



## Speakers



Dr Rainer Gnibl  
GMP Inspector



Dr Ulrich Kissel  
Chair of the EQPA



Dr Maren Kopp  
Boehringer Ingelheim



Dr Lisa Matzen  
Boehringer Ingelheim



Luisa Paulo  
Hovione



Dr Jean-Louis Robert  
ICH Q12 EU topic lead  
FDA Speaker (invited)

# ICH Q12 - Product Life Cycle Management

How to deal efficiently with global post-approval changes

15/16 September 2020 | Berlin, Germany



## 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 conference in combination with the „ICH Q2/Q14 Analytical Procedure Life Cycle Management“ 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.

## Moderator

Dr Jean-Louis Robert

## Programme Day 1

### Update on ICH Q 12 – Current Status of the Final Document

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- Current status
- Timelines for Implementation

### Change Implementation Control now and with ICH Q12

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- How we control change implementation today
- How will ICH Q12 influence our future?
- Where do we need to develop our systems to
- Simplification or new complexity?
- Practical considerations

### Key Elements of Lifecycle Management: Quality and Supply Risk Management

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- Balance between quality, cost and risk
- Portfolio aspects
- Teams, processes and governance

### Key Elements of Lifecycle Management: Global Change Management

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- Multi-site change management: local vs. global
- Prioritisation, planning and efficiency
- Teams, processes and governance
- Change management and regulatory activities

### Views and Expectations of Assessors

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- Intentions, preconditions & the Assessor's expectations
- Identifying "Established Conditions" for manufacture and control
- Challenges

### Views and Expectations of Inspectors

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

## Programme Day 2

### How Could the Utility of Proposed Q12 Tools of Day 1 Simplify Post Approval Changes?

- Analytical methods
- Manufacturing process
- Manufacturing site

### How Quality Systems Have to Support the ICH Q12 Vision

- ICH Q10 pharmaceutical quality systems have to support ICH Q12 vision
- New importance of quality metrics
- Stronger interface of pharmaceutical quality system with regulatory
- ICH Q12 and reliable project management capabilities
- Practical experience

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

- What is a PACMP?
- Structure
- Examples

### Post-approval CMC Changes - How to Use ICH Q12 Effectively

- Agile post-approval change management within ICH Q12
- PACM protocols & classification of changes
- Established conditions
- Regulatory flexibility & robustness of current pharmaceutical quality systems

## 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 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.

FDA Speaker (invited)

## 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.



### Important Information

You will receive a USB memo stick with the presentations when you register in Berlin. Note: there will be no print-outs available during the conference.

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

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### Reservation Form (Please complete in full)

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

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34  
  
D-69007 Heidelberg  
GERMANY

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2. If you have to cancel entirely we must charge the following processing fees:
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  - Cancellation within 1 week prior to the conference 100 %

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German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at [http://www.gmp-compliance.org/eca\\_privacy.html](http://www.gmp-compliance.org/eca_privacy.html)). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

## Date

Tuesday, 15 September 2020, 9.00 to 17.45 h  
(Registration and coffee from 8.30-9.00 h)  
Wednesday, 16 September 2020, 8.30 to 13.30 h

## Venue

InterCityHotel Berlin Hauptbahnhof  
Katharina-Paulus-Straße 5  
10557 Berlin, Germany  
Phone +49(0)30 288 755 0  
Email [berlin-hauptbahnhof@intercityhotel.de](mailto:berlin-hauptbahnhof@intercityhotel.de)

## 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, lunch and dinner on the first day, business lunch on the second day and all refreshments. VAT is reclaimable.

## Accommodation

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### Would you like to save money?

You will save € 400,- if you book the ICH Q 12 course and the ICH Q14/ ICH Q2 course (from 16 to 17 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](http://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.

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
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### For questions regarding content please contact:

Dr Andrea Kühn-Hebecker (Operations Director) at  
+49(0)62 21/84 44 35, or at  
[kuehn@concept-heidelberg.de](mailto:kuehn@concept-heidelberg.de).

### For questions regarding reservation, hotel, organisation etc. please contact:

Ms Julia Grimmer (Organisation Manager) at  
+49(0)62 21/84 44 44, or at  
[grimmer@concept-heidelberg.de](mailto:grimmer@concept-heidelberg.de).

## Speakers



Chris Burgess  
Burgess Analytical Con-  
sultancy Limited, UK



Joachim Ermer  
Sanofi-Aventis  
Deutschland GmbH



Gerald Gellermann  
Novartis



Annick Gervais  
UCB Pharma



Rainer Gnihl  
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



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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

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- 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

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- 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

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

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

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- 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

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- 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

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- 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

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- 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

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- 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

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

## Robustness and DoE

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- 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

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

## TMU (Target Measurement Uncertainty)

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- Stimuli Article by USP
- Deriving TMU from Specification

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

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- 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.

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 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

Purchase Order Number, if applicable

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ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

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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

Katharina-Paulus-Straße 5

10557 Berlin, Germany

Phone +49(0)30 288 755 0

Email [berlin-hauptbahnhof@intercityhotel.de](mailto:berlin-hauptbahnhof@intercityhotel.de)

## Fees (per delegate, plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

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## Organisation and Contact

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CONCEPT HEIDELBERG

P.O. Box 10 17 64

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