5th US-FDA/MHRA-UK/Health Canada Symposium: Regulatory Perspectives in Good Clinical Practice, Bioequivalence & Good Pharmacovigilance Practice

All times are Eastern (ET)

TUESDAY, JUNE 2nd, 2026 (GCP sessions)

Navigating ICH E6 (R3) revision and regulatory updates: A cultural shift from trial design to execution

8:30 – 9:00	
Welcome, Opening Remarks & Keynote Address	
Moderator: **Myriam Salem, M.Sc.,** *National Supervisor*, Clinical Trial Compliance Program (CTCP), Regulatory Operations and Enforcement Branch (ROEB), Health Canada (HC) **Shalene Curtis-Micallef,** *Deputy Minister of Health,* Health Canada **Supriya Sharma, MD, MPH, FRCPC**, *Chief Medical Advisor & Senior Medical Advisor*, Health Products and Food Branch (HPFB), HC	
9:00 – 10:00	
Session 1: Shifting the mindset: embedding quality and proportionality in clinical trials	
Moderator: **Myriam Salem**, **M.Sc.**, *National Supervisor*, CTCP, ROEB, HC **Objectives** • Explain the foundational principles of ICH E6 (R3) and how they build upon the concepts introduced in ICH E8 (R1) • Describe the cultural and mindset shift needed across organizations to embed QbD and risk-proportionate approaches in the design and conduct of clinical trials • Demonstrate how QbD and risk-proportionate practices can be applied to ensure clinical trials address important research questions, operate efficiently, and produce reliable data that supports sound decision-making • Analyze case examples of simple and complex trial designs to distinguish effective from ineffective implementation of QbD and risk-based decision-making	**Jason Wakelin-Smith**, **B.Sc. (Hons**), **PG Dip**, *Expert GCP Inspector*, Medicines and Healthcare products Regulatory Agency (MHRA) **Elena Boley**, **MD, MBA**, *Senior Physician*, Good Clinical Practice Assessment Branch (GCPAB), Division of Clinical Compliance Evaluation (DCCE), Office of Scientific Investigations (OSI), Center for Drug Evaluation & Research (CDER), Food and Drug Administration (FDA) **Andrea Ibrahim**, **M.Sc**., *Senior Clinical Evaluator*, Office of Clinical Trials (OCT), Pharmaceutical Drugs Directorate (PDD), HPFB, HC
10:00 – 10:20	**BREAK**
10: 20 – 11:30	

<table>
<tr><td colspan="2">Session 2: Beyond the checklist: culture, critical thinking, and case examples of risk-based quality management (RBQM) in action</td></tr>
<tr><td>Moderator: Kassa Ayalew, MD, MPH., Division Director, DCCE, OSI, CDER, FDA

Objectives
Describe the purpose and components of RBQM and its alignment with QbD.
Explain how risk assessments drive proactive trial management including expectations for documented risk assessments and their role in trial oversight.
Identify regulatory expectations for RBQM implementation and fostering a culture of transparency.
Apply RBQM principles to real-world scenarios, using case examples</td><td>Iram Hassan, PhD, Reviewer, U.S. Public Health Service (USPHS) Scientist Officer, DCCE, OSI, Office of Compliance (OC), CDER, FDA

Debbi Fox, B.Sc., Regulatory Compliance and Enforcement Specialist, CTCP, ROEB, HC

Andrew Fisher, B.Sc. (Hons), PGDip, M.Sc., Lead Senior GCP Inspector, MHRA</td></tr>
<tr><td colspan="2">11:30 – 12:00</td></tr>
<tr><td colspan="2">Q&A discussion panel (for sessions 1 and 2)</td></tr>
<tr><td colspan="2">Moderator: Myriam Salem, M.Sc., National Supervisor, CTCP, ROEB, HC

Panelists session 1: Jason Wakelin-Smith (MHRA), Elena Boley (FDA), Andrea Ibrahim (HC)
Panelists session 2: Iram Hassan (FDA), Debbi Fox (HC), Andrew Fisher (MHRA)</td></tr>
<tr><td colspan="2">12:00 – 1:15 LUNCH</td></tr>
<tr><td colspan="2">1:15 – 2:15</td></tr>
<tr><td colspan="2">Session 3: Balancing oversight and burden: fostering a culture of risk proportionate expectations across the clinical trial</td></tr>
<tr><td>Moderator: Shila Rastegar, M.Sc., Regulatory Compliance and Enforcement Specialist, CTCP, ROEB, HC

Objectives
Describe expectations for implementing ICH E6(R3), including responsibilities of sponsors and investigators.
Explain how risk-proportionate approaches can be applied to oversight, documentation, and operational expectations to support efficiency without compromising quality.
Discuss how to operationalize ICH E6(R3) and to reduce unnecessary complexity and burden at</td><td>Shila Rastegar, M.Sc., Regulatory Compliance and Enforcement Specialist, CTCP, ROEB, HC

Lydia Kim, MD, Physician, Good Clinical Practice Assessment Branch (GCPAB), DCCE, OSI, CDER, FDA

Kamaldeep Ajimal, MPharm, GCP Inspector, MHRA</td></tr>
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investigator sites, balancing quality expectations with site-specific capabilities and workflows	
2:15 – 3:15	
Session 4: Applying risk proportionate strategies to innovative clinical trial designs	
Moderator: **Jason Wakelin-Smith**, **B.Sc. (Hons)**, **PG Dip**, *Expert GCP Inspector*, MHRA **Objectives** • Discuss regulatory expectations for clinical trials incorporating decentralized and pragmatic trial elements, emphasizing alignment with ICH E6(R3) Annex 2 • Explore key considerations for using real-world data (RWD) into clinical trials, focusing on ensuring data quality, meeting regulatory requirements, and supporting effective risk-based quality management. • Discuss risk-based oversight strategies throughout the lifecycle of the clinical trial. • Evaluate case examples to assess data quality, integrity, and effective oversight practices in trials incorporating decentralized elements, pragmatic elements, and real-world data sources	**Cheryl Grandinetti, Pharm D.**, *Associate Director for Clinical Policy*, DCCE, OSI, CDER, FDA **Jennifer Evans, B.Sc.,** *Regulatory Compliance and Enforcement Specialist*, CTCP, ROEB, HC **Michelle Gabriel, B.Sc. (Hons)**, **M.Sc**, *Head of GCP & GCP Inspector*, MHRA
3:15 – 3:35	**BREAK**
3:35 – 4:30	
Session 5: Clinical trial quality at the core: ensuring reliable safety decisions in modern clinical trials	
Moderator: **Ryan Raffaelli**, **MD,** *Team Lead*, GCP Compliance Oversight Branch (GCPCOB), DCCE, OSI, CDER, FDA **Objectives** • Discuss the prioritization of trial quality and safety by fostering a shift in organizational mindset • Explain the critical role of data reliability in safety-related decisions throughout the clinical trial lifecycle	**Nahid Bibak**, **B.Sc.**, *Regulatory Compliance and Enforcement Specialist*, CTCP, ROEB, HC **Leigh Marcus**, **MD**, *Senior Physician*, GCPAB, DCCE, OSI, CDER, FDA **Rachel Mead**, **B.Sc. (Hons)**, *Senior GCP Inspector*, MHRA

• Identify critical to quality factors related to participant safety and describe quality control expectations. • Analyze case studies illustrating the impact of data errors on participant safety	
4:30-5:00	
Panel Discussion (for sessions 3, 4, 5)	
Moderator: **Regina Zopf**, **MD, MPH,** *Senior Physician,* GCPAB, DCCE, OSI, OC, CDER, FDA Panelists session 3: **Shila Rastegar (HC), Lydia Kim (FDA), Michelle Gabriel (MHRA)** Panelists session 4: **Cheryl Grandinetti (FDA), Jennifer Evans (HC), Michelle Gabriel (MHRA)** Panelists session 5: **Leigh Marcus (FDA), Nahid Bibak (HC), Michelle Gabriel (MHRA)**	
5:00 – 5:15	
Wrap-Up and Closing Remarks	
Laurie Muldowney, MD, *Deputy Director*, OSI, OC, CDER, FDA	

WEDNESDAY, JUNE 3rd, 2026 (GCP topics - morning, BE topics - afternoon)

Navigating ICH E6 (R3) revision and regulatory updates: A cultural shift from trial design to execution

8:30 – 9:00	
Welcome, Opening Remarks & Keynote Address	
Moderator: **Myriam Salem, M.Sc.,** *National Supervisor*, CTCP, ROEB, HC **Alex Basiji**, **M.Sc**., *National Director*, Clinical and Border Compliance Programs (CBCP), ROEB, HC **David Burrow, Pharm.D., J.D,** *Director*, OSI, OC, CDER, FDA **Mandy Budwal-Jagait, M.Sc.**, *Deputy Director,* Standards and Compliance, MHRA	
9:00 – 10:05	
Session 1: Preparing for change: building a culture of quality through regulatory insights and international partnership	
Moderator: **Myriam Salem, M.Sc**., *National Supervisor*, CTCP, ROEB, HC **Objectives** • Summarize recent updates to GCP-related regulations and guidance from FDA, MHRA, and	**Stephen Vinter, B.Sc. (Hons), CChem FRSC**, *Head of Compliance,* Standards and Compliance, MHRA **Hocine Abid**, **MD**, **MBA**., *National Manager*, CTCP, ROEB, HC

Health Canada, highlighting their impact on clinical trial quality and inspection readiness. • Discuss the global harmonization of GCP regulations and collaborative efforts to support consistent implementation of ICH E6(R3) and facilitate international trial compliance. • Highlight organizational strategies to prepare for upcoming regulatory changes, including insights from Pharmaceutical Inspection Co-operation Scheme and the role of intelligence sharing to enhance quality and oversight. • Highlight recent achievements and joint initiatives since the last symposium, reinforcing the value of regulatory collaboration in advancing clinical trial quality.	**Cheryl Grandinetti, Pharm D**., *Associate Director for Clinical Policy*, DCCE, OSI, CDER, FDA
10:05 – 10:25	**BREAK**
10:25 -11:25	
Session 2: Beyond the findings: regulators driving a culture shift in inspection	
Moderator: **Jenn Sellers**, **MD, PhD,** *Branch Chief,* GCPAB, DCCE, OSI, OC, CDER, FDA **Objectives** • Discuss inspections, including remote inspections or remote regulatory assessments (RRA), to support effective compliance oversight • Explore the impact of ICH E6(R3) and the adoption of risk-proportionality approaches in regulatory inspections • Discuss the role of sponsor and regulator collaboration in fostering transparency and applying risk-proportionate strategies	**David Burrow, Pharm.D., JD**, *Director*, OSI, OC, CDER, FDA **Reza Salehzadeh-Asl, M.Sc**., *National Supervisor*, CTCP, ROEB, HC **Mandy Budwal-Jagait, M.Sc.**, *Deputy Director,* Standards and Compliance, MHRA
11:25 -12:00 Q&A discussion panel (for sessions 1 and 2)	
Moderator: **Shila Rastegar**, **M.Sc**., *Regulatory Compliance and Enforcement Specialist*, CTCP, ROEB, HC Panelists session 1: **Hocine Abid (HC), Stephen Vinter (MHRA), Cheryl Grandinetti (FDA)** Panelists session 2: **Mandy Budwal-Jagait (MHRA), Reza Salehzadeh-Asl (HC), David Burrow (FDA)**	
12:00 – 1:15	**LUNCH BREAK**

<table>
<tr><td colspan="2">Bioequivalence: Enhancing oversight in bioequivalence trials: sharing insights from regulators on methods of review, case studies, and ensuring data integrity</td></tr>
<tr><td colspan="2">1:15 – 1:30</td></tr>
<tr><td colspan="2">Bioequivalence compliance keynote</td></tr>
<tr><td colspan="2">Stephen Vinter, B.Sc., (Hons), CChem FRSC, Head of Compliance, Standards and Compliance, MHRA</td></tr>
<tr><td colspan="2">1:30 – 2:30</td></tr>
<tr><td colspan="2">Session 3: Regulatory perspectives and insights on bioequivalence studies</td></tr>
<tr><td>Moderator: Scott Appleton, PhD, Manager, Division of Biopharmaceutics Evaluation 1 (DBE1), PDD, HPFB, HC

Objectives
Highlight how sponsors, applicants and researchers can learn from agency case studies and experience of bioequivalence trials
Explore case studies that will highlight opportunities to critical thinking to applications prior to submission
Explore the challenges regulators have following high-profile lapses in data integrity</td><td>Julia Cho, PhD, Division Director, Division of Generic Drug Study Integrity (DGDSI), Office of Study Integrity and Surveillance (OSIS), Office of Translational Sciences (OTS), CDER, FDA

Anna Edmison, PhD, Senior Clinical Assessment Officer, DBE1, PDD, HPFB, HC

Susan Stojdl, MSc., Senior Clinical Assessment Officer, DBE1, PDD, HPFB, HC

Emma Whale, B.Sc., Senior GCP & GLP Inspector, MHRA</td></tr>
<tr><td colspan="2">2:30 – 3:30</td></tr>
<tr><td colspan="2">Session 4: Inspector perspectives and insights on bioequivalence studies</td></tr>
<tr><td>Moderator: Reza Salehzadeh-Asl , M.Sc., National Supervisor, CTCP, ROEB, HC

Objectives
Highlight how sponsors, applicants and researchers can learn from inspections of bioequivalence trials
Analyze Case studies that will highlight:
areas of serious non-compliance
methods of review to provide sponsors / applicants potential tools when looking at their own studies
what to consider if faced with data integrity concerns</td><td>Reza Salehzadeh-Asl, M.Sc., National Supervisor, CTCP, ROEB, HC

Arindam Dasgupta, PhD, Division Director Acting, Division of New Drug Study Integrity (DNDSI), OSIS, OTS, CDER, FDA

Michael McGuinness, Head of GLP & Laboratories, Head UK GLPMA, MHRA</td></tr>
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3:50 – 4:45
Q&A discussion panel (for sessions 3 and 4)
Moderator: **Stephen Vinter, B.Sc. (Hons)**, **CChem FRSC,** *Head of Compliance*, Standards and Compliance, MHRA Panelists sessions 3 and 4: **Anna Edmison (HC), Susan Stojdl (HC), Seonguen Julia Cho (FDA), Reza Salehzadeh-Asl (HC), Arindam Dasgupta (FDA), Michael McGuinness (MHRA)**
4:45 – 5:00
Wrap-up and closing remarks
Sean Kassim, **PhD**, *Office Director*, OSIS, OTS, CDER, FDA

THURSDAY, JUNE 4th, 2026 (Pharmacovigilance)

Collaborative views on Pharmacovigilance inspections; current and future thinking

8:30 – 9:00	
Welcome, opening remarks and keynote address	
Moderator: **Dalia Haddad, B.Sc. (Hons),** *Senior Advisor*, Health Product Compliance Directorate (HPCD), ROEB, HC **Kim Godard, PhD**, *Director general,* HPCD, ROEB, HC **David Burrow, Pharm.D., JD,** *Director*, OSI, OC, CDER, FDA **Stephen Vinter, B.Sc. (Hons)**, **CChem FRSC,** *Head of Compliance*, Standards and Compliance, MHRA	
9:00 – 9:50	
Session 1: Beyond borders: international collaboration in GVP inspections	
Moderator- **Chris Chen**, **M.Sc., PhD,** *Regional Regulatory Compliance and Enforcement Officer,* HPCD, ROEB, HC **Objectives** Representatives from the three regulatory GVP inspection programs will discuss tripartite efforts to collaborate and reduce burden on industry by: • explaining how agencies collaborate in enhancing information sharing on GVP inspection, regulatory expectations and new technologies • updating the status of ongoing projects and highlight learnings and outcomes	**Paul Baillargeon**, **B.Sc.,** *Regional Regulatory Compliance and Enforcement Specialist*, HPCD, ROEB, HC **Claire Longman**, **M. Sc**., *Expert Pharmacovigilance Inspecto*r, MHRA **Sherry Bous, Pharm.D**. *Director*, Division of Enforcement and Postmarketing Safety (DEPS), Office of Compliance, FDA

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- exploring ongoing and future involvement in international regulatory projects beyond the tripartite framework

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<tr><td colspan="2">9:50 – 10:45</td></tr>
<tr><td colspan="2">Session 2: Artificial intelligence (AI) in pharmacovigilance systems</td></tr>
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Moderator: Chris Chen, M.Sc., PhD, Regional Regulatory Compliance and Enforcement Officer, HPCD, ROEB, HC

Objectives

A joint panel of regulators from GVP inspection programs will share their insights on the current landscape of AI/ML integration in pharmacovigilance systems. They will also discuss their vision for inspection readiness in the context of evolving AI technologies:

- International collaboration for AI in PV (PICS WG and CIOMS WG)
- Thoughts for inspection approaches for AI/ML PV systems
- Inspection readiness for AI systems
- Potential document requests

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Benny Ling, M.sc., Scientific Reviewer, Marketed Pharmaceuticals Directorate (MHPD), HPFB, HC

Ricardo Hernandez, PharmD, MPH, Pharmacist, CDER, OCD, DSO, FDA

Sophie Radicke, M.Sc., Head of GPvP and Senior Pharmacovigilance Inspector, MHRA

Koby Philip Joseph, B.Sc., Regional Regulatory Compliance and Enforcement Officer, HPCD, ROEB, HC

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<tr><td>10:45 – 11:05</td><td>BREAK</td></tr>
<tr><td colspan="2">11:05– 12:10</td></tr>
<tr><td colspan="2">Session 3: Division updates and inspection strategies</td></tr>
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Moderator: Chris Chen, M.Sc., PhD, Regional Regulatory Compliance and Enforcement Officer, HPCD, ROEB, HC

Objectives:

- Receive the latest updates from the division of each agency
- Discuss collaboratively on inspection strategies
- Facilitate inspection readiness in achieving successful inspections

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Evangeline Cheung, B.Sc., Good Pharmacovigilance Practices National Coordinator, HPCD, ROEB, HC

Claire Longman, M.Sc., Expert Pharmacovigilance Inspector, MHRA

Namita Kothary, PharmD, RAC (US), Associate Director for Scientific Affairs, DEPS, FDA

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<tr><td colspan="2">12:10 – 12:30 Q&A discussion panel (for sessions 1 and 2)</td></tr>
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<tr><td colspan="2">Moderator: Jason Wakelin-Smith, B.Sc. (Hons), PG Dip, Expert GCP Inspector, MHRA

Panelists sessions 1 and 2: Paul Baillargeon (HC), Claire Longman (MHRA), Sherry Bous (FDA), Koby Philip Joseph (HC), Sophie Radicke (MHRA), Namita Kothary (FDA), Benny Ling (HC)</td></tr>
<tr><td colspan="2">12:30 – 1:45 pm LUNCH BREAK</td></tr>
<tr><td colspan="2">1:45 – 2:45</td></tr>
<tr><td colspan="2">Session 4: Inspection insights: key metrics and common pitfalls</td></tr>
<tr><td>Moderator : Koby Philip Joseph, B.Sc., Regional Regulatory Compliance and Enforcement Officer, HPCD, ROEB, HC

Objectives

• Review inspection metrics and trends
• Highlight the most frequent inspection findings
• Discuss case studies with recommended corrective and preventive actions
• Identify recurring global deficiencies affecting local compliance</td><td>Anastasia Daskajiannis St John, B.Sc., GPvP inspector, MHRA

Dipti Kalra, RPh, MS, MBA, Branch Chief, Postmarketing Safety Branch (PSB), Office of Compliance, FDA

Tatiana Stankevitch, B.Sc., Regional Regulatory Compliance and Enforcement Specialist, HPCD, ROEB, HC</td></tr>
<tr><td colspan="2">2:45 – 3:45</td></tr>
<tr><td colspan="2">Session 5: A robust pharmacovigilance system that drives continuous improvement</td></tr>
<tr><td>Moderator : Koby Philip Joseph, B.Sc., Regional Regulatory Compliance and Enforcement Officer, HPCD, ROEB, HC

Objectives

• Discuss robust quality management principles that support the delivery of comprehensive safety data
• Identify best practices in vendor management that ensures accountability and addresses hidden risks early</td><td>Chris Chen, M.Sc., PhD, Regional Regulatory Compliance and Enforcement Officer, HPCD, ROEB, HC

Sophie Radicke, M.Sc., Head of GPvP and Senior Pharmacovigilance Inspector, MHRA</td></tr>
<tr><td colspan="2">3:45 – 4:05 BREAK</td></tr>
<tr><td colspan="2">4:05 – 4:35</td></tr>
<tr><td colspan="2">Q&A discussion panel (for sessions 3, 4 and 5)</td></tr>
<tr><td colspan="2">Moderator: Paul Baillargeon, B.Sc., Regional Regulatory Compliance and Enforcement Specialist, HPCD, ROEB, HC</td></tr>
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Panelists sessions 3, 4 and 5: **Evangeline Cheung (HC), Claire Longman (MHRA), Namita Kothary (FDA), Tatiana Stankevitch (HC), Dipti Kalra (FDA), Chris Chen (HC), Sophie Radicke (MHRA)**
4:35 – 4:50
Wrap-up and closing remarks
Christine Leckie, **B.Sc.,** *Director General,* Medical Devices and Clinical Compliance (MDCCD), ROEB, HC