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GMP Webinar
ICH Q12 – New approach to support innovation

Date:
Tuesday, 5 November 2019, 14.00 - 15.30 h CET

Speaker:
Dr Ulrich Kissel,
European QP Association, KisselPharmaConsulting, Germany

ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

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Background
Progress has been made towards developing the new **ICH Q12 Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management:**
The draft document has been published for comment and is currently in Step 3 of the ICH process. 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") and **analytical methods.**

This Webinar will help participants learn more about the lifecycle management of pharmaceutical products and the concepts of ICH Q12 including tools like **Established Conditions (ECs) and Post Approval Change Management Protocols (PACMPs)**.

Programme
- The Product Lifecycle Management in ICH Q12
  - Starting from product development and product design
  - Based on a reliable wealth of generated data
  - Looking for an approach to simplify global regulatory change management
  - Product development continues at the same speed also after product launch
- Current systemic resistances to innovation
  - External and organizational internal limitations
  - Expectations addressed to an active change management approach
  - Reality and experience from regulatory changes
  - The practical experience slows down any initiative
  - Without initiative no innovation
- New toolbox will ensure flexibility and innovation
  - New tools used during registration will reduce external hurdles to change
  - New tools will support planning and flexibility
  - Established Conditions, Product Lifecycle Management and Post Approval Change Management Protocol will bring us forward
  - The outlook to reliably be successful will fertilize innovation
  - Experience based on knowledge and data will ensure speed in the process
  - As a consequence innovation will explode
- Change Control and regulatory variations
  - Future regulatory change management under ICH Q12 implementation
  - The importance of a risk-based change management concept
  - A potential path to regulatory harmonization
  - Practical consequences applying these priniciples
- Reflection on required key milestones to success
  - How are the chances to success of the ICH Q12 approach?
  - How likely is missing success of the ICH Q12 approach?
  - ICH Q12 in relation to ICH Q8 – ICH Q11
  - How long may it take?

Target Audience
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.

Speaker

Dr Ulrich Kissel, European QP Association, KisselPharma-Consulting, Germany
Ulrich Kissel is Qualified Person and Member 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.

Fees (plus VAT)
Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members
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You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de** for details.

Group Participation (fee per person):
3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

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Registration
By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Presentation/Certificate
The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Do you have any questions?
For questions regarding content:
Dr Andrea Kühn-Hebecker, phone +49 62 21 - 84 44 35,
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For questions regarding technical aspects:
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Registration for the GMP-Webinar: ICH Q12 – New approach to support innovation, 5 November 2019, 14.00 - 15.30 h, Speaker: Dr Ulrich Kissel
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
- ☐ **Single Participation**
- ☐ **Group Participation**
  - ☐ 3-10 Persons
  - ☐ 11-20 Persons
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Important: Deadline is 12 noon on 4 November

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