Speaker Biographies

(Listed alphabetically by last name)
February 4, 2021

Kimber Barnett, Ph.D.
Associate Research Fellow
Pfizer

Kimber Barnett is a Research Fellow working in Analytical Research and Development at Pfizer. She currently serves as a technical team leader responsible for drug product development.

Presentation: USP/BP AQbD Activities – An Expert's Perspective
ABSTRACT: The new draft chapter <1220> Analytical Procedure Life Cycle presents a framework for analytical procedures that holistically incorporates all of the events that take place over the procedure life cycle that demonstrate that a procedure is fit for the intended purpose. The procedure life cycle is based on process validation concepts that are described in ICH guidelines Q8, Q9, and Q10. The current chapters ⟨1224⟩ ⟨1225⟩ and ⟨1226⟩ provide guidance for formal validation, transfer, and verification of analytical procedures, while ⟨1220⟩ provides a framework that incorporates them, along with other activities, into the life cycle of the analytical procedure. This presentation will review the work of the Expert Panels towards developing the life cycle concepts into the draft chapter ⟨1220⟩ and next steps.

Phil Borman, D.Sc.
Senior Fellow and Director of Product Quality
GSK

Phil Borman is a Fellow of the Royal Society of Chemistry with more than 24 years of experience in the pharmaceutical industry, having obtained a Masters in Chemistry from Manchester University, a Masters in Applied Statistics from De Montfort (Leicester) University and more recently a Doctor in Sciences for his work in pioneering and developing QbD approaches for analytical procedures (also from De Montfort University). Phil is currently a Senior Fellow and the Director of Product Quality at GlaxoSmithKline. Phil pioneered the adaptation of QbD principles to Analytical methods and has published widely in the field of Analytical Chemistry. He is a member of the USP Measurement and Data Quality Expert Committee, the BP AQbD Working Party and co-leads the EFPIA ICHQ2(Q2)/Q14 support team.

Presentation: USP/BP AQbD Activities – An Expert's Perspective
ABSTRACT: Phil will provide an expert's perspective of the work performed to date by the MHRA/BP Working Party which included a case study that used the Analytical Target Profile and Method Operable Design region concepts. He will go on to discuss how this information can be used to improve the description of an analytical procedure in a pharmaceopeial monograph before discussing the future focus of the Working Party.

Graham Cook, Ph.D.
Senior Director
Pfizer

Graham leads Pfizer's Quality Intelligence and Compliance Information team. He is the chair of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Manufacturing and Quality Expert Group (MQEG) and is the EFPIA Topic Lead for ICH Q12 Product Lifecycle Management. He was appointed to the British Pharmacopoeia Commission in 2010 and chairs the MC2 Expert Advisory Group and AQbD Working Party. Between 2012-2018 he was Chairman of the ASTM International E55 Technical Committee developing pharmaceutical manufacturing standards, and continues to serve as a member of the E55 Executive Committee. He is a past chair of Pfizer's QbD Council and previous roles include Technical Director supporting Wyeth Europa Manufacturing and External Supply, and Director Formulation Development for Wyeth Consumer Healthcare (Richmond, VA, USA). Graham is a pharmacist with a Ph.D. in pharmaceutics.

Presentation: Product Lifecycle Management: Q12 Application
ABSTRACT: This presentation will give a brief overview of the ICH Q12 Product Lifecycle Management guideline. The use of certain Q12 tools for changes to analytical procedures will be highlighted.

Gerald Gellermann, Ph.D.
Senior Fellow
Novartis

Gerald currently works as Analytical Lead at Novartis TRD biologics. He is member of the Novartis ICHQ12 implementation team and co-leads the TRD biologics QbD initiative. Prior to joining Novartis he gained professional experience in CMC and analytical development during his time at Roche from 2008 to 2015. Gerald currently also represents Novartis in the EFPIA analytical workstream supporting ICH Q2R2 and ICH Q14.

Presentation: Risk Assessment for Analytical Method Changes
ABSTRACT: Analytical methods employed for batch release and stability testing are an important instrument to control impact of critical quality attributes on patient safety and product efficacy. The presentation focuses on risks associated with analytical procedure changes and reviews strategies to mitigate these risks e.g. by using an "Analytical Target Profile".

Amanda Guiraldelli, Ph.D.
Scientific Affairs Manager
U.S. Pharmacopeial Convention (USP-Brazil)

Dr. Amanda Guiraldelli is graduated in pharmacy biochemistry and holds a Ph.D. in analytical chemistry from the University of São Paulo - Brazil. Focus of her thesis was plant metabolomics by UHPLC-HRMS, GC-MS and 1H NMR and application of QbD principles in analytical procedure development. Currently, Dr. Amanda Guiraldelli is scientific affairs manager at U.S. Pharmacopeia and visiting professor at the Federal University of Campinas (Unicamp) at the Institute of Chemistry mentoring research projects on AQbD. Amanda is specialist in chromatography and mass spectrometry and has 12 years of experience in R&D areas, with strong expertise in analytical procedure development & validation, AQbD, stability studies of drug products, analysis of pharmaceutical impurities & degradation products,

chemometrics, omics science and characterization of compendial standards. Previously, Dr. Amanda Guiraldelli worked as senior scientist at the USP reference standard laboratory for 8 years with characterization of compendial standards. She also worked as R&D scientist in a brazilian pharmaceutical industry (Ourofino Agronegócio) and as visiting scientist at Technishe Universität Berlin in Germany working on proteins characterization by LC-HRMS and at Leiden University in Netherlands (Center for Proteomics and Metabolomics) working on method development for characterization of biological samples by UHPLC-HRMS. Dr. Amanda Guiraldelli is also a member of the North Jersey Chromatography Group (NJCG) - American Chemical Society (ACS).

Presentation: USP Case Study: Stability-indicating method development using AQbD concepts: AQbD workflow and MODR validation

ABSTRACT: This presentation will showcase the development of a stability-indicating method for quantification of Ondansetron related compounds (Impurity A, B, C, D, E, F and G) in the drug substance Ondansetron by UHPLC-UV using QbD principles. A comprehensive AQbD workflow and the method development strategy will be presented including the different AQbD elements and steps: Analytical Target Profile, Selection of Critical Procedure Parameters (CPP) and Critical Procedure Attributes (CPA) using risk assessment tools, use of Design of Experiment (DOE) in screening and optimization studies, generation of knowledge space, in-silico robustness study, generation & validation of Method Operable Design Region (MODR) and establishment of control strategies to ensure adequate performance throughout the procedure lifecycle. This presentation will cover how to conduct quality risk managment to identify appropriate controls on the procedure parameters and attributes and also how to optimize the method performance based on the acquired knowledge space.

Stephen Maddocks
Principal Pharmacopoeial Scientist – Operations Manager
British Pharmacopoeia/ Medicines and Healthcare products Regulatory Agency

Stephen is currently a Principal Pharmacopoeial Scientist and Operations Manager of the British Pharmacopoeia team at the UKs Medicines and Healthcare products Regulatory Agency. After studying for a degree in Medicinal Chemistry, Stephen spent some time in New Product introduction (analytical) at an Inhaled products manufacturing facility before moving into Chemical Development as an Analytical chemist, specialising in chromatographic techniques. At the British Pharmacopoeia, Stephen works closely with the AQbD Working party among other Expert Advisory Groups.

Presentation: MHRA/BP Case Study

ABSTRACT: The British Pharmacopoeia's Working party on Analytical Quality by Design performed a detailed practical study applying principles such as: Enhanced Risk assessments and Design of Experiments for robustness studies as well as studies into the application of the Analytical Target Profile to a compendial Assay method. This presentation will cover these investigations in detail as well as outlining some of the next steps for the work of the British Pharmacopoeia in AQbD.

Horacio Pappa, Ph.D.
Director, General Chapters
U.S. Pharmacopeial Convention (USP-US)

Dr. Pappa has been with USP since 2003. He is currently the Director of the General Chapters Department, Global Science division of the USP. He provides scientific leadership to a team of scientific liaisons responsible for the activities of seven different expert committees that cover the majority of the USP General Chapters. Horacio earned his Ph.D. in Pharmaceutical Chemistry from the University of Buenos Aires. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to Chromatography and Validation. Prior to joining USP, he worked in the pharmaceutical industry in QA/QC. Horacio held the position of Assistant Professor of Quality Control in the Faculty of Pharmacy at Buenos Aires University, and Executive Secretary of the Argentine Pharmacopeia in the period 1997-2001. He is a Quality Engineer certified by the American Society for Quality.

Presentation: Pharmacopeial Collaboration

James Pound
Acting Deputy Director Inspection, Enforcement & Standards Division;
Secretary & Scientific Director, British Pharmacopoeia Commission;
Group Manager, British Pharmacopoeia & Laboratory Services
British Pharmacopoeia/ Medicines and Healthcare products Regulatory Agency

Presentation: Pharmacopeial Collaboration

James Pound joined the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) in 2008. He has worked in a variety of roles within the British Pharmacopoeia (BP) & Laboratory Services Group and in 2017 was promoted to the role of Group Manager and Secretary & Scientific Director of the BP Commission. He is a senior leader within the Agency and has responsibility for both the pharmacopoeia and the Agency's regulatory laboratory testing activities, as well as acting as Deputy Director for the Inspection, Enforcement & Standards Division of MHRA. He holds an honours degree in Chemistry and has previously worked in a variety of roles focused on analytical chemistry for both multinational pharmaceutical manufacturers and independent UK analytical laboratories.

Elena Razzano
Senior Pharmaceutical Assessor
British Pharmacopoeia/ Medicines and Healthcare products Regulatory Agency

Elena Razzano is a Senior Pharmaceutical Assessor in the Licencing division of MHRA and is a member of the BP Working Party for Analytical QbD.

Elena has been working as a regulator for the past 8 years being responsible for the quality assessment of marketing authorisation applications and post approval procedures at national level as well as within the European networks, as an appointed CHMP expert.
Currently, Elena works in the Clinical Trial Unit of the Licencing Division, being responsible for the quality assessment of clinical trial applications and for providing scientific and regulatory advice to support the development of novel medicinal products and ATMPs.

Prior to joining MHRA, Elena has worked for 13 years in the pharmaceutical industry, where she matured experience in drug product development, from concept inception to process industrialization.

Presentation: MHRA – Regulator View
ABSTRACT: There is considerable interest in enhanced approaches for analytical method development, validation and lifecycle management which are aligned with Quality by Design (QbD); the recent efforts of USP and BP to apply QbD principles to the development and lifecycle management of compendial analytical methods have been widely recognised.

This presentation will provide an overview of the benefits that robust compendial analytical methods may have on regulatory approval and compliance.

Jinhui Zhang, Ph.D.
Chemist
U.S. Food & Drug Administration

Dr. Jinhui Zhang is a Chemist at the FDA/CDER. His research at FDA focuses on using advanced automation platforms and mass spectrometry for the characterization of biotherapeutics, complex drug products and clinical studies.

Prior joining FDA, he held a research faculty appointment at Texas Tech University. He has given over 30 invited podium presentations and over 40 peer reviewed publications on regulatory science, drug products quality, proteomics, clinical and preclinical pharmacokinetics, bio-analytical methodologies, pharmacogenomics and omics based therapeutic biomarkers.

Presentation: U.S. FDA – Analytical target profile, analytical quality by design and continual improvement of analytical procedure
ABSTRACT: Analytical procedures are necessary to help develop products and monitor the manufacturing process, measure critical quality attributes and to help ensure the quality of final products. These analytical procedures can be modified or improved throughout the product lifecycle because of continual improvement activities. The presentation will focus on: 1) importance of prior knowledge and knowledge gained during method development on the performance of analytical procedures; 2) special consideration for the selection of novel or. established technologies over the product lifecycle.