

Virtual Workshop

Analytical Quality by Design and the Analytical Method Lifecycle: compendial applications

February 4, 2021, 8:00 AM– 12:30 PM EST (1:00 PM– 5:30 PM GMT)



Event Agenda

Updated February 2, 2021

TIME (EST/GMT)	SESSIONS
8:00 – 8:20 AM EST (1:00 – 1:20 PM GMT)	Pharmacopeial Collaboration James Pound, <i>Acting Deputy Director Inspection, Enforcement and Standards Secretary and Scientific Director, MHRA</i> Horacio Pappa, Ph.D., <i>Director, General Chapters, USP</i>
8:20 – 8:40 AM EST (1:20 – 1:40 PM GMT)	Product Lifecycle Management: Q12 Application Graham Cook, Ph.D., <i>Senior Director, Pfizer</i>
8:40 – 9:10 AM EST (1:40 – 2:10 PM GMT)	USP/BP AQbD Activities – An Expert’s Perspective Kimber Barnett, Ph.D., <i>Associate Research Fellow, Pfizer</i> Phil Borman, D.Sc., <i>Senior Fellow and Director of Product Quality, GSK</i>
9:10 – 9:30 AM EST (2:10 – 2:30 PM GMT)	Panel Discussion Presenters from session 1
9:30 – 9:40 AM EST (2:30 – 2:40 PM GMT)	Break
9:40 – 10:00 AM EST (2:40 – 3:00 PM GMT)	MHRA/BP Case Study Stephen Maddocks, <i>Principal Pharmacopoeial Scientist–Operations Manager, MHRA</i>
10:00 – 10:20 AM EST (3:00 – 3:20 PM GMT)	USP Case Study: Stability-indicating method development using AQbD concepts: AQbD workflow and MODR validation Amanda Guiraldelli, Ph.D., <i>Scientific Affairs Manager, USP</i>
10:20 – 10:40 AM EST (3:20 – 3:40 PM GMT)	Risk Assessment for Analytical Method Changes Gerald Gellermann, Ph.D., <i>Senior Fellow, Novartis</i>
10:40 – 11:00 AM EST (3:40 – 4:00 PM GMT)	Panel Discussion Presenters from session 2
11:00 – 11:10 AM EST (4:00 – 4:10 PM GMT)	Break
11:10 – 11:30 AM EST (4:10 – 4:30 PM GMT)	MHRA – Regulator View Elena Razzano, <i>Senior Pharmaceutical Assessor, MHRA</i>

<p>11:30 – 11:50 AM EST <i>(4:30 – 4:50 PM GMT)</i></p>	<p>U.S. FDA – Analytical target profile, analytical quality by design and continual improvement of analytical procedure Jinhui Zhang, Ph.D., <i>Chemist, U.S. Food & Drug Administration</i></p>
<p>11:50 AM – 12:15 PM EST <i>(4:50 – 5:15 PM GMT)</i></p>	<p>Panel Discussion All presenters</p>
<p>12:15 – 12:20 PM EST <i>(5:15 – 5:20 PM GMT)</i></p>	<p>Conclusion James Pound, <i>Acting Deputy Director Inspection, Enforcement and Standards Secretary and Scientific Director, MHRA</i> Horacio Pappa, Ph.D., <i>Director, General Chapters, USP</i></p>