Enhanced Approaches for Analytical Procedure Lifecycle

September 24-25, 2018 at USP Headquarters, Rockville, Maryland

Workshop Overview

Gain a better understanding of how lifecycle principles can be applied to analytical testing procedures. This workshop will include interactive breakout discussions, case studies and hands-on applications.

Key Workshop Topics will Include:

- Case studies that illustrate the concepts of the lifecycle approach.
- Hands-on applications such as drafting an ATP, developing a control strategy, qualifying a method, and monitoring method performance during routine use.
- Opportunities to provide feedback about the USP proposal for adopting a General Chapter on the lifecycle approach to analytical procedures.

Who Should Attend

- Analytical chemists
- Quality control analysts
- Quality assurance associates, managers
- Research and development scientists, statisticians, managers
- Manufacturing scientists, managers
- Regulatory affairs specialists
- Contract laboratories
- Federal regulatory reviewers

Participating Organizations

- AOAC INTERNATIONAL
- ECA Academy
- IQ Consortium
- Product Quality Research Institute (PQRI)

Registration and Additional Information

Advance registration will be available through Thursday, September 20, 2018.

Website: www.usp.org/events-training/workshops/enhanced-approaches-for-analytical-procedure-lifecycle

Email: conferences@usp.org

Phone: 301-816-8130

Upcoming events: www.usp.org/events-training/workshops

For more information

Visit us online at www.usp.org/events-training/workshops to learn more.
Workshop Participating Organizations:

AOAC INTERNATIONAL
ECA
Innovation Quality
INSTITUTIONS
Product Quality Research Institute

Draft Agenda
(as of June 26, 2018)

DAY ONE: Monday, September 24, 2018

8:30 – 9:00 a.m. Registration & Coffee

9:00 – 9:30 a.m. Overview of the Analytical Procedure Lifecycle
Members, USP Validation and Verification Expert Panel

9:30 – 10:15 a.m. Method Lifecycle: from Development to Qualification
Antonio Ramos, Hovione

10:15 – 11:00 a.m. Analytical Method Lifecycle: Current Status and Opportunities – EFPIA perspective
Phil Borman, GSK

11:00 – 11:15 a.m. Morning Break

11:15 a.m. – 12:00 p.m. Define and Verify: Enhanced Tools in an Analytical Procedure Lifecycle Approach
Brent Harrington, Pfizer

12:00 – 1:00 p.m. Lunch
USP Museum is open

1:00 – 1:15 p.m. Break Out Instructions
Greg Martin, USP Expert Panel Chair
Attendees will do 3 rotations:
1:15 - 2:15 p.m.
2:30 - 3:30 p.m.
3:45 - 4:45 p.m.
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1:15 – 4:45 p.m. Break Out Topics:
Development of an ATP
Kimber Barnett, Pauline McGregor, Steven Walfish

Procedure Understanding and Control Strategy
Elisabeth Kovacs, Greg Martin, Phil Nethercote

Procedure Qualification
Joachim Ermer, Rosario LoBrutto

4:45 – 5:00 p.m. Day One Summary
Greg Martin, USP Expert Panel Chair

5:00 p.m. Day One Concludes

DAY TWO: Tuesday, September 25, 2018

8:30 – 8:45 a.m. Registration & Coffee

8:45 – 10:30 a.m. Summary of Breakout Sessions and Collect Feedback
Session Speakers

10:30 – 11:00 a.m. Morning Break

11:00 – 11:45 a.m. Analytical Method Lifecycle for Impurity Methodology: Some Strategies and Examples
Mark Argentine, Eli Lilly & Co.

11:45 a.m. – 12:45 p.m. Lunch
USP Museum is open

12:45 – 1:30 p.m. The work that BP is currently doing around AQbD and ATPs
Gary Kemp, British Pharmacopoeia

1:30 – 2:15 p.m. Speaker TBD

2:15 – 2:45 p.m. Afternoon Break

2:45 – 3:30 p.m. USP Vision for <1220> The Analytical Procedure Lifecycle
Horacio Pappa, Director, General Chapters, USP

3:30 – 4:15 p.m. Regulatory Perspective on Continuous Analytical Verification
Speaker TBD

4:15 – 5:00 p.m. Workshop Summary
Greg Martin, USP Expert Panel Chair

5:00 p.m. Workshop Adjourns