## AGENDA
All times are Eastern (UTC-5)

**View Start Time on World Clock**

### DAY ONE: Tuesday, February 13, 2024

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 – 8:40</td>
<td><strong>Welcome</strong>&lt;br&gt;<strong>Brenda Stodart, PharmD, MS, BCGP, RAC</strong>&lt;br&gt;**Captain</td>
</tr>
<tr>
<td>8:40 – 8:55</td>
<td><strong>Opening Remarks &amp; Keynote Address</strong>&lt;br&gt;<strong>Dr. Patrizia Cavazzoni</strong>&lt;br&gt;**Director</td>
</tr>
<tr>
<td>9:00 – 9:55</td>
<td><strong>Session 1 – Good Clinical Practice (GCP) Harmonization: Updates to ICH E6(R3)</strong>&lt;br&gt;**Moderator: Kassa Ayalew, MD, MPH</td>
</tr>
<tr>
<td>10:00 – 10:20</td>
<td><strong>BREAK</strong></td>
</tr>
</tbody>
</table>
### Session 2: Technology in Clinical Trials – Digital Health Technology (DHT)

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

**Panelists:**
- 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

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

### Session 3: Trials Incorporating Decentralized Elements or Pragmatic Features

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

**Panelists:**
- Hayley Dixey | Lead Senior GCP Inspector | MHRA
- Alicja Kasina, MSc | Senior Regulatory Advisor | ROEB | HC
- Lee Pai-Scherf, MD | Senior Medical Officer | OSI | 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

### 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.

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.
### 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
### 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 | OSI | 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
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
Mei Ou, PhD
OSIS | FDA
Michael McGuinness
Head of GLP & Laboratories | Head UK GLPMA | MHRA
Remote Regulatory Assessments (RRAs) – A valuable tool for OSIS to support drug application review in FDA

9:40 – 10:20
Session 2 (BE) - Bioanalytical Issues
Moderator: Sean Kassim, PhD | OSIS | FDA
Yiyue Cynthia Zhang, PhD
OSIS | FDA
Michael McGuinness
Head of GLP & Laboratories | Head UK GLPMA | MHRA
Bioanalytical Issues from Recent FDA BIMO Inspections and Remote Regulatory Assessments

10:20 – 10:40
Panel Discussion
Moderator: Sean Kassim, PhD | OSIS | FDA

10:40 – 11:00: BREAK
**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 | Doug Pham, JD, PharmD | OSIS | FDA |
| Emma Whale | Senior GCP & GLP Inspector | MHRA |
| FDA perspectives on Clinical Trial conduct |

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

Sherry Bous, PharmD

Division Director | DEPS | OSI | FDA

Claire Longman

Expert Pharmacovigilance Inspector | MHRA

Paul Baillargeon

Regulatory Compliance and Enforcement Specialist | HC

- 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

2:00 – 3:00

**Session 5 (PV) - Future of Inspections**

Moderator: Carolyn Volpe, PharmD, MS

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

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

3:00 – 3:15: BREAK

All times shown are Eastern (UTC-5)
### 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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lauren Bateman, MS</td>
<td>Health Scientist</td>
</tr>
<tr>
<td>Suranjan De, MS, MBA</td>
<td>Deputy Director of the Regulatory Science Staff</td>
</tr>
<tr>
<td>Claire Longman</td>
<td>Expert Pharmacovigilance Inspector</td>
</tr>
</tbody>
</table>

#### 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