

Speakers



Chris Burgess
Burgess Analytical Con-
sultancy Limited, UK



Joachim Ermer
Sanofi-Aventis
Deutschland GmbH



Gerald Gellermann
Novartis



Annick Gervais
UCB Pharma



Rainer Gnibl
Local Government of
Upper Bavaria



Patrick Jackson
GSK



Luka Kosec
Agency for Medicinal
Products and Medical
Devices of the Republic
of Slovenia



Jürgen Martin
Martin-Consulting,
Germany



Xaver Schrott
GBA Pharma



Mijo Stanic
Chromicent

ICH Q2/Q14 Analytical Procedure Life Cycle Management

From development to continued verification

16/17 September 2020 | Berlin, Germany



Highlights

- Regulatory Developments and Expectations
- Compendial vs. Modern Approaches
- Analytical Target Profile (ATP)
- Validation for MAA/NDA
- ECA Guide for APLM
- Robustness and DoE
- Control Strategy



Save money and book this conference in
combination with the „ICH Q12 Product
Life Cycle Management“ conference!

Objective

This conference provides a comprehensive overview of the new ICH Quality Guideline Q14 on Analytical Procedure Development, and the revised Q2 Guideline on Validation of Analytical Procedures. Experts from authorities, industry and contract laboratories will discuss with you the contents, their significance for practice and approaches for implementation in your company.

Background

As early as 2018, the ICH announced that the Q2(R2)/Q14 Expert Working Group (EWG) would develop a new ICH quality guideline, ICH Q14, for the development of analytical methods and revise the ICH Q2(R1) guideline for the validation of analytical procedures. This will complement the existing ICH Q8 to Q12 guidance and the current ICH Q13 guidance for continuous manufacturing. The new Analytical Procedure Development Guideline (Q14) will then be relevant for sections S4, P4 and P5 of the CTD and should be seen together with Q8(R2) and Q11 as a supplement to the guidelines. The use of the enhanced approach to analytical procedures development and validation can contribute to resource-efficient drug development as well as submission process or facilitate changes after CMC approval. The revised Q2(R1) guideline will also be relevant for sections S4, P4 and P5 of the CTD, with an emphasis on systematic analytical development. As development and validation are linked and subsequent steps, both guidelines will be worked on by the same Expert Working Group, with a potential to combine both documents into one.

Q2(R1) Revision

The current Q2(R1) „Guideline on Validation of Analytical Procedures: Text and Methodology“ does not yet include modern analytical methods (e.g. near infrared (NIR) spectroscopy or Raman spectroscopy). This gap can lead to insufficient validation data for submissions and thus to additional official queries and thus to a delay in the approval of the application. This applies in particular to methods based on multivariate models, a category for which there is currently no guidance in ICH Q2(R1). NIR or Raman spectroscopy is often used in process control and real-time release testing (RTRT) using multivariate analytical methods. Therefore, the revision of ICH Q2(R1) will specifically serve the validation of modern analytical methods, including a discussion of statistical aspects. Common validation characteristics for methods such as NIR, nuclear magnetic resonance spectroscopy (NMR) and hyphenated techniques such as CE-MS, CE-ICP-MS, LC-NMR, GC-MS, LC-MS will also be considered.

Q14 Analytical Method Development Guide

As there is no ICH guideline for the development of analytical methods yet, it is often the case that applicants only report on analytical validation results and seldom present a performance evaluation with analytical development results. This makes communication with the regulatory authorities more difficult, especially when unconventional analytical methods are used (e.g. RTRT and multivariate models for process control). In addition, the lack of guidelines excludes the possibility for the applicant to provide a scientific basis for flexible regulatory approaches (e.g. Quality by Design (QbD) concept) to change analytical methods after approval.

According to ICH, the new directive is proposed to harmonise the scientific approaches to analytical process development and to provide the principles for the description of the analytical process development process. The new guideline should improve communication between industry and regulators and allow for more efficient, sound scientific and risk-based authorisation and change management for post-authorisation changes to analytical methods.

Issues to be addressed

Q14 Analytical Procedure Development guideline

Main technical and scientific elements, which require harmonization, include:

- Submission of analytical procedure development and related information in CTD format,
- The concept and strategy of enhanced approaches for analytical procedures,
- Performance criteria of analytical procedures,
- In line with ICH Q8 to ICH Q12, a greater understanding of analytical procedures can create the basis for more efficient, sound science and risk-based lifecycle management (e.g., using analytical QbD (AQbD) principles),
- Key elements and terminology,
- Demonstration of suitability for RTRT.

Q2(R1) Revision

For procedures reliant on multivariate methods the following will be addressed:

- Definition of validation characteristics applicable to multivariate methods which may differ with the area of application (e.g., identification vs. quantitation, batch vs. continuous process, dosage form assay vs. blending monitoring),
- Important method parameters (e.g., the number of latent variables) established during method development,
- Robustness which is well understood, however does not have a quantitative measure,
- Inclusion of post-approval verification and maintenance considerations as a part of the validation,
- Requirements for validation data sets.

Target Audience

This conference is addressed to all persons from

- Development
- Quality Control
- Quality Assurance
- Regulatory departments
- Contract labs
- Authorities

who are involved in the development and validation of analytical procedures or their evaluation.

Moderator

Dr Joachim Ermer

Programme

Current Status: The Revision of ICH Q2 and Development of ICH Q14

- Important gaps and deficiencies in current ICH Q2(R1)
- Content of the draft Guidelines Q2 / Q14
- Small step or giant leap?
- Have industry's expectations been met?

Description of Analytical Procedure and Validation - a Regulator's View

- Development of analytical method vs validation of analytical method
- Overall control strategies

Product Life Cycle Concept from the Perspective of the Authorities -

Focus: New Approaches in Process Development/Validation & Production Routine

- Quality by Design Lifecycle
- Realtime Release Testing
- Modern Process Analysis

How to establish an Analytical Target Profile (ATP) for Small Molecules

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

How to establish an Analytical Target Profile (ATP) for Large Molecules

- ATP as the corner stone of the analytical procedure development strategy
- How to set up an ATP for methods applied to biologics
- Case studies

How Software Tools can Support QbD Method Development

- Modern Quality-by-Design approach
- Statistical concepts with experimental design plans (also referred to as Design-of-Experiments) as an efficient and fast tool for method development
- Multivariate data analysis software package Fusion QbD®
- Chromatography simulation software DryLab®
- Workflow and examples in using software packages for method development

The ECA APLM Guide

- The ECA Analytical Quality Control Group
- Interactions between the Groups within ECA
- Drivers for and the process of the guideline development
- Contents and structure of version 1 July 2018
- Going forward; the journey to version 2

Verifications of Compendial Methods in Pharmaceutical QC

- Requirements for verification of compendial methods
- Verification versus validation versus analytical transfer
- Life cycle approach for compendial methods
- Design ranges for compendial methods
- Typical verification approaches

Analytical Lifecycle Management Using an Enhanced versus Traditional Approach

- ATP, DOE and MODR on a case study
- Risk based approach and patient impact considerations
- Analytical method changes post approval

Robustness and DoE

- Experimental Design
- Method Optimisation – Response Surface Designs
- Robustness Testing – Fractional Factorial Designs
- Ruggedness Testing – Measurement Systems Analysis
- Equivalent Testing – Two One Sided Tests

Validation for MAA/NDA. Planning and Execution

- Overview of relevant guidelines, pharmacopeial monographs
- ICH Q2 current version
- Practical Aspects of Method Validation (incl. examples)

TMU (Target Measurement Uncertainty)

- Stimuli Article by USP
- Deriving TMU from Specification

How to Establish an Efficient and Relevant Continued Performance Monitoring Program in Pharmaceutical Analysis

- What method performance information is available? (conformity, validity, numerical performance parameter)
- Identification of performance characteristics relevant for the analytical procedure: exploitation of available routine data
- Use of control charts
- Assay of control batches (virtual and concrete)
- The power of multiplicity: Calculation of long-term performance parameters (precisions)

Speakers

Chris Burgess,
Burgess Analytical Consultancy Ltd, UK
Chairman of the Analytical QC Group

Dr Burgess is a "Qualified Person" and was a member of the European QP Association advisory board. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and re-elected for the 2015 to 2020 cycle. In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

Joachim Ermer,
Sanofi-Aventis Deutschland GmbH
Head of QC Lifecycle Management Chemistry and
Global Reference Standards Coordinator

He studied biochemistry at University of Halle and has almost 30 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 USP Analytical Procedure Lifecycle Expert Panel and of the EFPIA support team for the update/establishment of ICH Q2/Q14.

Gerald Gellermann,
Novartis, Analytical Lead

Gerald currently works as 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. Before joining Roche he was working at Abbott in neuroscience research and later in the diagnostic division. Gerald is currently the Novartis representative in the EFPIA analytical workstream supporting ICH Q2 and Q14.

Annick Gervais,
UCB Pharma, Head of Analytical Development
Sciences for Biologicals

Annick is a chemical engineer by education and has a PhD from University Louis Pasteur, Strasbourg (France). She has more than 24 years of experience on biotech products working in analytical and process development of recombinant proteins.

Rainer Gnihl,
Local Government of Upper Bavaria, GMP Inspector
for EMA and local Government, Germany

Rainer is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnihl also holds a lectureship at the University Erlangen-Nurnberg

Patrick Jackson,
GSK, Investigator in Chemistry, Manufacturing and
Controls - Analytical

Joined GSK in 2005 following the completion of his MChem at York University. Joined the Analytical Method Robustness Testing group in 2008, took over leadership of this group in 2012 and oversaw its transition to a general AQBD support group handing on the leadership in 2016. Completed an MSc in Applied Statistics with Sheffield Hallam 2010-2013. Founded and still currently leads the Analytical Quality by Design Community in 2014.

Luka Kosec,
Agency for Medicinal Products and Medical Devices
of the Republic of Slovenia, Quality Assessor
Studied at the University of Ljubljana. Worked 2013- 2014 at Lek
Pharmaceuticals. After a trainee in community pharmacy he
joined University of Ljubljana as associate in academic research.
Since 2017 he is a quality assessor at the Slovenian Agency.

Jürgen Martin,
Martin-Consulting, Germany, Consultant
Jürgen has more than 25 years of experience in pharmaceutical
industry and quality control. After his education at the university
of Konstanz he has held different leading positions focusing on
quality control topics at Byk Gulden, Altana Pharma and Ny-
comed. Between 2011 and 2019 he was building up and heading
the quality control of the BIPSO GmbH. Since 2019 he is operat-
ing his own consultancy and software development office. As exp-
ert in qualification, validation and tech transfer projects he is
focused on chromatographic and instrumental analytical meth-
ods.

Xaver Schratt,
GBA Pharma, Special Projects
Dr Schratt studied Chemistry at the University of Bayreuth,
where he specialized in HPLC and HPLC/MS. In 2005 he joined
GBA Pharma (former LAT) and until 2020 he was head of depart-
ment "special projects". In 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.

Mijo Stanic,
Chromicent, Technical Director/General Manager
Mijo Stanic is General Manager and Technical Director at Chro-
micent GmbH in Berlin, Germany, a company specialized in all
stages of the lifecycle of analytical methods, particular in meth-
od development using Quality by Design tools. Mijo has more
than 15 years' experience in the pharmaceutical industry in the
position as Head of Analytical Development and is an expert in
DryLab, Fusion QbD and Design Expert software.

Social Event



At the end of the first course day 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.

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

Reservation Form (Please complete in full)

- ICH Q2/Q14 - Analytical Procedure Life Cycle Management, 16/17 September 2020, Berlin, Germany
 ICH Q12 - Product Life Cycle Management, 15/16 September 2020, Berlin, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

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Date

Wednesday, 16 September 2020, 13.30 – 18.00 h

(Registration and coffee 13.00 -13.30 h h)

Thursday, 17 September 2020, 08.30 – 17.00 h

Venue

InterCityHotel Berlin Hauptbahnhof

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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, business lunch and dinner on the first day, lunch on the second day 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/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.



Would you like to save money?

You will save € 400,- if you book the ICH Q14/ ICH Q2 course and the ICH Q 12 course (from 15 to 16 September 2020, Berlin, Germany) together.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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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