



GMP Webinar

Method Transfer: New EU and WHO Requirements and Practical Implementation

Date:

Tuesday, 16 December 2014, 14.00 – 15.30 h CET

Speaker:

Dr Ralph Nussbaum

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

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GMP-Webinar **Method Transfer**

Background

Transfer of analytical methods is always an issue, especially during GMP inspections. Method transfers are an important part of pharmaceutical development. Compliance with international guidelines as well as cooperation between the transferring and the receiving laboratory are crucial.

This webinar was designed in order to show practical aspects of method transfer in compliance with current regulatory guidelines, especially the new EU GMP Chapter 6 and the detailed requirements of WHO Guideline Annex 7.

Educational Objectives

This webinar aims at giving you a comprehensive but still compact overview about the transfer of analytical methods.

Current Guidelines:

- WHO Guideline Annex 7
- New EU GMP Guide Chapter 6
- USP <1224>

Practical aspects:

- When does method transfer take place?
- Which guidelines to follow?
- How does method transfer take place?
- Transfer protocol and transfer report
- Practical examples

Target Audience

The webinar targets executives and staff in quality control laboratories, who want to get a compact but yet comprehensive overview of the transfer of analytical methods.

Speaker



Dr. Ralph Nussbaum

Ralph Nussbaum was head of an F&E analytical laboratory at Grunenthal GmbH in Aachen, before he joined Carbogen Laboratories as head of quality control in Hunzenschwil, Switzerland. In 2002 he took over responsibility for quality assurance as qualified person for drug substances at Carbogen. Since 2003 he is heading Analytical Services in Aachen.

Fees

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The registration fee only authorises an individual to take part in the Webinar. Therefore, we do not issue more than one certificate per registration. With the registration fee being paid only once, it would infringe the copyright of CONCEPT HEIDELBERG as well as that of the speaker if the transmission was followed by several persons.

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Technical Requirements

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Your Internet browser must have following features to use the GMP Webinar system:

1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.

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 download. After the Webinar, we will automatically send you a certificate of participation.

Do you have any questions?

For questions regarding content:

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For questions regarding technical aspects:

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