
ECA ACADEMY

# GMP Webinar
# **Analytical Test Procedures: Content of a validation protocol or plan**

Date:
Tuesday, 22 March 2016, 14.00 – 15.30 h CET

Speaker:
Dr Gerd Jilge, Boehringer Ingelheim Pharma GmbH & Co. KG

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

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# GMP Webinar: Analytical Test Procedures - Content of a validation protocol or plan

## Background
According the FDA Guideline on „Analytical Procedures and Methods Validation for Drugs and Biologics" validation of the analytical procedures should be carried under an approved validation protocol or plan which contains all relevant information, e.g. description of the validation parameters including the responsibilities, materials used, testing conditions and the respective acceptance criteria.

## Educational Objectives
This webinar gives an introduction of the content of a validation protocol using a chromatographic example for the determination of impurities.

The content of the validation protocol will be discussed with respect to

- information on specific data for the protocol,
- detailed information how to carry out the validation experiments,
- evaluation of data and test results for each validation parameter as well as
- a proposal for the setting and reporting of the acceptance criteria.

Furthermore, information on an error handling plan are provided if acceptance criteria cannot be fulfilled, an important topic which is also discussed in the current EMA GMP regulations.
The webinar also considers the validation protocol as an ideal tool for an instruction (SOP) to perform validation experiments.

## Target Audience
The webinar targets laboratory managers, supervisors and analysts in pharmaceutical quality control departments who have responsibility for the validation of analytical test procedures. Furthermore, this Webinar is designed for personnel from Quality Assurance, Regulatory Affairs and Contract Laboratories.

## Speaker


**Dr Gerd Jilge**
Dr Jilge is working in Quality Management on method development for new drug substances at Boehringer Ingelheim Pharma GmbH & Co. KG, Germany. Before that he held 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.

## 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.
**Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de for details.**

## Fees (plus VAT)
Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

**Group Participation (fee per person):**
3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

## Technical Requirements
To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.
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.
Please read the detailed technical requirements in this document:
http://www.gmp-compliance.org/webinar/webinar_requirements.htm

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

## Do you have any questions?
For questions regarding content:
Dr Gerhard Becker, phone +49 62 21 - 84 44 65,
E-Mail: becker@concept-heidelberg.de

For questions regarding technical aspects:
Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59,
zimmermann@concept-heidelberg.de.

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**Registration for the GMP Webinar:**
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**Speaker: Dr Gerd Jilge, Boehringer Ingelheim Pharma**
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34
or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
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  ☐ 3-10 Persons
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**Important:**
**Deadline is 12 noon on**
**21 March 2016**

Title, First Name, Last Name

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