA

All times are Eastern (EDT UTC-5)
View start time on World Clock - *Add the event to your calendar*

Wednesday, February 16, 2022

1:00 – 1:05 PM

Welcome & Introduction

Forest "Ray" Ford, Jr., PharmD
CAPT, USPHS, *Pharmacist*
CDER Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | Center for Drug Evaluation and Research (CDER)

1:05 – 1:25

Center for Drug Evaluation and Research (CDER) Bioresearch Monitoring (BIMO) Program – A General Overview

Kelly M. K. Nolen, PhD
GCP Compliance Reviewer
Compliance Enforcement Branch (CEB)
Division of Enforcement and Postmarketing Safety (DEPS)
Office of Scientific Investigations (OSI) | Office of Compliance (OC)
CDER

1:25 – 1:55

CDER Good Clinical Practice (GCP) Inspections and Outcomes

Faranak Jamali, MD
GCP Compliance Reviewer
CEB | DEPS | OSI | OC | CDER

1:55 – 2:25

Life after Official Action Indicated (OAI)

Rachelle Marie L. Swann, PharmD
Team Lead (Acting)
CEB | DEPS | OSI | OC | CDER

Wednesday, February 16, 2022

2:25 – 2:55

Moderated Panel Discussion

Moderator:
Michelle Anantha, MSPAS, PA-C, RAC (US)
GCP Compliance Reviewer
CEB | DEPS | OSI | OC | CDER

David Burrow, PharmD, JD
Director
OSI | OC | CDER

Chrissy Cochran, PhD
Director
Office of Bioresearch Monitoring Operations
Office of Regulatory Affairs (ORA)

Karen Bleich, MD
Team Lead
Good Clinical Practice Assessment Branch (GCPAB)
Division of Clinical Compliance Evaluation (DCCE)
OSI | OC | CDER

2:55 – 3:25

Live Q&A

Kelly Nolen, Faranak Jamali, Rachelle Swann, David Burrow, Chrissy Cochran, Karen Bleich, and Michelle Anantha

3:25 – 3:30

Closing Remarks

Michelle Anantha

3:30 PM: Webinar Concludes

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