



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.

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de



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.

Registration for the GMP Webinar:
Analytical Test Procedures: Content of a validation protocol or plan on Tuesday, 22 March 2016, 14.00 – 15.30 h CET
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**
 - ☐ **Group Participation**
 - ☐ 3-10 Persons
 - ☐ 11-20 Persons
 - ☐ more than 20 Persons

Important:
Deadline is 12 noon on 21 March 2016

Title, First Name, Last Name		
Company	Department	VAT ID No. (mandatory)
Street	Postal Code/City	
Phone	Fax	
E-Mail (mandatory for your registration)		

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. If the event must be cancelled, registrants will be notified as soon as possible and will

receive a full refund of fees paid.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!