Validation of Analytical Methods and Life Cycle Management of Analytical Procedures

Live Online Conference on 23 November 2021

From USP to ICH

This Live Online Conference is part of PharmaLab 21 LIVE ONLINE
Analytics•Bioanalytics•Microbiology
22-26 November 2021

Highlights

- USP <1220> "The Analytical Procedure Lifecycle"
- Establish ATP for Small Molecules Establishing APLM
- ATP and TMU
- Transfer of Methods

Speakers

Ulla Bondegaard, Novo Nordisk
Jean Francois Dierick, GSK
Dr Joachim Ermer, Ermer Consulting
Dr Markus Fido, MFI Bioconsulting
Dr Gerald Gellermann, Novartis
Alexander Gill, VelaLabs
Patrick Jackson, GSK
Isabelle Moineau, AKTEHOM
Dr Pavel Parkhomyuk, Teva
Dr Xaver Schratt, GB Pharma

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CHATS WITH CHAUDHREY

Validation of Analytical Methods and Life Cycle Management of Analytical Procedures

23 November 2021, 09.00 - 17.30 h CET

Objectives

The Live Online Conference will present and highlight the current developments in the field of method validation and life cycle management. Experts from industry and laboratories will present the current status of the revision and the contents of the guidelines on the one hand; and their own experiences in the establishment and validation of methods and procedures on the other hand.

Background

On 14 November 2018, a final concept paper "ICH Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation" was published. It proposed to develop a new quality guideline for analytical procedure development and to revise the ICH Q2(R1) Guideline on Validation of Analytical Procedures: Text and Methodology. Meaning:

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Guideline Q14 Analytical Procedure Development
"The new guideline is proposed to harmonise the scientific approaches to analytical procedure development and to provide the principles for describing the process of analytical procedure development. The use of this guideline will improve communication between industry and regulatory authorities and facilitate more efficient, science-based and risk-based approval and post-approval change management of analytical procedures."

Q2(R1) Revision
"The scope of the revision will include validation principles covering the analytical use of spectroscopic or spectrometric data (e.g. NIR, Raman, NMR or MS), some of which often require multivariate statistical analyses. The guideline will continue to provide a general framework for the principles of analytical method validation applicable to products that fall primarily within the scope of Q6A and Q6B."

Unfortunately, development is currently treading water a bit, but nevertheless many laboratories are already running corresponding methods and procedures and report on their experiences here. Also the USP has published a corresponding document with Chapter <1229>, which will also be presented during this conference.

Target Group

The ECA Academy aims to actively engage analytical chemists, QC analysts, quality assurance staff and managers, R&D scientists, statisticians and managers, as well as production scientists and managers, regulatory affairs specialists and contract laboratories in this critical area for analytical science.
It is also useful for service providers, such as contract research organisations and contract manufacturers.

Programme

New USP General Information Chapter <1220> Analytical Procedure Lifecycle
- Valid from May 1st, 2022
- Holistic consideration of validation activities across the entire lifecycle of an analytical procedure
- Emphasis on sound scientific approaches and quality risk management
- Analytical Target Profile – requirements to the reportable value
- 3-Stages of the analytical lifecycle: Procedure Design, Procedure Performance Qualification, Ongoing Procedure Performance Verification

Dr Joachim Ermer, Ermer Quality Consulting

Analytical Development & Control for Complex Therapeutics – an Expedition via several Set-ups
- Complex drugs - complex analytics
- Challenges for complex Potency assays
- Alternative approach via orthogonal methods
- From feasibility to method validation – time required
- Different view from different assays

Dr Markus Fido, MFI Bioconsulting

Analytical Procedure Lifecycle Management, Stage 2 Transfer of Analytical Procedures
- How does the transfer fit into the life cycle of the analytical procedure
- Planning and preparations for method transfer
- How to benefit from a risk-based approach

Ulla Bondegaard, NovoNordisk

Established Conditions for Analytical Procedures & Application During the Analytical Life Cycle Management
- To assure product quality (for EC related to manufacturing process parameters)
- To assure method performance (for EC related to analytical procedure variables)
- To maintain reliable results for an efficient product control strategy
- Changing ECs and required regulatory activity

Isabelle Moineau, AKTEHOM, Jean-François Dierick, GSK

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How to Establish ATP for Small Molecules

- What needs an ATP
- When to Establish ATPs
- How to Write ATPs
- How to Use/Update ATPs

Patrick Jackson, GSK

Update TMU

- Stimuli Article by USP
- Deriving TMU from Specification

Dr Xaver Schratt, GB Pharma

Use of ATP to Guide Analytical Method Changes of Large Molecules

- What is the required content of an ATP for supporting risk and change management post approval?
- What is an analytical level concept and what knowledge is required to define performance requirements, technology specific requirements and parameter settings?

Dr Gerald Gellermann, Novartis

Analytical Procedure Lifecycle Management, Practical Implementation of Stage 3

- Elements of Analytical Procedure Life Cycle, Stage 3
- Activities in the routine testing laboratory
- Practical handling of simple procedures

Ulla Bondegaard, Novo Nordisk

Optimization, Qualification and Validation of FcgR binding using SPR

- Introduction:
  - SPR
  - FcRs
  - Standard kinetic / affinity method from Cytiva
- Optimization:
  - Different Ig-Subtypes (IgG1, IgG4)
  - Capture levels → issues
  - What else to adapt? Analyte concentrations (0.1 – 10 x KD)
- Qualification / Validation:
  - Based on ICH Q2(R1): selection of parameters
  - Qualifcation design for SPR kinetic and affinity assays: No sample mimics → no accuracy and no linearity possible
  - Acceptance criteria (% CV, repeatability, intermediate precision)
- Routine measurement
  - SOP
  - Assay and sample-validity criteria
  - Automated evaluation procedure (combined fitting model)

Alexander Gill, Vela Labs

Deriving Fit-to-Purpose Validation Acceptance Criteria Based on Actual Testing Procedures by HPLC

- The difference between analytical procedure and analytical method - which of them do we validate?
- Replicates: preparations vs. injections. How the precision criteria are influenced?
- Quantitation vs. external standard or by area normalization: to what extent the response should be linear?
- Accuracy of determination: validation vs. verification

Dr Pavel Parkhomyuk, Teva

Speakers

Ulla Bondegaard, Novo Nordisk, Denmark
Ulla Bondegaard has many years of experience in management of quality control laboratories covering a wide range of analytical techniques. Currently she is responsible for maintaining cross-organisational (and cross-country) laboratory processes in Novo Nordisk, including general laboratory GMP, handling of laboratory computerised systems and transfer of analytical procedures.

Jean Francois Dierick, GSK
Jean Francois studied Biology at the University of Namur. After positions a at BioVallée and SGS, he joined GSK in 2008 as Manager Analytical Method Validation QC Biochemistry. Since 2018 he is Global Subject Matter Expert Analytical Validation & Lifecycle.

Dr Joachim Ermer, Ermer Quality Consulting, Germany
Dr Ermer has 30 years of experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, Head of Quality Control, and Head of QC Lifecycle Management Frankfurt Chemistry at Sanofi. He is member of the USP Expert Committee Measurement and Data Quality, of the Chromatographic Separation Techniques Working Party of the European Pharmacopoeia, and of the EFPIA support team for the update/establishment of ICH Q2/Q14.

Dr Gerald Gellermann, Novartis, Switzerland
Analytical Lead at Novartis Biologics Development. Prior to joining Novartis he gained professional experience during his time at Roche from 2008 to 2015 in CMC and analytical method development. Gerald is currently the Novartis representative in the EFPIA analytical workstream supporting ICH Q2 and Q14.

Alexander Gill, VelaLabs, Austria
Alexander is a Lab Technician at VelaLabs. He studied biochemistry and molecular biology at the University of Vienna and his Master's degree at the Vienna University of Technology. He has been working for VelaLabs since 2019.

Patrick Jackson, GSK, UK
Patrick is an Investigator in Chemistry, Manufacturing and Controls at GSK. He joined the Analytical Method Robustness Testing group in 2008, took over leadership of this group in 2012 and oversaw it's transition to a general AQBD support group handing on the leadership in 2016. Patrick founded and still currently leads the Analytical Quality by Design Community in 2014.

Isabelle Moineau, AKTEHOM, France
Isabelle is an Analytical Expert Consultant for AKTEHOM. She is leading the Analytical Quality by Design implementation in pharmaceutical industries in Quality Control and Development laboratories. She is listening, guiding and assisting customers to evolve with the ever changing Pharmaceutical industry.

Dr Pavel Parkhomyuk, Teva Pharmaceutical Industries, Israel Analytical development manager with 17 years' experience in generic pharmaceutical industry. Member of USP small molecules expert committee (2020 – 2025 cycle).

Dr Xaver Schratt, GB Pharma, Germany
Dr Schratt is responsible for special projects at GB Pharma. He is charge of national and international pharmaceutical companies, he manages all analytical aspects of projects from preclinical stage up to phase III and post market approval. Since 2020 he is Head of Global Quality Management with focus on Data Integrity and Validation of Computerized Systems.

Easy Registration

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Date of the Live Online Conference

Tuesday, 23 November 2021, 09.00 – 17.30 h CET

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Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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- ❑ 23 November: Validation of Analytical Methods and Life Cycle Management of Analytical Procedure
- ❑ 24 November: Alternative- and Rapid Microbiological Methods
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- ❑ 26 November: Endotoxin and Pyrogen Testing (Day 2)

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