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

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

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

Now available:
Step 2 Draft document on ICH Q12 has been published in December 2017!
ICH Q12 - 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?

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
Dr Bernhard Böhm
• Multi-site change management: local vs. global
• Prioritisation, planning and efficiency
• Teams, processes and governance

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

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.
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
  *Dr Jean-Louis Robert*

Speakers
  *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. Within Boehringer 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 pharmaceutics. 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.

  *Dr 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
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:
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.

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.

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
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.

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.

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 1 week prior to the conference 100 %.
   until 1 weeks prior to the conference 50 %
   until 2 weeks prior to the conference 10 %
   of this event cannot take place.
   If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
   Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!). As of January 2012, 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/privacy-policy). I note that I can ask for the modifications, correction or deletion of my data at any time via the contact form on this website.

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

Reservation Form (Please complete in full)
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)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34
69007 Heidelberg
Germany

© Concept Heidelberg 2018