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# ICH Q12 - Product Life Cycle Management

13-14 November 2018, Berlin, Germany

Now available:

Step 2 Draft document on ICH Q12 has  
been published in December 2017!

## Speakers



**DR BERNHARD BÖHM**  
Boehringer Ingelheim



**DR GRAHAM COOK**  
Pfizer, ICH Q12 EWG Member



**DR HILTRUD HORN**  
HORN Pharmaceutical  
Consulting



**LUISA PAULO**  
Hovione, ICH Q12 EWG Member



**DR JEAN-LOUIS ROBERT**  
EMA, ICH Q12 EWG Member  
(EU topic leader for ICH Q12)



**DR FRANZ SCHÖNFELD**  
GMP Inspector

## HIGHLIGHTS:

- Current Status of the proposed document
- Views and expectations of regulators & inspectors
- Key elements of Lifecycle Management:
  - Quality & Supply Risk Management
  - Global Change Management
  - Use of Knowledge
- “Established Conditions” and “Comparability Protocols”
- Application of ICH Q12 for currently marketed products
- Industry strategies to use ICH Q12 effectively



This conference is recognised for the ECA GMP Certification Programme, „Certified Pharmaceutical Development Manager“.  
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# ICH Q 12 - Product Life Cycle Management

13-14 November 2018, Berlin, Germany

## Objectives & Background

The **ICH Q12** topic was endorsed by the ICH Steering Committee in September 2014. Now progress has been made towards developing the draft ICH Q12 Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management:

The Step 2 a/b draft document has been published for comment **since December 2017**.

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 (i.e., active pharmaceutical ingredients, **APIs**) and pharmaceutical drug products, including marketed chemical, and biotechnological/biological products. The guideline also applies to drug-device combination products („Drug-delivery products“) that meet the definition of a pharmaceutical or biotechnological/biological product.

Therefore, the Q12 draft includes chapter on Established Conditions (**ECs**), Post Approval Change Management Protocols (**PACMPs**), Product Lifecycle Management (**PLCM**) documents, Pharmaceutical Quality System (**PQS**) and Change Management, categorization of post-approval CMC changes, relationship between regulatory assessment and inspection, and the application of Q12 for currently marketed products. 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 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:

- Identifying "Established Conditions" for Manufacture and Control
- How could Postapproval Change Management Protocols ("Global Comparability Protocols") look like?
- Validation as part of lifecycle activity: What is the impact of ICH Q12 on analytical method and process transfer?
- What are the skills and interfaces a „Global Life Cycle Manager“ or „Global Change Manager“ needs?

## 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.

## Programme

### ► Day 1

#### Update on ICH Q 12 – Current Status of the proposed document

*Dr Jean-Louis Robert*

- Current status

#### How ICH Q8-Q12 Guidelines work together from Development to Product Realization and Continuous Improvements

*Dr Hiltrud Horn*

- What is important for Development of APIs and Drug Products in EU and US?
- What are key points of discussion for APIs and Excipients?
- How will ICH Q12 influence our future?
- What are key aspects that you should know to avoid unnecessary variations?

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

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

*Dr Bernhard Böhm*

#### Key elements of Lifecycle Management: Global Change management

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

*Dr Bernhard Böhm*

#### Identifying "Established Conditions" for Manufacture and Control

*Luisa Paulo*

#### Views and expectations of Inspectors

*Dr Franz Schönfeld*

### ► Day 2

#### How could the utility of proposed Q12 tools of Day 1 simplify post approval changes?

*Dr Jean-Louis Robert*

- Analytical methods
- Manufacturing process
- Manufacturing site

#### What is the impact of ICH Q12 on analytical method and process transfer?

- How can you use ICH Q12 for method and process changes?
- What is the difference prior and after ICH Q12?
- How should you proceed in your daily practice?
- What should you know about CMC vs. GMP-aspects (dossier/inspections)?
- Practical examples

*Dr Hiltrud Horn*

### What are the skills and interfaces a „Global Life Cycle Manager“ or „Global Change Manager“ needs?

- Scope models: how comprehensively to manage products?
- Matrix management
- Leadership skills
- The ideal team – experience and diversity

*Dr Bernhard Böhm*

### How could Post-approval Change Management Protocols (“Global Comparability Protocols”) look like?

*Luisa Paulo*

### Industry strategies to use ICH Q12 effectively

*Dr Graham Cook*

- How much the industry will benefit from the guideline
- How it will impact the post approval changes
- What type of changes will benefit

### End of Life Cycle – How to manage?

- Portfolio analysis and pruning: selection criteria
- Divestiture and withdrawal: what to consider
- Efficient clean-up

*Dr Bernhard Böhm*

### “Issues under Discussion” and Next Steps

*Dr Graham Cook*

- Concerns and implications

## Moderator

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Dr Jean-Louis Robert

## Speakers

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### ► DR BERNHARD BÖHM

Boehringer Ingelheim, Germany



Bernhard Böhm is Vice President Global Product Lifecycle Management Operations. After joining the pharmaceutical industry at Solvay Pharmaceuticals, he held various positions in production, QA and

Regulatory Compliance at Solvay’s German and French manufacturing sites. WithinB oehringer Ingelheim, he headed R&D Project Management units in Germany and the US.

### ► DR GRAHAM COOK

ICH Q12 EWG Member, Pfizer, UK



Graham is part of Pfizer’s Global Quality Strategy group working on regulatory intelligence and external engagement, and leading the Pfizer team implementing the GMP aspects of the EU Falsified

Medicines Directive. He was appointed to the British Pharmacopoeia Commission in 2010 and elected Chairman of the ASTM International E55 Technical Committee developing pharmaceutical manufacturing standards in 2012. He is a pharmacist with a Ph.D. in pharmaceuticals. Currently he is one of the members of the ICH Q12 Expert Working Group (EWG) representing EFPIA.

### ► DR HILTRUD HORN

HORN Pharmaceutical Consulting, Germany



Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs (EU and US). She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (now Abbott) in Ludwigshafen with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing. She was consultant for the biotech and life science industry at Cap Gemini Ernst & Young prior to starting her own business more than 15 years ago. She is pharmacist with a Ph.D. and holds a Diploma in Pharmaceutical Medicine (Basel). Furthermore she is specialized pharmacist for pharmaceutical analytics and for drug information.

### ► 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, UK



Dr Jean-Louis Robert 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 European Medicines Agency (EMA) in London and was chairman of the CHMP/CVMP Quality Working Party from 1995 - 2017. Within the International Conference on Harmonization (ICH), he is or was involved in different topics mainly Validation of Analytical Procedures, Common Technical Document-Quality, revision of the guidelines on impurities (Q3A and Q3B), Pharmaceutical Development (Q8 and Q8R1), Pharmaceutical Quality System (Q10). 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 Life Cycle Management ICH Q12.

### ► DR FRANZ SCHÖNFELD,

District Government of Upper Franconia, Germany



Franz Schönfeld is GMP Inspector and Head of the Expert Working Group for APIs and excipients at the German Central Authority of the Federal States for Health Protection (EFG 07/ ZLG).


## Social Event


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In the evening of the first conference 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.

## Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg, Germany

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.gmp-compliance.org

### Date

Tuesday, 13 November 2018, 9.00 to 17.00 h  
(Registration and coffee from 8.30 - 9.00 h)  
Wednesday, 14 November 2018, 8.30 to 16.45 h

### Venue

Steigenberger Hotel Berlin  
Los-Angeles-Platz 1  
10789 Berlin, Germany  
Phone +49 30 21 27 0  
Email berlin@steigenberger.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, dinner on the first day, 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/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

### 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  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
info@concept-heidelberg.de  
www.concept-heidelberg.com

#### For questions regarding content please contact:

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

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


Ms Katja Kramer (Organisation Manager) at +49-62 21/84 44 16, or per e-mail at [kramer@concept-heidelberg.de](mailto:kramer@concept-heidelberg.de).

#### Important Information!

There will be no print-outs available during the conference. Instead you will receive all presentations prior to the event as downloads as well as after the event, in case of updates. You will also receive a USB memo stick with the presentations on it when you register in Berlin.

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

Reservation Form (Please complete in full)

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**ICH Q12 - Product Life Cycle Management**  
13-14 November 2018, Berlin, Germany

Mr  Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

#### General terms and conditions

If you cannot attend the conference you have two options:  
1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely we must charge the following processing fees: Cancellation

- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %

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**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.

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