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GMP Webinar
Transfer in Pharmaceutical Analysis

Date:
Friday, 15 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

The transfer of analytical procedures is a frequent activity during the lifecycle of a drug substance or drug product. Thus, it is regularly in the focus of audits and inspections. According to the EU GMP guide part 1, chapter 6, Quality Control, and US 21 CFR 211.194, QC laboratories which did not perform the original validation should verify the appropriateness of the testing method. The EU GMP guide (6.38 – 6.40) requires a protocol for this analytical transfer. The General Information Chapter of USP <1224> „Transfer of analytical procedures" provides some detailed discussion of the transfer process.

Transfer can be regarded as the ultimate robustness check of the analytical procedure. Aspects neglected or missed during method development will often become evident. Therefore, a meticulous planning and a prudent management of issues during the transfer are vital.

Educational Objectives

The webinar provides regulatory requrements and recommendations with respect to the transfer of analytical procedures, e.g. from WHO and ISPE.

The following aspects will be covered:

- Regulatory requirements and recommendations
- Analytical transfer as part of the lifecycle management
- Management of the transfer process (transfer team, documentation, strategy, protocol, training, report)
- Design of experimental studies
- Transfer acceptance criteria (accuracy and precision)
- Evaluation of results (simple and statistical comparison)
- Root causes of issues during transfer
- Management of deviations, suspect and out-of-specification results

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 an efficient planning, execution, and evaluation of a succesful method transfer.

Speaker

Dr Joachim Ermer, Sanofi, Frankfurt, Germany 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 development, global 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.

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 211,15
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
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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 GMP Webinar "Transfer in Pharmaceutical Analysis"
on Friday, 15 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.

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☐ **Single Participation**
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☐ 11-20 Persons
☐ more than 20 Persons

Important: Deadline is 12 noon on 14 May 2020

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