GMP Webinar Series on
Validation in Pharmaceutical Analysis

Accuracy, 29 May 2020, 10.00 – 11.30 h CEST
Calibration (Linearity), 04 June 2020, 14.00 – 15.30 h CEST
Impurities Determination, 19 June 2020, 10.00 – 11.30 h CEST
Precision, 22 June, 10.00 – 11.30 h CEST

ECA Academy
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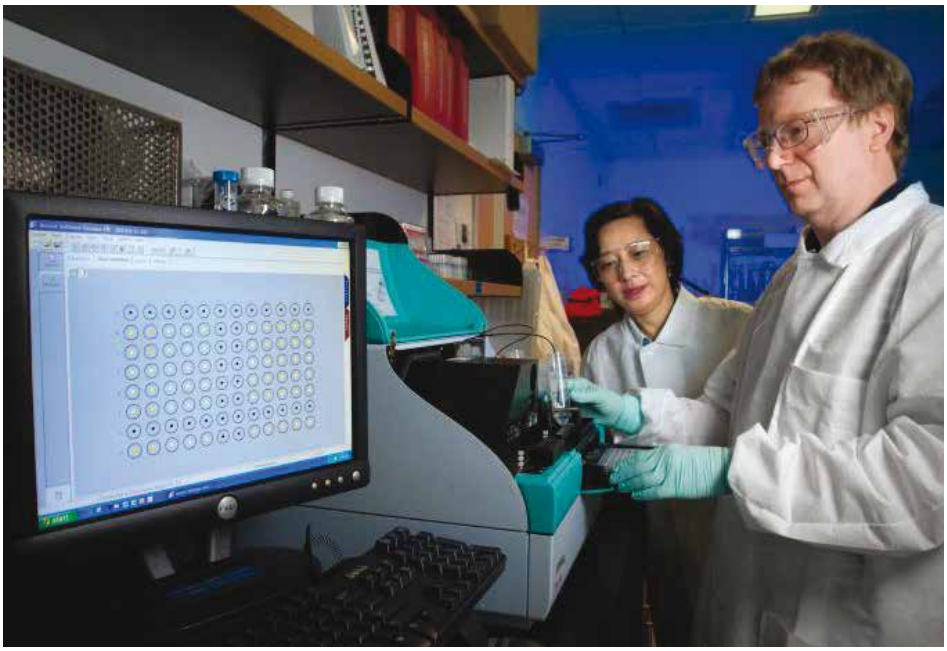
GMP Webinar Series on Validation in Pharmaceutical Analysis

Accuracy

Date:
Friday, 29 May 2020, 10.00 – 11.30 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 EU GMP Guide Part 1, Chapter 6, Quality Control (6.15) and US 21 CFR 211.194, analytical procedures must be suitable for their intended purpose. The regulatory requirements to validation of analytical procedures utilised for release and stability studies of drug substances and drug products are described in the ICH guideline Q2(R1). However, its degree of detail is rather low and the discussion is mainly focused on chromatographic methods. The latter is one of the reasons for the just started revision of the guideline, as well as inclusion of lifecycle and risk management aspects, which gained increasing attention in the last years.

Educational Objectives
Besides regulatory expectations, the Webinar series provides practical recommendations and orientation for demonstration of the suitability of analytical procedures. A rational and efficient validation approach is ultimatly based on the respective routine application, which should be reflected in the validation design. This includes the identification of the relevant performance parameters, the selection of appropriate tests and calculations and, in particular the establishment of acceptance criteria for the evaluation.

The following topics will be covered in the part „Accuracy":
- regulatory requirements
- Error types, link between systematic (bias) and random error
- Specificity
- Separate and combined evaluation of accuracy and precision
- Simple (point estimator) and statistical evaluation (confidence intervals)
- Comparison and recovery
- Statistical significance and equivalence tests
- Variability and expected difference between means
- Acceptance criteria for assay and impurity determinations

Target Audience
The webinar is aimed at executives and employees from Quality Control, Quality Assurance, and regulatory who want to gain a better understanding of the GMP requirements as well as current trends and are interested in practical recommendations for an efficient design, execution, and evaluation of a succesful analytical validation.

Speaker

Dr Joachim Ermer, Sanofi, Frankfurt, Germany
Dr Ermer is is Head of QC Lifecycle Management Frankfurt Chemistry and Sanofi Global Reference Standards Coordinator. Dr. Ermer 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 "Accuracy" on Friday, 29 May 2020, 10.00 – 11.30 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:
☐ **Single Participation**
☐ **Group Participation**
☐ 3-10 Persons
☐ 11-20 Persons
☐ more than 20 Persons

Important: Deadline is 12 noon on 28 May 2020

Title, First Name, Last Name

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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 2 weeks prior to the conference 10 %, until 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.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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German law shall apply. Court of jurisdiction is Heidelberg.