GMP Webinar Recording
ICH Q12 – New approach to support innovation

Date of the recording: 5 November 2019

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

- 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

(This fee does not include the ECA Membership. You will find more about the ECA Membership at http://www.gmp-compliance.org/eca_about.html.)

**Participation of a Group**

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 +49/06221-844413, 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

**Technical Requirements**

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

**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-Hebeker, phone +49 62 21 - 84 44 35, email: kuehn@concept-heidelberg.de.

For questions regarding technical aspects: Mr Rouwen Schopka, phone +49 62 21 - 84 44 13 email: schopka@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 fee:
   - Cancellation up to 2 weeks prior to the conference 10 %, within 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

**Important:** This is a binding registration and above fees are due in case of cancellation or non-attendance. 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).

---

**Registration for the GMP-Webinar Recordings**

ICH Q12 – New approach to support innovation of 5 November 2019, Speaker: Dr Ulrich Kissel

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

**Date on which you want to watch the recording online**

<table>
<thead>
<tr>
<th>Company</th>
<th>Department</th>
<th>VAT ID No. (mandatory)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street</td>
<td>Postal Code/City</td>
<td>Phone</td>
</tr>
</tbody>
</table>

**E-Mail (mandatory for your registration)**

If you have any questions or further information you need, please contact Mr Rouwen Schopka, phone +49 62 21 - 84 44 13, email: schopka@concept-heidelberg.de.