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GMP Webinar
Continuous Verification in Pharmaceutical Analysis

Date:
Thursday, 30 July 2020, 14.00 – 15.30 h CEST

Speaker:
Dr Joachim Ermer, Sanofi

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

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Background
According to the FDA-Guidance „Analytical procedures and methods validation for drugs and biologics", it should be continually assured that an analytical procedure remains fit for its intended purpose throughout its application. This includes an ongoing program for routine monitoring of analytical performance data, and the systematic evaluation of changes with the objective to evaluate regularly the need for optimization and revalidation, if needed. These activities belong to stage 3 of the analytical lifecycle management as discussed in the draft of the new USP information chapter <1220>. The on-going performance verification is also intended to be included in the revision of the ICH validation guideline Q2.

Educational Objectives
Besides regulatory expectations, the Webinar provides practical recommendations and orientation for demonstration of the on-going suitability of analytical procedures. In particular, efficient approaches will be presented to extract information and data from routine analysis. This will be illustrated with examples from quality control of chemical drug substances and biopharmaceuticals. A comprehensive understanding of the real analytical performance is extremely helpful to investigate and evaluate suspect or out-of specification (OOS) results as well as for a continuous process validation.

The following topics will be covered in the webinar:
- Regulatory requirements
- Integration into the analytical lifecycle concept (draft USP information chapter <1220>)
- Benefits of monitoring analytical performance
- What are the sources of analytical performance information?
- Risk-based identification of suitable performance parameters (SST, from sample analysis, control samples)
- Evaluation of information and data (OOS, invalid results, control charts, average parameters)
- Continual improvements

Target Audience
The webinar is aimed at executives and employees from Quality Control, Quality Assurance, and production who want to gain a better understanding of the GMP requirements as well as current discussions with respect to the lifecycle management of analytical procedures and are interested in practical recommendations for an efficient design, execution, and evaluation of a continuous analytical performance verification.

Speaker

Dr Joachim Ermer, Sanofi, Frankfurt, Germany
Dr Ermer is Head of QC Lifecycle Management Frankfurt Chemistry and Sanofi Global Reference Standards Coordinator. He has almost 30 years of experience in pharmaceutical analytics in drug development, global quality functions, and head of industrial QC. He is member of the USP Analytical Procedure Lifecycle Expert Panel, of the Ph.Eur. Working Group Chromatographic Separation Techniques und of the EFPIA support team for the revision von ICH Q2/Q14. Dr Ermer authored more than 50 publications on analytical topics and is editor and author of the two editions of the book "Method Validation in Pharmaceutical Analysis. A Guide to Best Practice" (Wiley-VCH, 2005 and 2015).

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 EUR 211,65
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

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.

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.

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 GMP Webinar "Continuous Verification in Pharmaceutical Analysis" on Thursday, 30 July 2020, 14.00 – 15.30 h CEST
Speaker: Dr Joachim Ermer, Sanofi
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
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  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important: Deadline is 12 noon on 29 July 2020

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2. If you have to cancel entirely we must charge the following processing fees:
Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.
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