U.S. FOOD & DRUG ADMINISTRATION

Good Clinical Practice Day 2

James Pound
Deputy Director, Standards & Compliance
Healthcare Quality and Access
MHRA

A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Workshop
February 13, 2024

Medicines & Healthcare products Regulatory Agency

Health Canada Santé Canada

Welcome to Day 2

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, BSc, CChem
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

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

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

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

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, PhD** | *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

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

Jennifer Evans, BSc
Compliance Specialist | ROEB | HC

Richard Berning
Foreign BIMO Cadre | ORA | FDA

Day 2

Oversight

Day 2

Post pandemic

Day 2

Collaboration

Overview

Todays Agenda:

- Sponsor Oversight
- Clinical Trials Post Pandemic
- The Future of GCP Inspections
- Regulatory Updates and Collaboration
- Panel Discussion

Please enjoy day two of our symposium!

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