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Speakers

Dr Rainer Gnibl
GMP Inspector

Dr Ulrich Kissel
Chair of the EQPA

Dr Maren Kopp
Boehringer Ingelheim

Dr Jennifer Maguire
FDA

Dr Lisa Matzen
Boehringer Ingelheim

Luisa Paulo
Hovione

Dr Jean-Louis Robert
ICH Q12 EU topic lead

ICH Q12 - Product Life Cycle Management

How to deal efficiently with global post-approval changes

Live Online Conference on 15/16 September 2020

With Case Studies from the U.S. Established Conditions Pilot!

Highlights

- Status of the Final Document
- Views and Expectations of Assessors & Inspectors
- Key Elements of Lifecycle Management:
  - Quality & Supply Risk Management
  - Global Change Management
  - Use of Knowledge
- "Established Conditions" (ECs) for
  - the Manufacturing Process
  - Analytical Procedures
- Examples for "Postapproval Change Management Protocols (PACMPs)"
- Application of ICH Q12 for Currently Marketed Products
- Industry Strategies to Use ICH Q12 Effectively

Save money and book this live online conference in combination with the „ICH Q2/Q14 Analytical Procedure Life Cycle Management" live online conference!

Objective & Background

The **ICH Q12** topic was endorsed by the ICH Steering Committee in September 2014 and the draft ICH Q12 Guideline on **Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management** was published for comment in December 2017. The final ICH Q12 Post-Approval Changes Guideline including two Annexes has been adopted in November 2019. The guideline aims to promote innovation and continual improvement, and strengthen quality assurance and reliable supply of product, including proactive planning of global supply chain adjustments.

The next phase will be the implementation of ICH Q12 across the ICH regions. However, especially in the EU, revision of local regulations (e.g. the EU Variations Regulation) will have to be performed to fully implement the concepts of Q12.

The new guideline has been developed to complement the existing **ICH Q8 to Q11 guidelines**, especially to enable full realization of more flexible regulatory approaches to **post-approval CMC changes**. The guideline applies to pharmaceutical drug substances and products (both chemical and biological). The guideline also applies to drug-device combination products that meet the definition of a pharmaceutical or biological product and to analytical methods.

In order to ensure a standardized approach, the guidance defines the categorization of Post-Approval CMC changes, Established Conditions (ECs), Post-Approval Change Management Protocols (PACMPs), and Product Lifecycle Management (PLCM) concepts. In particular, the guideline emphasizes the relationship between **Regulatory Assessment and GMP Inspection**.

Furthermore, the guideline describes how ECs are identified as well as what information can be designated as supportive information that would not require a regulatory submission, if changed. Guidance is also included for managing revisions of the ECs over a product's lifecycle.

Conference presentations, case studies and open discussions will help participants learn more about the lifecycle management of pharmaceutical products and provide a forum for discussing ICH´s new guideline.

Participants will thus have the opportunity to give feedback and ask questions directly to ICH´s Q12 Expert Working Group (EWG) members on how to move forward with the transition to and implementation of the lifecycle approach.

The meeting will also address topics such as:

- What are "Established Conditions" for Manufacture and Control?
- How could Postapproval Change Management Protocols look like?
- What is the impact of ICH Q12 on analytical method and process validation and transfer?
- What are the views and expectations of assessors and inspectors?

Target Audience

The ECA wishes to actively involve QA personnel dealing with global change management, analytical chemists, QC analysts, R&D scientists, as well as manufacturing scientists (process developers) and managers, and regulatory affairs specialists and regulators.

Moderators

Dr Jean-Louis Robert, Dr Andrea Kühn-Hebecker

Programme Day 1

09.00 - 09.15 Welcome and Introduction

09.15 - 10.30
Update on ICH Q 12 – Current Status of the Final Document

- Current status
- Implementation in Europe
- Application of Q12 tools on post approval changes for:
  - Analytical methods
  - Manufacturing process
  - Manufacturing site

10.30 - 10.45 Break

10.45 - 11.45
Key elements of Lifecycle Management and implications from ICH Q12

- Quality (and Supply) Risk Management
- Multi-site Change Management
  - Prioritization, planning, processes and governance

11.45 - 12.15 Q & A Session 1

12.15 - 13.15 Break

13.15 - 14.15
Change Implementation Control now and with ICH Q12

- How we control change implementation today
- How will ICH Q12 influence our future?
- Simplification or new complexity?
- QP considerations

14.15 - 15.15
How Quality Systems have to support the ICH Q12 vision

- ICH Q10 Pharmaceutical Quality System (PQS)
- Importance of Quality Metrics
- Interplay between the PQS and Regulatory Affairs
- QP experience

15.15 - 15.30 Break

15.30 - 16.45
Established Conditions Pilot (U.S.)

- Case studies for process and product
- Innovative analytic approaches
- Lessons learned

16.45 - 17.15 Q & A Session 2

Programme Day 2

08.30 - 09.15
How could Post-approval Change Management Protocols (PACMPs) look like?

- What is a PACMP?
- Structure
- Examples

09.15 - 10.00
Post-approval CMC Changes - How to Use ICH Q12 Effectively

- Global Regulatory Complexity
- Agile post-approval change management within ICH Q12 including examples for
  - Classification of changes
  - Established Conditions / PACMPs / PLCM

10.00 - 10.15 Break

10.15 - 11.30
Views and Expectations of Inspectors

- Interfaces between ICH Q12 & GMP
- Intentions, preconditions & the Inspector's expectations
- Challenges

11.30 - 12.00 Q & A Session 3

12.00 End of conference

Speakers

Dr Rainer Gnibl, 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 Gnibl also holds a lectureship at the University Erlangen-Nurnberg.

Dr Ulrich Kissel, European QP Association, KisselPharma-Consulting, Germany

Ulrich is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Dr Maren Kopp, Boehringer Ingelheim, Germany

Maren is currently Head of Global PLM Operations at Boehringer. In her role she is leading the Global Product Lifecycle Management (PLM) for NCE and NBE projects starting in the Development Phase, including launch preparation and launch. She is responsible for managing the matrix organization for Operations with regard to PLM including governance of product related Operations Steering Committees.

Dr Jennifer Maguire, FDA, USA

Jennifer has been working for the US FDA since 2010. She was CMC Reviewer, Lead Chemist, Branch Chief, and Division Director (Division of Quality Intelligence, Risk Analysis and Modelling) at FDA´s CDER/OPQ/Office of Surveillance. In December 2019 Jennifer started a new position as Deputy Director (OPQ, Office of Quality Surveillance) at FDA.

Dr Lisa Matzen, Boehringer Ingelheim, Germany

Lisa has held several positions within Boehringer including CMA RA Manager, Office Head CMC RA and Head of Cardiovascular Office (Global Regulatory Affairs). Currently she is Head of the Global CMC RA Group, (Global Regulatory Affairs) at Boehringer.

Luisa Paulo, ICH Q12 EWG Member, Hovione, Portugal

Luisa is Compliance Director at Hovione and Chair of APIC's Quality Metrics Task Force. Currently she is member of the ICH Q12 Expert Working Group (EWG) representing APIC.

Dr Jean-Louis Robert, Co-opted CHMP member, ICH Q12 EU topic lead, Luxemburg

Jean-Louis was head of the Service de Chimie Pharmaceutique, an official medicines control laboratory, at the LNS, before retiring in March 2015. He is a member of the Committee for Human Medicinal Products (CHMP) since 1995 (co-opted member since 2004) at the EMA in Amsterdam and was chairman of the CHMP/CVMP Quality Working Party from 1995 - 2017. He was rapporteur for the Implementation Working Group ICH Q8, Q9, Q10 and in charge of the ICH Quality Topic Recommendation Working Group. Currently he is EU topic leader for ICH Q12.

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Live Online Conferences

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

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Date of the Live Online Conference

Tuesday, 15 September 2020, 9.00 to 17.30 h CEST
Wednesday, 16 September 2020, 8.30 to 12.00 h CEST

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Organisation and Contact

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Speakers


Chris Burgess
Burgess Analytical Consultancy 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 Schratt
GBA Pharma


Mijo Stanic
Chromicent

ICH Q2/Q14 Analytical Procedure Life Cycle Management

From development to continued verification

Live Online Conference on 16/17 September 2020

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 training in combination with the „ICH Q12 Product Life Cycle Management“ training!

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 risked-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.

Moderators

Dr Joachim Ermer
Axel H.Schroeder

Programme 16 September 2020

13.00 – 13.15 h
Welcome and Introduction

13.15 – 14.00 h
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?

14.00 – 15.30 h
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

15.30 – 15.45 h Break

15.45 – 16.15 h
Description of analytical Procedure and Validation, a Regulator's View

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

16.15 – 16.45 h
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

16.45 – 17.15 h
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

17.15 – 18.00 h
Questions & Answers

Programme 17 September 2020

08.30 – 09.00 h
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

09.00 – 09.45 h
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

09.45 – 10.00 h Break

10.00 – 10.45 h
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

10.45 – 11.30 h
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

11.30 – 12.00 h
Questions & Answers

12.00 – 13.00 h Break

13.00 - 13.45 h
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

13.45 – 14.30 h
Validation for MAA/NDA. Planning and Execution

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

14.30 -14.45 h Break

14.45 – 15.30 h
TMU (Target Measurement Uncertainty)

- Stimuli Article by USP
- Deriving TMU from Specification

15.30 – 16.15 h
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)

16.15 – 17.00 h
Questions & Answers

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.

Speakers

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 Gnibl, 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 Gnibl 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 it's 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 Nycomed. Between 2011 and 2019 he was building up and heading the quality control of the BIPSO GmbH. Since 2019 he is operating his own consultancy and software development office. As expert in qualification, validation and tech transfer projects he is focused on chromatographic and instrumental analytical methods.

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 department "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 Chromicent GmbH in Berlin, Germany, a company specialized in all stages of the lifecycle of analytical methods, particular in method 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.

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Wednesday, 16 September 2020, 13.00 – 18.00 h
Thursday, 17 September 2020, 08.30 – 17.00 h

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Organisation and Contact

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