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Analytical Procedure Lifecycle Management

Featuring Speakers from ECA Analytical QC Group and USP Validation and Verification Expert Panel

SPEAKERS

Speakers from the Validation & Verification Expert Panel at United States Pharmacopeia (USP):

KIMBER BARNETT
Pfizer



DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy Limited



DR JOACHIM ERMER
Sanofi



PHIL NETHERCOTE
Former GSK



JANE WEITZEL
Consultant

Speakers from the ECA Analytical QC Group:



SILVIYA DIMITROVA
Actavis, a TEVA Company



DR GERD JILGE
Boehringer Ingelheim Pharma GmbH & Co. KG



MARGARITA SABATER
Dako Denmark A/S, an Agilent Technologies Company



A holistic Approach to Design, Development, Qualification and Control of Analytical Procedures and Inputs to the ICH Q2A Revision Process

23 - 24 November 2017, Vienna, Austria

HIGHLIGHTS:

- Scope and Application of the new Analytical Procedure Lifecycle Management (APLM) Guideline
- Quality by Design - Application to Analytical Procedures
- Development of an ATP
- The importance of Target Measurement Uncertainty in an ATP
- Defining an Analytical Control Strategy
- Aims and Objectives of the ICH Q2A Revision Process
- Designing Procedure Performance Qualification (PPQ) - Stage 2
- On Going Performance Verification; Stage 3
- Procedure Verification Strategy to Confirm a State of Control



Analytical Procedure Lifecycle Management

23 - 24 November 2017, Vienna, Austria

Objectives & Background

The assurance of 'fitness for purpose' of analytical procedures is a critical part of any process for ensuring drug quality. Since 2014, USP's Validation and Verification Expert Panel has been considering how the modern concept of lifecycle model process validation can be applied to analytical procedures and has published articles and a proposal for a new General Chapter <1220> aligned with the principles of US FDA and EU Annex 15 guidance on process validation.

In November 2016, ECA held a joint workshop with USP in Prague to discuss developments. In addition, ICH have instigated a revision workplan for Q2(R1) on Analytical Method Validation scheduled for completion by 2019/2020. Also the new ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Step 1 Core guideline, June 2017, provides further support for the analytical procedure lifecycle and preparing the way for performance based procedures.

In 2017, the board of the ECA's Analytical Quality Control Group (AQCG) decided to support the lifecycle approach for analytical procedures by drafting a new Guideline on 'Analytical Procedure Lifecycle Management' (APLM).

This workshop conference will launch this draft guideline and actively discuss and review it as well as provide inputs for the finalized version 1. In addition, there will be an opportunity to discuss and generate input for the ICH Q2(R1) revision process. The speakers will be from both the ECA board and members of the USP's Validation and Verification of Analytical Procedures Expert Panel.

Conference presentations, case studies and workshop discussions will help participants learn more about the current thinking on lifecycle management of analytical procedures and provide a forum for discussing how to move forward with the transition to and implementation of the lifecycle approach.

This meeting features 4 specifically designed interactive workshops on:

- Analytical Target Profiles (ATPs)
- Using Analytical Quality by Design methodology (AQbD) to deliver an ATP
- Designing a Procedure Performance Qualification (PPQ) protocol to confirm the ATP
- Designing a Procedure Verification strategy to confirm a state of control

Target Audience

The ECA Academy wish to actively involve analytical chemists, QC analysts, quality assurance associates & managers, R&D scientists, statisticians & managers as well as manufacturing scientists and managers, regulatory affairs specialists and contract laboratories in this critical area for analytical science.

Programme

Introduction to the ECA Foundation and Academy

Dr Christopher Burgess, Chairman of the ECA AQCG Board

Overview of the Workshop

- Limitations of the current ICH Q2(R1) & USP General Chapters
- Principles of Analytical Procedure Lifecycle Management (APLM)
- Importance of adopting an APLM approach in the context of data integrity governance
- Workshop intent and process

Dr Christopher Burgess, Chairman of the ECA AQCG Board

Overview of the new APLM Guideline

- ECA Guidelines; intent and applications
- APLM process overview
- Regulatory background
- Content of new guideline

Dr Christopher Burgess, Chairman of the ECA AQCG Board

Programme (cont'd)

Quality by Design; Application to Analytical Procedures

- History and background to the initiative to apply QbD principles to analytical procedures
- Advantages
- Key elements of this approach

Phil Nethercote (USP V&V Expert Panel)

Development of an ATP

Kimber Barnett (USP V&V Expert Panel)

The importance of Target Measurement Uncertainty in an ATP

- Target measurement uncertainty (TMU) is the maximum value for the uncertainty associated with a reportable value in order for it to be fit for purpose. It is one of the key components in the Lifecycle approach to analytical procedures
- TMU helps define the analytical target profile (ATP)
- TMU is required to determine the probability stated in a decision rule
- TMU is a key performance criterion for analytical procedure performance throughout its life, from development through qualification and continued verification of performance

Jane Weitzel (USP V&V Expert Panel)

Workshop 1 on ATPs

Moderators: Kimber Barnett & Jane Weitzel (USP V&V Expert Panel)

Defining an Analytical Control Strategy

- Definition of an ACS
- Identification of the analytical procedure variables that impact the ATP based on Risk Management
- Key elements of this approach

Margarita Sabater (ECA AQCG Board)

Workshop 2 on AQbD to deliver an ATP (Stage 1)

Moderators: Phil Nethercote (USP V&V Expert Panel) & Margarita Sabater (ECA AQCG Board)

Panel Q&A and Review of Day 1

ICH Q2A Revision Process; Aims and Objectives

- A general approach for the validation of all relevant analytical procedures
- Discussion on the revision of the terminology of validation parameters
- Definition of a "variability" of an analytical procedure
- Implementation into the process of the "Analytical Target Profile" and the Life cycle process

Dr Gerd Jilge, (ECA AQCG Board)

Stage 2: Procedure Performance Qualification (PPQ)

- Alignments, differences and advantages to traditional validation
- General and procedure-specific performance attributes
- Experimental confirmation in stage 2 or reference to stage 1?
- Precision of the reportable value and replication strategy

Dr Joachim Ermer, (USP V&V Expert Panel)

Workshop 3

Designing a Procedure Performance Qualification (PPQ) protocol to confirm the ATP

Moderators: Dr Gerd Jilge, (ECA AQCG Board) & Dr Joachim Ermer, (USP V&V Expert Panel)

On going Performance Verification; Stage 3 (Principles & Approaches)

- Analytical Procedures as processes
- Process stability and capability
- Requirements for routine process monitoring of analytical procedures
- Quality Metrics

Dr Christopher Burgess, Chairman of the ECA AQCG Board

Programme (cont'd)

On going Performance Verification; Stage 3 (Analytical trending to ensure a state of control)

- What to trend and what not to trend
- Trending as part of the analytical control strategy and confirmation of the ATP
- Are we trying to control means or individuals?
- Overview of trending tools for discrete and variable data

Silviya Dimitrova (ECA AQCG Board)

Workshop 4

Designing a Procedure Verification Strategy to confirm a State of Control

- Defining critical analytical procedure steps
- Specification limits versus analytical trend limits
- Selecting the right statistical tools for the job
- Evaluating and interpreting trend data

Dr Christopher Burgess and Silviya Dimitrova (ECA AQCG Board)

Final Panel Discussion - "The Way Forward"

Speakers

KIMBER BARNETT,

Pfizer, Member of the Validation & Verification Expert Panel at USP

Kimber Barnett, Ph.D. is a Research Fellow working in Analytical Research and Development at Pfizer Inc. in Groton, CT. In her current role, Kimber serves as a technical team leader responsible for late stage analytical development of drug substances and drug products as well as the late stage LC Method Development Group. Kimber obtained her Ph.D. in Analytical Chemistry from the University of Missouri focusing on chiral separations under the guidance of Professor Daniel Armstrong.



DR CHRISTOPHER BURGESS,

Burgess Analytical Consultancy Limited, Member of the Validation & Verification Expert Panel at USP and Member of the ECA QC Group

Dr Burgess is a Chartered Chemist and has more than 40 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and was a member of the European QP Association advisory board for 10 years. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and again for 2015 to 2020 as well as being on the Expert Panel for Validation and Verification of Analytical Procedures. He is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group Board and a member of ECA's Extended Board and member of ECA's Task Force on Data Integrity.



SILVIYA DIMITROVA,

Actavis, a TEVA Company, Member of the ECA QC Group

Silviya Dimitrova is Associate Director EU Third Party Testing and Release at Actavis, a TEVA company, Bulgaria and has 28 years experience in pharmaceutical industry. She started her career in R&D as an analytical chemist and more recently as Head of Analytical activities department with a focus on method development and validation. Since 2008 she has been working in Quality and currently is Associate Director in charge of the department with responsibilities for Quality Control of imported products supplied by manufacturers from non EU countries. She has an experience in analytical transfers between sites within the company and with contract manufacturers, and also in Quality Control/testing and QP release of the imported to EU products.



DR JOACHIM ERMER,

Sanofi, Member of the Validation & Verification Expert Panel at USP

Dr Ermer is Head of Quality Control Services Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany and Global Reference Standards Coordinator of Sanofi Industrial Affairs. He studied biochemistry at University of Halle and has over 25 years experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, and Head of Quality Control. He is member of the EFPIA QbD working group and of the USP Expert Panel Validation & Verification.



DR GERD JILGE,

Boehringer Ingelheim Pharma GmbH & Co. KG, Member of the ECA QC Group

After finishing the PhD in fast HPLC separations on proteins Gerd became a product specialist employed at Shimadzu followed by a post-doctoral fellowship in Paris on chromatography on biopolymers in 1990. In 1991 Dr Gerd Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000 Gerd took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007 he is working in Quality Control on topics like method transfer as well as method optimization and validation for active drug substances. In 2014 Gerd became a member of the EDQM expert group II.



PHIL NETHERCOTE,

Member of the Validation & Verification Expert Panel at USP

Phil Nethercote has recently retired from GSK where he was Head of Analytical for the GSK manufacturing division. He is a member of the USP Expert Panel on Method Validation and Verification and the BP Analytical QbD working party as well as co-editor of the book Method Validation in Pharmaceutical Analysis. Phil has a degree in Chemistry and a PhD in HPLC.



MARGARITA SABATER,

Dako Denmark A/S, an Agilent Technologies Company, Member of the ECA QC Group

Margarita Sabater is currently Process and Method Validation specialist and educator at Dako (Agilent Technologies). She has more than 20 years experience within analytical Research and Development as well as QC from pharmaceutical companies. Her main area of expertise is within development and validation of bioanalytical and biological assays. Margarita has applied risk-based approaches in the development and validation of analytical procedures and established control and monitoring strategies through the analytical procedure life cycle. She also has experience in analytical transfers between sites within the company and with contract manufacturers.



JANE WEITZEL,

Consultant, Member of the Validation & Verification Expert Panel at USP

Jane Weitzel has been working in analytical chemistry for over 40 years for mining and pharmaceutical companies. She is currently a consultant specialising in laboratory management systems and ISO/IEC 17025, an auditor, and an educator. Jane has applied Quality Systems and statistical techniques, including the estimation and use of measurement uncertainty, in a wide variety of technical and scientific businesses. She has obtained the American Society for Quality Certification for both Quality Engineer and Quality Manager. For the 2010 – 2015 cycle, Jane was a member of the USP Reference Standards committee and she is also a member of the USP Statistics Expert Committee for 2015 to 2020. In 2014 she was pointed to the Chinese National Drug Reference Standards Committee and attended their inaugural meeting in Beijing.





Social Event


On 23 November 2017, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

 **Reservation Form:**
+ 49 6221 84 44 34

 **e-mail:**
info@concept-heidelberg.de

 **Internet:**
www.validation-analytical.eu

Date

Thursday, 23 November 2017, 9.00 h – 17.30 h

(Registration and coffee 8.00 h – 9.00 h)

Friday, 24 November 2017, 8.30 h – 16.30 h

Venue

AUSTRIA TREND HOTELS
HOTEL SAVOYEN VIENNA
Rennweg 16, 1030 Vienna, Austria
Phone +43 (1) 206 33 0
Fax +43 (1) 206 33 9110
Email savoyen@austria-trend.at

Fees (per delegate plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event & dinner, lunch on both days, and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message.

Or you register online at www.validation-analytical.eu.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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www.concept-heidelberg.de

Do you have any questions?

For questions regarding content:


Dr Günter Brendelberger (Operations Director)
at +49 (0)62 21 / 84 44 40, or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Weidemaier (Organisation Manager)
at +49 (0)62 21 / 84 44 46, or per e-mail at
weidemaier@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

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Analytical Procedure Lifecycle Management

A holistic approach to Design, Development, Qualification and Control of

Analytical Procedures and Inputs to the ICH Q2A Revision Process

23 - 24 November 2017, Vienna, Austria

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