Validation of Analytical Test Procedures & Measurement Uncertainty

Qualification and Validation in an uncertain analytical world – a holistic approach

2 – 4 April 2019, Vienna, Austria

LEARNING OBJECTIVES:

- Analytical Instrument Qualification
- Measurement Uncertainty and its Impact on Analytical Methods Validation
- Practical Determination of Validation Characteristics
- Regulatory Requirements
- Statistical Aspects of Analytical Methods Validation
- Documentation of Analytical Validation
- Error Budgets and Reportable Values
- Transfer of Analytical Test Procedures
- Analytical Procedure Life Cycle Management

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“.
Please find details at www.gmp-certification.eu
Learning Objectives

The objectives of this Education Course are

- to offer practical solutions for determining the validation characteristics
- to learn how to deal with measurement uncertainty and to understand its impact on analytical methods validation
- to understand the qualification of laboratory equipment as a pre-condition of reliable analytical testing
- to discuss the scope of qualification & validation necessary to obtain approval by the Registration Authorities (EMA, FDA, MHRA, etc.)
- to become familiar with the statistical parameters to be applied
- to outline the documentation (SOPs, Validation Protocols and Reports, etc.) which you should have in your lab.
- Provide an outline of the new USP & ICH developments of procedure validation

In order to improve the understanding and practical application of the contents of the lectures, workshops will be part of the training course.

Background

The current ICH guideline Q2(R1) lists all characteristics to be considered during validation and describes the method of determining the various validation characteristics. Reliable analytical results do not only require validated test procedures but also the use of analytical equipment qualified for its intended purpose. In order to obtain regulatory approval, the qualification of all critical laboratory equipment must be performed and documented ensuring “fitness for purpose”. Furthermore, measurement uncertainty is of key importance in analytical instruments qualification as well as in analytical methods validation and transfer. Therefore it is absolutely essential that measurement uncertainty is well understood by everybody who is responsible for generating and evaluating analytical results in GMP controlled laboratories. In addition there are major revisions planned for both ICH Q2 and a new Q14 on Analytical Procedure Development.

Target Audience

This interactive Education Course will be of particular interest to Laboratory Managers, Supervisors and Analysts in pharmaceutical quality control departments who have responsibility for the validation of analytical test procedures. Furthermore, this Course is designed for personnel from Quality Assurance, Regulatory Affairs and Contract Laboratories.

Moderator

Dr Christopher Burgess
Practical Determination of: Robustness Leading to System Suitability Tests

- Method development cycle
- Analytical process capability
- Selecting factors and levels
- HPLC experimental design example
- Impact on system suitability tests

Method Validation During the Development Lifecycle

- Product Development Life Cycle
- Sources of Guidance
- ICH Q14 Concept paper
- Screening and Early Safety Studies
- Phase 1 Volunteer Studies
- Phase 2 Clinical trials
- Towards MAA/NDA

Validation for MAA/NDA Planning and Execution

- Analytical validation according to USP
- FDA Guidances for method validation

Validation for MAA/NDA Documentation

- Validation report
- Transfer protocol/report
- Validation documentation for registration
- Validation software
- Other Sources of Guidance

Error budgets and reportable values

- What is a reportable value?
- OOS, OOE & OOT
- Method performance and process capability
- ICH precision approach
- Measurement Uncertainty approach combined sources of variation

Transfer of Analytical Test Procedures

- Statistical Tests
- Analytical significance vs statistical significance
- Acceptance criteria setting
- Interval hypotheses

Comparison of the APLM and current ICH & USP approaches

- Traditional approach to analytical method (procedure) validation, verification and transfer
  - ICH Q2(R1)
  - USP <1225> & <1226> [& <1224>]
- FDA process validation guidelines 2011
- USP initiatives: Application to analytical processes
- Proposed General Chapter <1220>
- Statistical toolbox for <1225>; General Chapter <1210>
- New ECA AQC Guideline;
- Analytical Procedure Lifecycle Management
- New ICH initiatives

Workshops

During the course 4 workshops will be conducted in order to deepen the content of the lectures and to discuss practical aspects in detail. Workshops will be offered on the following topics:

Analytical Instrument Qualification

The participants will debate the impact of USP proposals in a practical context

Validation Plan

The participants will work on testing schedules for the relevant validation parameters.

Method Transfer

The participants will discuss practical details of an Analytical Methods Transfer.

Validation documents critique

The participants will work, in detail, on a typical case study proposing a suitable program of work for a validation dossier.

Speakers

**Dr Christopher Burgess**, Burgess Analytical Consultancy Ltd., Barnard Castle, UK

He has more than 40 years’ experience in the pharmaceutical industry initially within international consultancy. He is a “Qualified Person” in the European Union. He was appointed to the United States Pharmacopeia’s Council of Experts 2010 to 2015 and re-elected 2015 to 2020. He is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>. In addition, he is a member of the Executive committee of European Compliance Academy.

**Trevor Coomber**, Pharmaceutical Development Consultant, UK

Trevor Coomber is a Pharmaceutical Development Consultant with over 40 years experience in the industry. He spent six years as a Senior Project Team Leader and Analytical Science Manager in Pharmaceutical Development in Glaxo Wellcome. Prior to that, he was a Team Leader in the Analytical Development Laboratories in Wellcome with 25 years experience in pharmaceutical analysis of NCEs. He has particular expertise in the development of unstable compounds and the use of kinetics to predict shelf lives. He was the project leader for the technical development of an NCE from discovery to market.

**Dr Xaver Schratt**, GBA Pharma GmbH, Germany

Dr Schratt studied Chemistry at the University of Bayreuth, where he specialized in HPLC and HPLC/MS. In 2005 he joined GBA Pharma (former LAT) and since 2006 he is head of department “special projects”. In charge of national and international pharmaceutical companies he manages all analytical aspects of projects from preclinical stage up to phase III and post market approval. As an expert for chromatography and mass spectrometry he mainly focuses on method development, validation and qualification of reference substances.
## Reservation Form (Please complete in full)

### Validation of Analytical Test Procedures and Measurement Uncertainty
2 - 4 April 2019, Vienna, Austria

- [ ] Mr  - [ ] Ms

**Important:** Please indicate your company's VAT ID Number

**P.O. Number (if applicable)**

<table>
<thead>
<tr>
<th>Street/P.O. Box</th>
<th>City</th>
<th>Zip Code</th>
<th>Country</th>
</tr>
</thead>
</table>

**Phone/Fax**

**E-Mail (please fill in)**

**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. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.**

**Terms of payment**: Payable without deductions within 10 days after receipt of invoice.

**Cancellation terms**: 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-attendance. If you cannot take part, you have to inform us in writing. The cancellation fees 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 full registration fees, 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)!

German law shall apply. Court of jurisdiction is Heidelberg.

**ECA has entrusted Concept Heidelberg with the organisation of this event.**

**Venue**

**Date**

- **2 - 4 April 2019, 8.30 – 17.30 h**

**Registration and coffee 8.30 – 9.00 h**

**Wednesday, 3 April 2019, 8.30 – 17.30 h**

**Thursday, 4 April 2019, 8.30 – 16.30 h**

**APIC Members € 1,890**

**ECA Members € 1,790**

**Non-ECA Members € 1,990**

**EU GMP Inspectorates € 995**

**Fees (per delegate plus VAT)**

**For questions regarding reservation, hotel organisation, etc. please contact:** Mr Niklaus Thiel (Organisation Manager) at +49 (0) 62 21 / 84 44 43, or by e-mail at thiel@concept-heidelberg.de.

**For questions regarding content please contact:** Dr Gerhard Becker (Operations Director) at +49 (0) 62 21 / 84 44 65, or by e-mail at becker@concept-heidelberg.de.

**For questions regarding reservation, hotel organisation, etc. please contact:** Mr Niklaus Thiel (Organisation Manager) at +49 (0) 62 21 / 84 44 43, or by e-mail at thiel@concept-heidelberg.de.