ALPHATOPICS ONLINE INTENSIVE TRAINING

Development and Validation of Analytical Procedures for Small Molecules

(Recording: 7 lectures in 4 modules)

Trainer: Prof. Dr. Markus Veit

ALPHATOPICS

TRAINER

Prof. Dr. Markus Veit
is the managing director of ALPHATOPICS GmbH. He studied pharmacy in Frankfurt, obtained his doctorate at the Julius-Maximilians-University in Würzburg and habilitated there. He is a pharmacist with special training and experience in pharmaceutical analysis and validation. He is a member of the German pharmacopeial expert committee at BfArM.

In the past 25 years, he has worked as a managing director in companies providing services for the pharmaceutical industry with a focus on pharmaceutical development, testing and regulatory affairs. At the same time, he designed and led numerous trainings and continuing education events for employees in the pharmaceutical and medical device industry.

ALPHATOPICS
WEBINAR

Online training – webinar instead of seminar
A webinar is a concentrated transfer of knowledge within the framework of an online event as a lecture or small seminar. With our online intensive training, you receive the content in e-learning format. You see and hear the on your screen, no matter where you are. No travelling is necessary.

Maximum flexibility: We have also recorded the topics so that you can access them at any time. So you can easily integrate them into your daily routine.

For all topics covered, you can contact Prof. Veit via the email address **fragen@alphatopics.de** and ask questions, which he will be pleased to answer – if necessary, also by phone. This is included in the training fees.

INTRODUCTION

DEVELOPMENT AND VALIDATION OF ANALYTICAL PROCEDURES FOR SMALL MOLECULES

Background
The development of appropriate analytical procedures and their validation, if applicable with subsequent transfer to routine laboratories, is one of the essential prerequisites for pharmaceutical quality control of active substances and medicinal products as well as drug-related products such as food supplements and medical devices. The intensive training covers all aspects to be considered for the analysis of small molecules. The focus is not only on the regulatory requirements (US, Europe, ANVISA, ICH, WHO), but rather on their practical implementation. A special focus is on current developments such as life cycle concepts and the new requirements for analytical validation in the US USP. Most of the aspects will be covered using HPLC as exemplarily testing procedure.

Type of Training
The training is designed as intensive training in four modules of approx. 3 hours each, 11 hours in total. The training is not only designed for less experienced participants but is also very well suited to deepen and consolidate existing knowledge for more experienced participants. The training is provided in English.

Who should participate?
Personnel in R&D and QC laboratories for the testing of active substances and pharmaceutical products, medical devices and food supplements. Members RA-CMC teams implementing analytical, validation and stability testing data into the dossier. Quality assurance personnel with focus on analytical laboratory and related responsibilities.

Format
With this intensive training, you receive the content in an e-learning format. You can listen to and watch the lecture comfortably on your computer screen. Conveniently, no matter where you are. Since it is a recording, you can choose and schedule your own training times and interrupt at any time if necessary.

The presentations will be made available after booking as PDF files together with your certificate of participation.

TOPICS

Module 1 / 160 min

Regulatory Requirements & Guidance Documents

- ICH | EMA | FDA | ANVISA | ASEAN | WHO | ZLG
- Ph. Eur | USP
- General Requirements Analytical Procedure Validation

Processing quality control data and data from analytical validation

- Processing of the (raw) data
- Significant figures of significant digits
- Correct presentation and documentation of the data (rounding/truncating/averaging)
- Data integrity

Module 2 / 180 min

Basic requirements and validation parameters

- Parameters to be validated
- Verification of compendial methods
- Acceptance criteria (with different regional requirements)
- Descriptive statistics
- Equivalence *versus* significance tests
- Single *versus* multiple determinations
- Setting of acceptance criteria
- OOS | OOE | OOT

REGISTRATION

Participation fee:
1,890.00 EUR per person plus VAT.
The fee includes the viewing of this webinar series by the named person. The series consists of 7 parts. In addition, we will send you the slides shown as a printable PDF file.

You can also book only individual parts of the series – please contact us. We can offer you favourable graduated prices for group training courses. You can book these events as a series or individually as part of your webinar contingent. We would be pleased to welcome you to the online training.

Here you can register and get further information:

Module 3 / 150 min

Analytical procedure Development and Prevalidation

- Starting points for the development of analytical procedures
- Optimization of separation | Simulation software
- Development of sufficiently robust test procedures
- Development of stability indicating test methods
- System Suitability testing
- Use of response factors

Life cycle Management of analytical procedures

- Life cycle of analytical procedures (FDA, WHO, ICH Q14)
- New USP chapter <1220> Lifecycle Management of Analytical Procedures and <220> Basic requirements for Lifecycle Management of Analytical Procedures der USP
- Control charts and trending
- Postapproval validation activities and change control
- Adjustment of analytical methods and procedures *versus* changes

Module 4 / 180 min

Stress test & forced degradation testing

Validation of analytical procedures in dissolution testing

Transfer of analytical procedures (co-validation), cross-validation, revalidation

- Regulatory requirements (ZLG, Ph. Eur., EU-GMP, USP, FDA, ANVISA)
- Project management
- Success factors

Regulatory documents and GMP-Documentation related to analytical validation

- Responsibilities
- GMP validation masterplan
- GMP validation protocol
- GMP validation record
- GMP validation report
- Regulatory report

CONTACT

For group enquiries or interest in individual parts of the webinar series, please contact us directly.

Ms Katrin Kurtz and
Ms Daniela Müller will be
happy to assist you with your
booking and are available to
answer any further questions.

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