Event Agenda

Draft as of September 7

DAY 1: Thursday, September 30, 2021	
TIME (EDT/BST)	**PRESENTATION**
SESSION: Day 1 opening statements Moderators: James Pound & Horacio Pappa	
8:00 – 8:10 AM EDT *(1:00 – 1:10 PM BST)*	**Welcome** James Pound, *Acting Deputy Director Inspection, Enforcement and Standards Secretary and Scientific Director, MHRA* Horacio Pappa, Ph.D., *Director, General Chapters, USP*
SESSION: Introduction and history of AQbD Moderator: Phil Borman	
8:10 – 8:30 AM EDT *(1:10 – 1:30 PM BST)*	**Introduction and history of AQbD** Phil Borman, D.Sc., *Senior Fellow and Director of Product Quality, GSK*
SESSION: Industry experts share their experiences of adopting the Analytical Target Profile Moderator: Horacio Pappa	
8:30 – 8:50 AM EDT *(1:30 – 1:50 PM BST)*	**Making the most out of the ATP*** Peter Hamilton, Ph.D., *Analytical Project Expert, Astra Zeneca*
8:50 – 9:10 AM EDT *(1:50– 2:10 PM BST)*	**Using the ATP to drive performance-based changes for analytical procedures** Jörg Hoffmann, Ph.D., *Director, Reg.CMC Marketed, Merck Healthcare KGaA*
9:10 – 9:40 AM EDT *(2:10 – 2:40 PM BST)*	**Panel Discussion / Q&A**
9:40 – 9:50 AM EDT *(2:40 – 2:50 PM BST)*	**Break**
SESSION: Case studies discussing the adoption of Quality Risk Management Principles in analytical laboratories Moderator: Stephen Maddocks	
9:50 – 10:10 AM EDT *(2:50 – 3:10 PM BST)*	**British Pharmacopoeia Laboratories, how are QRM concepts built into our processes?** Stephen Young, *Head of Analytical Science, MHRA*
10:10 – 10:30 AM EDT *(3:10 – 3:30 PM BST)*	**Quality Risk Management for Analytical procedures** Amanda Guiraldelli, Ph.D., *Scientific Affairs Manager, USP*
10:30 – 11:00 AM EDT *(3:30 – 4:00 PM BST)*	**Panel Discussion / Q&A**
11:00 – 11:10 AM EDT *(4:00 – 4:10 PM BST)*	**Break**
SESSION: The important role of experimental design in analytical development Moderator: Amir Malek	

11:10 – 11:30 AM EDT *(4:10 – 4:30 PM BST)*	**Application of DOE in Biotherapeutics** Joe Callahan, Ph.D., *Technical Development Scientist, Genentech* Toby Reichenberg, *QC/Research Associate, Genentech*
11:30 – 11:50 AM EDT *(4:30 – 4:50 PM BST)*	**DOE Lessons learned and best practices** Rosario LoBrutto, Ph.D., *Executive Director, Head of Scientific Affairs, Sandoz*
11:50 AM – 12:10 PM EDT *(4:50 – 5:10 PM BST)*	**Industry experience of DoE** Kimber Barnett, Ph.D., *Associate Research Fellow, Pfizer*
12:10 – 12:50 PM EDT *(5:10 – 5:50 PM BST)*	**Panel Discussion / Q&A**
12:50 – 1:00 PM EDT *(5:50 – 6:00 PM BST)*	**Day 1 Closing Remarks**

DAY 2: Friday, October 1, 2021	
TIME (EDT/BST)	**PRESENTATION**
SESSION: Day 2 opening statements Moderator: James Pound & Horacio Pappa	
8:00 – 8:10 AM EDT *(1:00 – 1:10 PM BST)*	**Welcome, Day 1 Recap** James Pound, *Acting Deputy Director Inspection, Enforcement and Standards Secretary and Scientific Director, MHRA* Horacio Pappa, Ph.D., *Director, General Chapters, USP*
SESSION: AQbD and the Analytical Procedure Lifecycle: replication strategies, control strategies and ongoing verification Moderator: James Pound	
8:10 – 8:30 AM EDT *(1:10 – 1:30 PM BST)*	**Risk assessment techniques in Analytical Control Strategy** Phil Nethercote, Ph.D., *Independent Consultant*
8:30 – 8:50 AM EDT *(1:30 – 1:50 PM BST)*	**Analytical Control Strategy** Tim Schofield, M.A., *Owner & Consultant, CMC Science, LLC*
8:50 – 9:10 AM EDT *(1:50 – 2:10 PM BST)*	**Ongoing performance verification** Joachim Ermer, Ph.D., *Owner, Ermer Quality Consulting*
9:10 – 9:40 AM EDT *(2:10 – 2:40 PM BST)*	**Panel Discussion / Q&A**
9:40 – 10:00 AM EDT *(2:40 – 3:00 PM BST)*	**Break**
SESSION: BP & USP discuss guidance on AQbD and the Analytical Procedure Lifecycle Moderator: Graham Cook	
10:00 – 10:20 AM EDT *(3:00 – 3:20 PM BST)*	**British Pharmacopoeia AQbD Supplementary chapter and ongoing projects.** Laxsaan Elanganathan, MSc., *Senior Pharmacopoeial Scientist, MHRA*
10:20 – 10:40 AM EDT *(3:20 – 3:40 PM BST)*	**USP chapter <1220>** Jane Weitzel, *USP Expert Volunteer (Chair of General Chapters, Measurement & Data Quality Expert Committee)*
SESSION: Regulatory stories and experiences Moderator: Elena Razzano	
10:40 – 11:00 AM EDT *(3:40 – 4:00 PM BST)*	**MHRA perspective** Chris Gray, *GMDP inspector/Operations Manager, MHRA*

11:00 – 11:20 AM EDT *(4:00 – 4:20 PM BST)*	**U.S. FDA perspective** Jinhui Zhang, Ph.D., *Chemist, U.S. Food & Drug Administration*
11:20 – 11:50 AM EDT *(4:20 – 4:50 PM BST)*	**Panel Discussion / Q&A**
11:50 – 12:00 PM EDT *(4:50 – 5:00 PM BST)*	**Workshop Conclusion** James Pound, *Acting Deputy Director Inspection, Enforcement and Standards Secretary and Scientific Director, MHRA* Horacio Pappa, Ph.D., *Director, General Chapters, USP*