Small Business and Industry Assistance

A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Workshop

FEBRUARY 13 – 15, 2024
In-Person and Webcast

Version 4 – Updated December 14, 2023

For files and resources, please visit
The Event Page on SBIAevents.com
Add Event to Your Calendar

AGENDA

All times are Eastern (UTC-5)

View Start Time on World Clock

DAY ONE: Tuesday, February 13, 2024

8:30 – 8:40

Welcome

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain | United States Public Health Service (USPHS)
Director | Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) | FDA

8:40 – 8:55

Opening Remarks & Keynote Address

Dr. Patrizia Cavazzoni
Director
CDER / FDA

Your SBIA Host for Day One

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

9:00 – 9:55

Session 1 – Good Clinical Practice (GCP) Harmonization: Updates to ICH E6(R3)

Moderator: **Kassa Ayalew, MD, MPH** | OSI | FDA

- Discuss the basis for updates, status, and timeline
- Provide an overview of draft GCP principles and Annex 1 guideline, including a highlight of areas that have been updated/changed from ICH E6 (R2)
- Discuss plans for Annex 2

Leigh Marcus, MD
Senior Physician | OSI | FDA

Hocine Abid, MD, MBA
National Manager | ROEB | HC

Andrew Fisher
Lead Senior GCP Inspector | MHRA

10:00 – 10:20: BREAK

DAY ONE: Tuesday, February 13, 2024

10:25 – 11:05

Session 2- Technology in Clinical Trials – Digital Health Technology (DHT)

Moderator: **Debbi Fox, BSc** | *Compliance Specialist*
ROEB | HC

Discuss important considerations for sponsor for the appropriate management, traceability and security for data derived from DHTs and other computerized systems used to manage the study data, including, but not limited to, considerations for the following:

- Audit trails and metadata maintenance, review, and retention
- Data corrections
- Data transfer, exchange, and migration
- User training and other technical support provided during the trial

Elena Boley, MD
Senior Physician | OSI | FDA

Mandy Budwal-Jagait
Head of GCP and *Lead Senior GCP Inspector* | MHRA

Debbi Fox, BSc
Compliance Specialist | ROEB | HC

11:10 – 12:05

Session 3 – Trials Incorporating Decentralized Elements or Pragmatic Features

Moderator: **Karen Bleich, MD** | *Lead Physician* | OMP | FDA

- Discuss decentralized elements and pragmatic features
- Discuss modernization efforts underway in support of innovative trial designs
- Highlight special considerations for use of technology in trials using decentralized elements and pragmatic features

Hayley Dixey
Lead Senior GCP Inspector | MHRA

Alicja Kasina, MSc
Senior Regulatory Advisor | ROEB | HC

Lee Pai-Scherf, MD
Senior Medical Officer | OSI | FDA

12:10 – 1:10 PM: LUNCH BREAK

All times shown are Eastern (UTC-5)

DAY ONE: Tuesday, February 13, 2024

1:15 – 2:15

Session 4 – Good Data Governance Practice Updates

Moderator: **Shila Rastegar, MSc** | *Compliance Specialist*
ROEB | HC

- Discuss the importance of good data governance practices in the conduct of a clinical trial
- Provide updates to ICH E6R3 related to data governance, including updates to sponsor and investigator responsibilities
- Discuss the risk proportionate management of computerized systems and data governance processes.

Cheryl Grandinetti, PharmD
Pharmacologist | OSI | FDA

Shila Rastegar, MSc
Compliance Specialist | ROEB | HC

Andrew Fisher
Lead Senior GCP Inspector | MHRA

2:20 – 3:20

Panel Discussion (Q&A)

Moderator: **Courtney McGuire, MD** | *Senior Medical Officer*
OSI | FDA

3:25 – 3:45

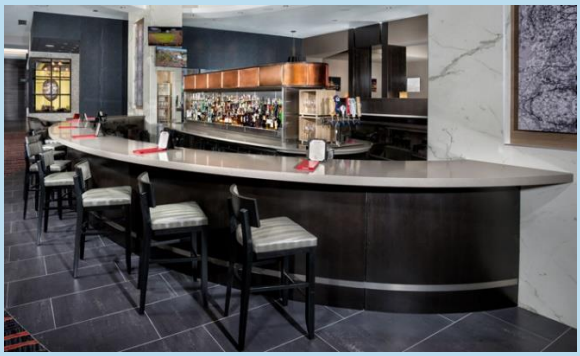
Wrap-Up & Closing Remarks

Alex Basiji, MSc
Director
ROEB | HC

3:45: ADJOURN DAY ONE

4:00 – 5:00 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at THE HOTEL's Lobby Bar to continue the conversation with fellow attendees.



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DAY TWO: Wednesday, February 14, 2024

8:30 – 8:40

Day Two Welcome

Forest "Ray" Ford, PharmD, BCPS
Captain | United States Public Health Service (USPHS)
Pharmacist | Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:40 – 8:55

Opening Remarks & Keynote Address

James Pound
Deputy Director | Standards & Compliance
MHRA

9:00 – 10:00

Session 1- Sponsor Oversight in Clinical Trials

Moderator: **Adil Nashed, BVSc, DHMS** | *Compliance Specialist*
ROEB | HC

- Discuss sponsor role and oversight responsibilities in global clinical trials, including those trials incorporating novel designs, operational approaches, and data sources
- Highlight the expanding use of 3rd parties and service providers performing clinical trial-related activities
- Discuss risk proportionate sponsor oversight measures that focus on what is important to ensure reliable trial results, trial participant's safety, and appropriate decision making

Barbara Wright
Foreign Cadre Director | Foreign BIMO Cadre
FDA | ORA

Jason Wakelin-Smith
Expert GCP Inspector and
Head of the Compliance Expert Circle | MHRA

Adil Nashed, BVSc., DHMS
Compliance Specialist | ROEB | HC

10:00 – 10:20: BREAK

10:25 – 11:25

Session 2 – Clinical Trials Post-Pandemic – Positive Disruption to Established Ways of Working?

Moderator: **Iram Hassan** | *LCDR* | USPHS | OSI | GCOB | FDA

- Discuss changes in the conduct of clinical trials and inspection activities post-pandemic
- Discuss the adoption of regulatory flexibilities into routine practice
- Insights from inspections on new approaches to clinical trial conduct

Richard Berning
Foreign BIMO Cadre | ORA | FDA

Jason Wakelin-Smith
Expert GCP Inspector and
Head of the Compliance Expert Circle | MHRA

Jennifer Evans, BSc
Compliance Specialist | ROEB | HC

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DAY TWO: Wednesday, February 14, 2024

11:25 – 12:15

Session 3 - The Future of GCP Inspections

Moderator: **Kassa Ayalew, MD, MPH** | OSI | FDA

- Discuss experiences and lessons learned during the pandemic regarding inspections supporting marketing application review
- Discuss the development of the remote regulatory assessments (RRA)/remote inspections (RI) tool
- Discuss current and future use of RRAs/RIs

Jenn Sellers, MD, PhD
Branch Chief | OSI | FDA

Jennifer Adams, MPH
LCDR | USPHS | *Foreign Cadre Director* | ORA | FDA

Rachel Mead
Senior GCP Inspector | MHRA

12:15 – 1:15: LUNCH BREAK

1:20 – 2:05

Session 4- Agency Updates: Policies, Guidance's, and Initiatives

Moderator: **Emily Gebbia, JD** | OSI | FDA

Stephen Vinter
Head of Compliance Team 1 | MHRA

Emily Gebbia
Associate Director of Regulatory Development | OSI | FDA

Hocine Abid, MD, MBA
National Manager | ROEB | HC

2:10 – 2:40

Session 5 – Collaboration Between Agencies and Future Expectations

Moderator: **Mandy Budwal-Jagait** | *Head of GCP* and *Lead Senior GCP Inspector* | MHRA

Mandy Budwal-Jagait
Head of GCP and *Lead Senior GCP Inspector*, MHRA

LaKisha Williams, MSN
CDR | USPHS | FDA | OSI | DCCE

Reza Salehzadeh-Asl, MSc
National Supervisor | ROEB | HC

2:45 – 3:45

Panel Discussion (Q&A)

Moderator: **Ryan Raffaelli, MD** | OSI | GCOB | FDA

3:50 – 4:00

Wrap-up and Closing Remarks

Cheryl Grandinetti, PharmD
Pharmacologist | OSI | FDA

3:50: ADJOURN DAY TWO

4:30 – 5:30 PM: NETWORKING OPPORTUNITY

Onsite attendees are invited to gather at THE HOTEL's Lobby Bar

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DAY THREE: Thursday, February 15, 2024

8:30 – 8:45

Day Three Welcome

Forest "Ray" Ford, PharmD, BCPS
Captain | United States Public Health Service (USPHS)
Pharmacist | Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:45 – 9:00

Opening Remarks & Keynote Address

Seongeun (Julia) Cho, MD
Division Director | DGDSI | OSIS | FDA

Morning Sessions: Bioequivalence (BE)

9:00 – 9:40

Session 1 (BE) - Remote Evaluations

Moderator: **Sean Kassim, PhD** | OSIS | FDA

Remote Regulatory Assessments (RRAs) – A valuable tool for OSIS to support drug application review in FDA

Mei Ou, PhD
OSIS | FDA

Michael McGuinness
Head of GLP & Laboratories | *Head UK GLPMA* | MHRA

9:40 – 10:20

Session 2 (BE) - Bioanalytical Issues

Moderator: **Sean Kassim, PhD** | OSIS | FDA

Bioanalytical Issues from Recent FDA BIMO Inspections and Remote Regulatory Assessments

Yiyue Cynthia Zhang, PhD
OSIS | FDA

Michael McGuinness
Head of GLP & Laboratories | *Head UK GLPMA* | MHRA

10:20 – 10:40

Panel Discussion

Moderator: **Sean Kassim, PhD** | OSIS | FDA

10:40 – 11:00: BREAK

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DAY THREE: Thursday, February 15, 2024

11:00 – 11:40

Session 3 (BE) - Clinical Study Conduct

Moderator: **Jason Wakelin-Smith** | Expert GCP Inspector and Head of the Compliance Expert Circle | MHRA

FDA perspectives on Clinical Trial conduct

Doug Pham, JD, PharmD
OSIS | FDA

Emma Whale
Senior GCP & GLP Inspector | MHRA

11:40 – 12:00

Panel Discussion (Q&A)

Moderator: **Jason Wakelin-Smith** | Expert GCP Inspector and Head of the Compliance Expert Circle | MHRA

12:00 – 1:00: LUNCH BREAK

Afternoon Sessions: Pharmacovigilance (PV) Compliance

1:00 – 1:15

Pharmacovigilance Compliance Keynote

Stephen Vinter
Head of Compliance | Team 1 | MHRA

1:15 – 2:00

Session 4 (PV) - International Collaboration

Moderator: **Carolyn Volpe, PharmD, MS**

- How regulatory agencies collaborate to gain an understanding of pharmacovigilance inspections and share information in a global landscape
- Collaboration with international partners
- Health Canada's Joint Inspection Experience

Sherry Bous, PharmD
Division Director | DEPS | OSI | FDA

Claire Longman
Expert Pharmacovigilance Inspector | MHRA

Paul Baillargeon
Regulatory Compliance and Enforcement Specialist | HC

2:00 – 3:00

Session 5 (PV) - Future of Inspections

Moderator: **Carolyn Volpe, PharmD, MS**

- FDA's Remote Assessments
- FDA's Office of Regulatory Affairs (ORA) Perspective
- Emerging technologies and related advances in pharmacovigilance

Namita Kothary, PharmD, RAC
Associate Director for Scientific Affairs | DEPS | OSI | FDA

Ginneh Stowe, MS
Health Scientist | FDA Oncology Center of Excellence

Chrissy Cochran, PhD
Director | OBMO | FDA

Robert Ball, MD, MPH, ScM
Deputy Director | OSE | FDA

3:00 – 3:15: BREAK

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DAY THREE: Thursday, February 15, 2024

3:15 – 4:00

Session 6 (PV) - Regulatory Updates

- FDA Office of Combination Products Part 4 Requirements
- FDA Adverse Event Reporting System (FAERS) Updates
- MHRA Regulatory Updates

Lauren Bateman, MS
Health Scientist | OCPP | FDA

Suranjan De, MS, MBA
Deputy Director of the Regulatory Science Staff | OSE | FDA

Claire Longman
Expert Pharmacovigilance Inspector | MHRA

4:00 – 4:30

Panel Discussion (Q&A)

Moderator: **Carolyn Volpe, PharmD, MS**

4:30 – 4:45

Wrap-up and Closing Remarks

Laurie Muldowney, MD
Deputy Director | OSI | FDA

4:45: ADJOURN WORKSHOP

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