ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Development Manager

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

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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

Technical Requirements

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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.

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You will save € 400,- if you book both live online conferences (ICH Q 12 and ICH Q14/ ICH Q2) together.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Conferences as PDF files. After the event, you will automatically receive your certificate of participation.

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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