Workshop on
Lifecycle Approach of Analytical Procedures
November 8th - 9th, 2016
Prague, Czech Republic

Agenda

November 8, 2016 (Day 1)

08:30 Registration

09:00 Introduction to the ECA Foundation and Academy and the collaboration with USP

- **ECA intro;** Chris Burgess
- **USP collaboration design and intent;** Horacio Pappa

09:15 Session I – An Integrated Approach to Analytical Procedure Lifecycle; a USP perspective

Overview: This session will introduce the USP Validation and Verification Expert panel vision for the development of a new general chapter on analytical procedures over the life cycle which is consistent with the principles of FDA and EU Annex 15 guidance on process validation covering design, development, qualification, transfer and verification and aligned with the concepts of Analytical Quality by Design.

Moderator: Chris Burgess

- ***Presentation 1****:* Update from the Validation and Verification Expert Panel: Review of the revision process for USP General Chapters <1225>, <1224> and <1226> with an introduction to a new general chapter and the workshop – Greg Martin

10:00 Morning Break

10:15 Session II – Analytical Target Profile and Measurement Uncertainty

Overview: Results and reportable values generated using analytical procedures provide the basis for key decisions regarding compliance with regulatory, compendial, and manufacturing limits. Decision Rules are applied for the acceptance or rejection of a product based on the measurement result, its uncertainty, and acceptance criteria, taking into account the acceptable level of the probability of making a wrong decision.

Moderator: Greg Martin

- ***Presentation 1: What is an ATP*** – Pauline McGregor
- ***Presentation 2: Specifications,* Measurement Uncertainty and Decision Rules** – Jane Weitzel

Q & A panel session

12:30 Lunch

13:45 **Session III – Stage 1; Application of AQbD principles in procedure lifecycle**

Overview: During this session, examples of the use of AQbD tools and lifecycle approach for the validation of analytical procedures will be presented

Moderator: Elizabeth Kovacs

- ***Presentation1:*** Kimber Barnett; Case study
- ***Presentation 2:*** Mark Argentine; Case study

15:15 *Afternoon Break*

15:30 **Session IV – Establishing an Analytical Control Strategy**

Overview: An Analytical Control Strategy is an essential procedure in ensuring that the data quality requirements defined in the ATP are realized throughout the lifecycle.

Moderator: Horacio Pappa

- ***Presentation 1: What is a control strategy?***
- ***Presentation 2: Application of Quality Risk Management principles over the lifecycle*** - Elisabeth Kovacs

17:00 Q & A panel session from Day 1

18:00 End of Day 1

19:00. **Social Event**

November 9, 2016 (Day 2)

08:30 **Session V– Stage 2; Confirming the desired state in the routine analytical environment during procedure qualification and transfer**

Overview: Confirmation of procedure performance and 'fitness for purpose' (PPQ) in the operational laboratory is an essential step before routine testing is undertaken.

Moderator: Kimber Barnett

- ***Presentation 1: Fitness for purpose of analytical instruments and systems;*** **Data Integrity and Security confidence requirements over the Analytical Lifecycle**
- ***Presentation 2: Experimental evidence of adequate Analytical Procedure Performance Qualification*** – Joachim Ermer
- ***Presentation 3: Replication Strategy*** – Joachim Ermer

10:15 Morning Break

10:45 **Session V continued**

- ***Presentation 4: Overview of statistical tools for Analytical Procedure Performance Qualification - General Chapter <1210>*** – Jane Weitzel

11:30 **Session VI – Stage 3; Continued verification of performance of analytical procedures.**

Overview: This session will discuss statistical tests and tools that apply to the verification of analytical procedures. Statistical tools for procedure validation, a proposed new general information chapter, will be one of the topics for discussion

Moderator: Joachim Ermer

- ***Presentation 1 Overview of trend analysis and process capability and Application of statistical tools for the continued verification of performance of analytical procedures -*** Chris Burgess

12:15 Lunch

13:15 **Session VII Current regulatory vision for Analytical Lifecycle**

Moderator: TBD [5 mins]

- ***Presentation 1***: FDA,
- ***Presentation 2***: EU
- ***Presentation 3****: Examples for pharmacopoeial procedures*

14:45 . Q & A session on Stage 3

15:00. Afternoon Break

15:30 Session VII - Transitioning to the new paradigm

Overview: This session provides the forum for an open discussion between speakers, expert panel members and participants.

Moderator: Pauline McGregor

17:00 Q & A panel session from Day 2

17:30 Workshop Concludes