U.S. FOOD & DRUG ADMINISTRATION

AGENDA

Tuesday, October 23, 2018

FDA & MHRA Good Clinical Practice Workshop: *Data Integrity in Global Clinical Trials – Are We There Yet?*

8:00 AM	**Registration Opens**
8:50 - 9:00 AM	**Administrative Announcements**
9:00 - 9:10 AM	**Welcome & Opening Remarks**
	David Burrow, Pharm.D, J.D., Director, Office of Scientific Investigations | CDER | FDA
9:10 - 9:25 AM	**Key Note Speaker**
	Robert Temple, M.D., Deputy Director for Clinical Science | CDER | FDA
9:25 - 10:35 AM	**Session 1 – Data Integrity from International Perspectives (Moderator – Ni Khin)**
	Background and Purpose of Collaboration (15 min)
	Ni Khin, M.D., Director, Division of Clinical Compliance Evaluation (DCCE), Office of Scientific Investigations (OSI), CDER, FDA
	Gail Francis, Expert GCP Inspector, MHRA
	Quality Management System/Quality by Design (QMS/QbD) (15 min)
	Jean Mulinde, M.D., Senior Advisor, DCCE/OSI, CDER/FDA
	Overview of Data Integrity (20 min)
	Gail Francis, Expert GCP Inspector, MHRA
	Good Clinical Practice Assessment of Data Reliability in Registration Trials (20 min)
	Kassa Ayalew, M.D., M.P.H., Branch Chief, DCCE/OSI, CDER/FDA
10:35 - 10:50 AM	**BREAK**
10:50 - 12:05 PM	**Session 2: Data Management (Moderator – Kassa Ayalew)**
	Control and Quality of Clinical Data (55 min)
	Andy Fisher, Lead Senior GCP Inspector, MHRA
	The Data Management Plan – Pulling It All Together (20 min)
	Cynthia Kleppinger, M.D., Senior Medical Officer, DCCE/OSI, CDER/FDA
12:05 - 12:30 PM	**Q&A and Panel Discussion**
12:30 - 1:30 PM	**LUNCH** *(Self-Pay)*
1:30 - 2:45 PM	**Session 3: Controlling Bias: The Study Blind (Moderator – Cynthia Kleppinger)**
	Unblinding – Let Me Count the Ways (55 min)
	Gail Francis, Expert GCP Inspector, MHRA
	Jean Mulinde, M.D., Senior Advisor, DCCE/OSI, CDER/FDA
	Blinding of Bioequivalence Trials (20 min)
	Seongeun (Julia) Cho, Ph.D., Director, Division of Generic Drug Bioequivalence Evaluation, Office of Study Integrity and Surveillance (OSIS), CDER/FDA
2:45 - 3:00 PM	**BREAK**
3:00 - 4:00 PM	**Session 4: Know Your Audit Trails (Moderator - Jean Mulinde)**
	Design and Effective Use of Audit Trails (45 min)
	Stephen Vinter, Operations Manager GLPMA & Laboratories Group, MHRA
	A Case Example of the Review of Audit Trails in GCP Inspections (15 min)
	Phillip Kronstein, M.D., Team Lead, DCCE/OSI, CDER/FDA
4:00 - 4:55 PM	**Q&A and Panel Discussion**
4:55 - 5:00 PM	**Wrap-Up - Discuss Day 2 Case Study Expectations**
5:00 - 6:30 PM	**Networking Opportunity - TDCC Building 4 Lounge (Self-Pay)**

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Wednesday, October 24, 2018

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9:00 - 9:05 AM	**Introductions - Case Studies**
9:05 - 10:35 AM	**Session 1 - Case Studies on BE/GCP (Moderator - Cynthia Kleppinger)**

Vendor selection

Sean Kassim, Ph.D., Director, Office of Study Integrity and Surveillance, CDER/FDA

Stephen Vinter, Operations Manager GLPMA & Laboratories Group, MHRA

Unblinding

Charles Bonapace, Pharm.D., Director, Division of New Drug Bioequivalence Evaluation, OSIS, CDER/FDA

Gail Francis, Expert GCP Inspector, MHRA

Jean Mulinde, M.D., Senior Advisor, DCCE/OSI, CDER/FDA

10:35-10:50 AM	**BREAK**
10:50 - 12:20 PM	**Session 2 - Case Studies on BE/GCP (Moderator - Sean Kassim)**

Audit Trail

Arindam Dasgupta, Ph.D., Deputy Director, DNDBE/OSIS, CDER/FDA

Phillip Kronstein, M.D., Team Lead, DCCE/OSI, CDER/FDA

Ruben Ayala, Pharm.D., Team Lead, DNDBE/OSIS, CDER/FDA

Data Management

Seongeun (Julia) Cho, Ph.D., Director, DGDBE/OSIS, CDER/FDA

Andy Fisher, Lead Senior GCP Inspector, MHRA

Cynthia Kleppinger, M.D., Senior Medical Officer, DCCE/OSI, CDER/FDA

12:20 - 12:50 PM	**Q & A Session**
12:50 - 1:00 PM	**Closing Remarks**

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