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, MSc
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 access management

**Elena Boley, MD, MBA**
Senior Physician | OSI | FDA

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

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

11:10 – 12:05

**Session 3 – Clinical Trials with Decentralized Elements and GCP Inspections**

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

- Discuss clinical trials with decentralized elements
- Discuss regulatory challenges and GCP compliance of clinical studies with innovative features
- Highlight inspection case studies of clinical trials with decentralized elements and innovative features

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

**Alicja Kasina, MSc**
Senior Regulatory Advisor | ROEB | HC

**Hayley Dixey, BSc**
Lead Senior GCP Inspector | MHRA

12:10 – 1:10 PM: LUNCH BREAK
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.
- Provide case examples to illustrate the importance the new draft recommendations in E6R3 related to data governance

Cheryl Grandinetti, PharmD
Pharmacologist | OSI | FDA

Shila Rastegar, MSc
Compliance Specialist | ROEB | HC

Andrew Fisher, MSc
Lead Senior GCP Inspector | MHRA

2:20 – 2:35: BREAK

2:40 – 3:40

Panel Discussion (Q&A)

Moderator: Regina Zopf, MD
Senior Medical Officer | OSI | FDA

3:45 – 3:55

Wrap-Up & Closing Remarks

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

3:55: 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.
### DAY TWO: Wednesday, February 14, 2024

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<td><strong>Barbara Wright, BA</strong></td>
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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, BSc**
Senior GCP Inspector | MHRA

12:15 – 1:15: LUNCH BREAK

1:20 – 2:05

Session 4- Agency Updates: Policies, Guidances, and Initiatives

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

**Stephen Vinter, BSc, CChem**
Head of Compliance Team 1 | MHRA

**Emily Gebbia, JD**
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, MSc** | 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

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

2:45 – 3:00: BREAK

3:00 – 4:00

Panel Discussion (Q&A)

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

4:00 – 4:10

Wrap-up and Closing Remarks

**Cheryl Grandinetti, PharmD**
Pharmacologist | OSI | FDA

4:10: ADJOURN DAY TWO

4:30 – 5:30 PM: NETWORKING OPPORTUNITY
Onsite attendees are invited to gather at THE HOTEL’s Lobby Bar

All times shown are Eastern (UTC-5)
# DAY THREE: Thursday, February 15, 2024

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## 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)*

## Opening Remarks & Keynote Address

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

## Morning Sessions: Bioequivalence (BE)

### 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
- An overview of remote and hybrid Bioequivalence Inspections conducted by the UK MHRA

**Mei Ou, PhD**
*OSIS | FDA*

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

### Session 2 (BE) - Bioanalytical Issues

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

- Bioanalytical Issues from Recent FDA BIMO Inspections and Remote Regulatory Assessments
- UK MHRA Bioanalytical Observations and Findings from recent Inspections

**Yiyue Cynthia Zhang, PhD**
*OSIS | FDA*

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

## Panel Discussion

**Moderator:** **Sean Kassim, PhD** | OSIS | FDA
### 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
- MHRA Bioequivalence Inspections- Clinical

**Doug Pham, JD, PharmD**  
OSIS | FDA

**Emma Whale, MSc**  
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, BSc, CChem**  
Head of Compliance | Team 1 | MHRA

**1:15 – 2:00**  
**Session 4 (PV) - International Collaboration**

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

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

**Claire Longman, MSc**  
Expert Pharmacovigilance Inspector | MHRA

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

**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

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

**Peter Diak, PharmD, MPH**  
Branch Chief | PSB | DEPS | OSI | FDA

**Chrissy Cochran, PhD**  
Director | OBMO | FDA

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

**3:00 – 3:15: BREAK**
### Session 6 (PV) - Regulatory Updates

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

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

**Panelists:**
- Lauren Bateman, MS  
  Senior Informatics Advisor | OCPP | FDA  
- Suranjan De, MS, MBA  
  Deputy Director of the Regulatory Science Staff | OSE | FDA  
- Claire Longman, MSc  
  Expert Pharmacovigilance Inspector | MHRA

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### Panel Discussion (Q&A)

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

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### Wrap-up and Closing Remarks

**Laurie Muldowney, MD**  
Deputy Director | OSI | FDA

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**4:45:** ADJOURN WORKSHOP