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GMP Webinar
Early Analytical Life Cycle Management for Drug Substances and Drug Products

Date:
Thursday, 16 July 2020, 14.00 – 15.30 h CEST

Speaker:
Dr Gerd Jilge, Boehringer Ingelheim

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

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Background
The assurance of 'fitness for purpose' of analytical procedures is a critical part of any process for ensuring drug quality. The current situation for analytical control laboratories is unsatisfactory as the ICH Q2(R1) "Guideline on Validation of Analytical Procedures: Text and Methodology" does not cover more recent application of analytical procedures, (e.g., Near Infrared (NIR) Spectroscopy or Raman Spectroscopy). Moreover there is no ICH guideline on Analytical Procedure Development. As a consequence applicants often report analytical validation results alone and rarely present performance evaluation with analytical development outcomes which makes regulatory communication ineffective. Therefore there is a need for a revised ICH Q2 Guideline and a new Analytical Procedure Development Guideline (ICH Q14). For simplification and clarity the ICH Expert Working Group is currently developing a combined document ICH Q2(R2)/Q14 which is intended to be available for public consultation in June 2020.

While this work is still under progress ECA's Analytical QC Group has developed a new Guideline on Analytical Procedure Lifecycle Management. It is consistent with the ICH and USP principles and provides detailed assistance in their practical implementation.

Educational Objectives
This Webinar gives an explanation of the Analytical Lifecycle Management based on ideas created by a working group within the European Compliance Academy (ECA) but also includes trends which may be defined in the new ICH Guidelines.

Furthermore, this webinar gives an explanation,
- the meaning of Analytical Quality by Design
- how to apply the Analytical Target Profile (ATP) during development
- and the impact on the ICH Guideline Q12 with respect to „Established conditions"

In addition, the „Analytical Control Strategy" will be discussed demonstrating the so-called Criticality of an analytical procedure discussing first validation experiments to assess the procedures for its intented purpose.

Target Audience
The webinar addresses all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered.

Speaker

Dr Gerd Jilge, Boehringer Ingelheim, Germany
In 1991, Dr Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000, he took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007, he is working in Quality in method development for drug substances being involved e.g. in analytical validation and method optimisation. He is also a team member in the Analytical Quality Control working on Analytical Life Cycle Management within the ECA.

Fees (plus VAT)
Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at
https://www.gmp-compliance.org/about-the-academy).

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.

Group Participation (fee per person):
3-10 Persons € 211,65
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more than 20 Persons € 161,85

Registration
By mail, fax, e-mail or online on the Internet at
https://www.gmp-compliance.org/. 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.

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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.

Organisation/Contact
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Do you have any questions?
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Registration for the Webinar "Early Analytical Life Cycle Management for Drug Substances and Drug Products" on Thursday, 16 July 2020, 14.00 – 15.30 h CEST
Speaker: Dr Gerd Jilge, Boehringer Ingelheim
Please fax to CONCEPT HEIDELBERG, +49 (0)6221/84 44 34 or you register online at www.gmp-compliance.org.

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- ☐ more than 20 Persons

Important: Deadline is 12 noon on 15 July 2020

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