8:30 - 8:40 AM Welcome and Opening Remarks: EAS and 65th Birthday Celebration, Anthony Provatas, Ph.D., EAS Executive Committee, Co-Chair EAS-Mini Symposium.

8:40 - 9:10 AM Opening Keynote: *Partnership and Collaboration of Industry and Academia*, Manos Anagnostou, Ph.D., Executive Director, University of Connecticut

9:10 - 9:30 AM Exposition Break and Networking

Analytical Lifecycle Management Under ICH Q2(R2) and ICH Q14	
9:30am	*Managing Post-Approval Method Changes Within the Analytical Lifecycle,* Trevor Williams, Sr. Analytical Chemist, Jabil Corporation
9:50am	*From Sequence to Patient: ALCM Implementation for mRNA Vaccine Platform Analytics*, Rasangi Wimalasinghe, Ph.D., Principal Scientist, Sanofi
10:10am	*Approaches to Establish Analytical Method Qualification with ICH Q14*, Laura Pack, M.S., Sr. Director, Moderna

10:30 - 11:00 AM Exposition Break and Networking

Data Integrity and Digital Transformation in GMP Laboratories	
11:00am	*Regulatory Expectations for Data Integrity in Digital Review Submission Packages*, Shraddha Thakker, Ph.D., United States Food and Drug Administration
11:20am	*Establishing Digital Compendial Standards for Modern GMP Laboratories*, Michael Early, Sr Partnership Manager, Digital and Innovation Translational Informatics, United States Pharmacopeia
11:40am	Digital Transformation Accelerating Implementation of Method Lifecycle Management Guidelines, Pankaj Aggarwal, Ph.D., Principal Scientist, Merck & Co., Inc.

12:00 - 1:00 PM Light Lunch - Networking and Exposition Break

Stability Testing and Control Strategy for Pharmaceutical Products	
1:00pm	*Leveraging Stability Modeling to Enable QbD for Stability*, Ken Waterman, Ph.D., President, FreeThink Technologies, Inc.
1:20pm	*Implementation Challenges of ICH Q1 Stability Guidelines Draft Revision*, Jay Steinmetz, Senior Scientist, GMP Analytics - Analytical R&D, Pfizer
1:40pm	*Understanding the Expectations of Special Stability Studies,* Kim Huynh-Ba, Managing Director, Pharmalytik

2:00 - 2:30 PM Exposition Break and Networking

Advanced Analytics, Artificial Intelligence, and Predictive Quality in Pharmaceutical Analysis	
2:30pm	*Advanced Structure – Function Analysis of Lipid Nanoparticles*, Xiuling Lu, Ph.D., Professor of Pharmaceutics, AAPS Fellow, School of Pharmacy, University of Connecticut
2:50pm	*Generative AI + Deep Learning for Predictive Quality: Material-Sparing Calibration of a Tablet Vision Inspection System,* Giuseppe Cogoni, Ph.D., Senior Principal Scientist, ARD, Pfizer
3:10pm	*Artificial Intelligence Applications to Pharmaceuticals*, George Bollas, Ph.D., University of Connecticut

3:30 - 4:00 PM Exposition Break and Networking

4:00 - 4:30 PM Closing Keynote: *Enhancing Quality Control Testing through AI-Enabling Digitalization and a Risk-Based Analytical Lifecycle Strategy Execution*, Stephan Krause, Executive Director, CTGQ Analytical Strategy, Bristol Myers Squibb

4:30 PM Door Prizes, Conclusion and Adjourn

Advance registration is required; *click here for pricing and to register online*.

Half-Day Short Courses
Friday, June 5, 2026

Instructor: Kim Huynh-Ba, Managing Director, Pharmalytik

From Development to Validation: Practical Implementation of Q2(R2) and Q14

8:30am – 11:30am

Course Description:
This half-day course provides a focused, practical update on analytical procedure validation aligned with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ICH Q2(R2) and ICH Q14. Participants will gain clarity on lifecycle-based validation, enhanced performance characteristic expectations, revised accuracy and precision concepts, and integration of risk management principles into validation design.

The program emphasizes linking analytical method development knowledge to validation strategy, establishing scientifically justified performance characteristics, and defining appropriate control strategies. Real-world regulatory expectations, common inspection findings, and documentation best practices are discussed. Attendees will leave with practical tools to implement compliant, risk-based, and inspection-ready validation approaches within modern pharmaceutical quality systems.

Learning Benefits

- Understand lifecycle approach linking development and validation activities
- Apply risk management principles to analytical validation strategy
- Define appropriate performance characteristics based on method purpose
- Develop validation protocols supporting inspection-ready documentation practices
- Integrate Q14 development knowledge into validation justification framework
- Address common regulatory deficiencies observed during agency inspections

ICH Q1 Revision: Gap Assessment and Compliance for Stability Programs

1:30pm – 4:30pm

Course Description:
This half-day course provides a comprehensive technical examination of the transition from ICH Q1A(R2) to the revised ICH Q1 framework issued by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. The session analyzes structural consolidation of the Q1 series and key scientific shifts, including expanded climatic zone coverage, clarified intermediate storage conditions, modernization of bracketing and matrixing strategies, and strengthened statistical requirements for shelf-life extrapolation. Enhanced expectations for trend analysis, out-of-trend detection, and scientifically justified expiry dating are discussed in depth. The program also addresses increased emphasis on risk management, knowledge management, and lifecycle oversight beyond initial approval.

The second portion of the course focuses on practical implementation. Participants will conduct a structured gap assessment comparing legacy Q1A(R2)-based stability protocols against revised expectations. Areas evaluated include stability commitments, ongoing monitoring systems, statistical models, protocol design, data evaluation practices, and change management integration. The course provides a systematic methodology to prioritize remediation activities, align commercial stability programs with current regulatory standards, and strengthen inspection readiness through defensible, science-based stability strategies.

Learning Benefits

- Differentiate structural changes between Q1A(R2) and revised Q1 framework
- Interpret expanded climatic zone and storage condition expectations
- Apply updated bracketing and matrixing principles scientifically
- Evaluate strengthened statistical requirements for shelf-life extrapolation
- Conduct structured gap analysis of commercial stability programs
- Develop prioritized remediation plan ensuring regulatory compliance alignment

About the Instructor:

Kim Huynh-Ba is the Managing Director of Pharmalytik (www.pharmalytik.com) specializing in quality systems, validation, CMC and stability sciences. She is a member of the US Pharmacopeia's Biologics Expert Committee and former Council of Experts. She was a member of USP Organic Impurities Expert Panels. Kim is a member of the EAS Governing Board and their 2013 President. She is an adjunct professor at Temple University- RAQA Program and Illinois Institute of Technology teaching Pharmaceutical Analysis, Quality audit, ICH Quality Guidelines, and GMP. Kim is also a Short Course instructor of ACS, PittCon, EAS, USP, Pharma Webinars, ICH, CfPIE, and KENX. Kim authored over 50 technical publications and book chapters. She is the editor of the "Stability Handbook in Pharmaceutical Laboratories" and more recently the textbook of "Pharmaceutical Testing for the Pharmaceutical GMP Lab".

Registration for short courses is required and limited spots are available; *click here for pricing and to register*.