

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

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy Limited

GREG MARTIN
Complectors Consulting, Chairman of the Validation & Verification Expert Panel at USP

Dr HORACIO PAPPA
Director of General Chapters at USP

Dr PAULINE MCGREGOR
PMcG Consulting

JANÉ WEITZEL
Consultant

ELISABETH KOVACS
Apotex

KIMBER BARNETT
Pfizer

Dr JOACHIM ERMER
Sanofi

Speakers from Industry:

MARK ARGENTINE
Lilly

PATRICK JACKSON
GSK

Dr BOB MCDOWALL
R D McDowall Ltd.

Speakers from Authorities:

Dr LUCINDA BUHSE
Food and Drug Administration (FDA), Member of the Validation & Verification Expert Panel at USP

JAMES POUND
Editor-in-Chief British Pharmacopoeia (BP), MHRA

DR JOBST LIMBERG
Federal Institute for Drugs and Medical Devices, BfArM

Lifecycle Approach of Analytical Procedures

USP and ECA Joint Conference and Workshop



Prague, Czech Republic, 8-9 November 2016

HIGHLIGHTS:

- Introduction to a new USP General Chapter on Validation & Verification
- Review of the revision process for USP General Chapters <1225>, <1224> and <1226>
- Analytical Target Profile and Measurement Uncertainty
- Application of AQbD principles in procedure lifecycle
- Analytical Control Strategy
- Fitness for purpose of analytical instruments and systems
- Overview of statistical tools
- Continued verification
- Current regulatory vision for Analytical Lifecycle

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Objectives & Background

The validation 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. This conference will address how USP's proposed vision for the development of a new general chapter aligns with the principles of US FDA and EU Annex 15 guidance on process validation and analytical quality by design. This covers design, development, qualification, transfer and verification.

Conference presentations, case studies and open discussions will help participants learn more about the lifecycle management of analytical procedures and provide a forum for discussing USP's new general chapter and Stimuli articles related to this topic. Participants will thus have the opportunity to give feedback and ask questions directly to USP's Expert Panel Members on how to move forward with the transition to and implementation of the lifecycle approach.

The meeting will also address topics such as:

- a new calculation tool kit – General Chapter <1210> – to facilitate and simplify the statistical calculations required for validation
- establishing an analytical target profile as well as an analytical control strategy
- harmonization of nomenclature for development, qualification and verification of analytical procedures as part of a lifecycle concept.

Target Audience

The USP and 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 and the collaboration with USP

- ECA introduction (*Dr Christopher Burgess*)
- USP collaboration design and intent (*Dr Horacio Pappa*)

An Integrated Approach to Analytical Procedure Lifecycle; a USP perspective

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: Dr Christopher Burgess

- 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*)

Analytical Target Profile and Measurement Uncertainty

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

- What is an ATP? (*Dr Pauline McGregor*)
- Specifications, Measurement Uncertainty and Decision Rules (*Jane Weitzel*)
- Q & A panel session

Stage 1: Application of AQBd principles in procedure lifecycle

During this session, examples of the use of AQBd tools and lifecycle approach for the validation of analytical procedures will be presented.

Moderator: Elisabeth Kovacs

- Case study (*Kimber Barnett*)
- Case study (*Mark Argentine*)

Establishing an Analytical Control Strategy

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: Dr Horacio Pappa

- Application of Quality Risk Management principles over the lifecycle (*Patrick Jackson*)
- What is a control strategy? (*Elisabeth Kovacs*)

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Q & A panel session from Day 1

Stage 2: Confirming the desired state in the routine analytical environment during procedure qualification and transfer

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

- Fitness for purpose of analytical instruments and systems; Data Integrity and Security confidence requirements over the Analytical Lifecycle (*Dr Bob McDowall*)
- Experimental evidence of adequate Analytical Procedure Performance Qualification (*Dr Joachim Ermer*)
- Replication Strategy (*Dr Joachim Ermer*)
- Overview of statistical tools for Analytical Procedure Performance Qualification, General Chapter <1210> (*Jane Weitzel*)

Stage 3: Continued verification of performance of analytical procedures.

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: Dr Joachim Ermer

- Overview of trend analysis and process capability and Application of statistical tools for the continued verification of performance of analytical procedures (*Dr Christopher Burgess*)

Current regulatory vision for Analytical Lifecycle

Moderator: Jane Weitzel

- FDA Presentation (*Dr Lucinda Buhse*)
- EU Presentation (*Dr Jobst Limberg*)
- Examples for pharmacopoeial procedures – MHRA (*James Pound*)

Q & A session on Stage 3

Transitioning to the new paradigm

This session provides the forum for an open discussion between speakers, expert panel members and participants. The plan is to brainstorm the way forward for the industry with regards to implementation of the three stages of the lifecycle approach to analytical procedures.

All participants will have a SWOT form to complete during the Workshop (question cards and a SWOT form for all participants at registration). The objective is to generate a consolidated SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) for each stage of the life cycle. The collated output will be captured and made available on the ECA web site post workshop.

Moderator: Dr Pauline McGregor

- Introduction to SWOT analysis for each of the 3 phases of the lifecycle (*Kimber Barnett*)
- Brainstorming and capturing outputs on flip charts

Q & A panel session from Day 2 & Workshop Concludes

Speakers



Dr Christopher Burgess

Burgess Analytical Consultancy Limited, Member of the Validation & Verification Expert Panel at USP

Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and 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 and a member of the Executive committee of European Compliance Academy



Greg Martin

Complectors Consulting, Chair of the Validation & Verification Expert Panel at USP

Greg Martin is President of Complectors Consulting (www.complectors.com) which provides consulting and training in the area of Pharmaceutical Analytical Chemistry. Mr. Martin has over 25 years experience in the pharmaceutical industry and was Director of Pharmaceutical Analytical Chemistry (R&D) for a major PhRMA company for a number of years. In addition, he has volunteered for the USP for over 10 years, and currently serves on the General Chapters – Chemical Analysis Expert Committee. He has particular interest in QbD/Lean approaches to dissolution testing, impurity methods, method lifecycle (development/validation/transfer) and instrument qualification, and is passionate about using good science and sound logic to achieve high quality results, consistent with cGMPs, while minimizing resources. Mr. Martin is author of several papers in the areas of dissolution and analytical method validation, and is past

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chair of the AAPS In Vitro Release and Dissolution Testing Focus Group.



Dr Horacio Pappa

Director of General Chapters at United States Pharmacopeia, Member of the Validation & Verification Expert Panel at USP

Dr Pappa has been with USP since 2003. He is currently the Director of the General Chapters Department, Global Science division of the USP. He provides scientific leadership to a team of scientific liaisons responsible for the activities of six different expert committees that cover the majority of the USP General Chapters. Horacio earned his Ph.D. in Pharmaceutical Chemistry from the University of Buenos Aires. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to Chromatography and Validation. Prior to joining USP, he worked in the pharmaceutical industry in QA/QC. Horacio held the position of Assistant Professor of Quality Control in the Faculty of Pharmacy at Buenos Aires University, and Executive Secretary of the Argentine Pharmacopeia in the period 1997-2001. He is a Quality Engineer certified by the American Society for Quality.



Dr Pauline McGregor

PMcG Consulting, Member of the Validation & Verification Expert Panel at USP

Pauline McGregor is a pharmaceutical consultant and owner of PMcG Consulting. She has over twenty five years' experience in the Pharmaceutical industry and holds a Ph.D in chemistry. She is an expert in quality systems and procedures, GMP regulations and analytical chemistry. Pauline has been involved with and has had a passionate interest in the evolution of method development, validation, transfer and verification of analytical methods and has been actively involved in authoring a paper and presenting short talks and training courses on the application of QbD to analytical methods. Pauline is currently a member of the Royal Society of Chemistry, UK and is listed on the RSC Directory of Consultants.



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. In 2014 she was pointed to the Chinese National Drug Reference Standards Committee and attended their inaugural meeting in Beijing



Elisabeth Kovacs

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

Elisabeth Kovacs is Chief Scientific Officer at Apotex Inc. In this role she is responsible for provision of scientific expertise and strategic direction to the organization in managing scientific advancement at all stages of product lifecycle. She has been at Apotex for over 30 years primarily involved in analytical R&D, analytical support to new product development, especially dissolution and drug release. Member of the Leadership Team for development and implementation of QbD at Apotex, she developed programs and provided training to Apotex staff on QbD and Life Cycle concepts. Elisabeth is member of the CSPS (Canadian Society for Pharmaceutical Science) board of Directors, GPhA Sciences and Regulatory Advisory Board, GPhA USP Task Force, and USP Project Teams.



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



Mark Argentine

Lilly

Dr Argentine is a Senior Research Advisor in the Analytical Sciences Research and Development division of Lilly Research Laboratories, Eli Lilly and Company. He received a B.S. in chemistry from the College of William and Mary in Virginia and a Ph.D. in analytical chemistry from the University of Massachusetts, Amherst. He joined Eli Lilly and Company in 1993 and has been involved in analytical control strategy development and commercialization of synthetic and semi-synthetic drug substance and drug product materials for the past 22 years. Current responsibilities and interests continue to include the development of analytical control strategies for pharmaceutical commercialization as well as the regulatory and quality aspects of drug development.



Dr Lucinda Buhse

Food and Drug Administration (FDA), Member of the Validation & Verification Expert Panel at USP

Dr Buhse joined DPA in 2001 as Deputy Director of the Division of Pharmaceutical Analysis for Center for Drug Evaluation and Research in the FDA. She was promoted to Division Director in June, 2004 and has been Director for Office of Testing and Research since June 2013. Dr Buhse received a B.A. in Chemistry from Grinnell College and a Ph.D. in Physical Chemistry from the University of California, Berkeley. Before joining FDA, Dr Buhse worked in manage-

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ment positions in Production, Validation and Analytical Services at Sigma Aldrich Corporation and as a Senior Research Scientist for Rohm and Haas Company. She leads a laboratory based office in the Center for Drug Evaluation and Research (CDER) responsible for supporting FDA review, investigation and enforcement actions and for conducting research programs to advance the science needed to regulate the quality of human drugs



Dr Bob McDowall

R D McDowall Ltd.

Dr McDowall is an analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry. He is the principal of R D McDowall Ltd., UK. He has written and taught extensively on compliance within analytical laboratories including qualification of instruments and validation of informatics solutions. He is the recipient of the 1997 LIMS Award.



Patrick Jackson

GSK

Patrick Jackson is an analyst at GSK leading analytical quality by design application within Product Development, Stevenage, UK with more than 8 years experience in the pharmaceutical industry working on Active Pharmaceutical Ingredients and chemical route development. Pat studied at York University where he obtained a Masters in Chemistry and later obtained a Masters in Applied Statistics from Sheffield Hallam University. Pat is also an associate member of The Royal Society of Chemistry.



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.



James Pound

Editor-in-Chief British Pharmacopoeia (BP), MHRA

James Pound joined the British Pharmacopoeia in 2008. He has worked in a variety of roles within the BP including responsibility for medicinal chemicals, digital & publications and veterinary medicines. In addition to this he initiated and has led the joint BP and MHRA AQbD feasibility study and working party. He was promoted to Editor-in-Chief of the British Pharmacopoeia in mid-2015 and is now responsible for the management of the BP Secretariat

unit at the MHRA. He holds an honours degree in Chemistry and has previously worked in a variety of roles focused on analytical chemistry for both multinational pharmaceutical manufacturers and independent UK analytical laboratories.



Dr Jobst Limberg

Federal Institute for Drugs and Medical Devices, BfArM, Germany


Dr Limberg joined BfArM in 1990. From 1995 to 2005 he was head of the unit "Pharmaceutical Technology". Following an interdisciplinary reorganization in 2005, he was appointed head of regulatory unit "Cardiology". Starting 2012 he is head of section "Scientific Quality" in the department European and International Affairs. He is responsible for scientific coordination of pharmaceutical quality in the German Drug Regulatory Agency and is the nominated German member of the Quality Working Party of the European Medicines Agency (EMA). He is also involved in the national PAT group and the respective international groups at EMA in London and EDQM in Strasbourg.

Social Event


On 8 November 2016, 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

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

Date

Tuesday, 8 November 2016, 9.00 h – 18.00 h
(Registration and coffee 8.00 h – 9.00 h)
Wednesday, 9 November 2016, 8.30 h – 18:00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4
Czech Republic
Phone + (0) 420 261 191 111
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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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

The official conference language will be English.


Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event

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