

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.

For more information

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

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

USP Workshops

→ Enhanced Approaches for Analytical Procedure Lifecycle

September 24-25, 2018

Gain a better understanding of how lifecycle principles can be applied to analytical testing procedures.



Workshop Participating Organizations:



Academy
Your GMP/GDP
Information Source



INTERNATIONAL CONSORTIUM FOR
INNOVATION & QUALITY
= PHARMACEUTICAL DEVELOPMENT



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
<i>Members, USP Validation and Verification Expert Panel</i> |
| 9:30 – 10:15 a.m. | Method Lifecycle: from Development to Qualification
<i>Antonio Ramos, Hovione</i> |
| 10:15 – 11:00 a.m. | Analytical Method Lifecycle: Current Status and Opportunities – EFPIA perspective
<i>Phil Borman, GSK</i> |
| 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
<i>Brent Harrington, Pfizer</i> |
| 12:00 – 1:00 p.m. | Lunch
<i>USP Museum is open</i> |
| 1:00 – 1:15 p.m. | Break Out Instructions
<i>Greg Martin, USP Expert Panel Chair</i> |
- 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