Free brochure
"Validation of Analytical Test Procedures"

Validation of Analytical Test Procedures & Measurement Uncertainty

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

6 – 8 May 2014, Berlin, Germany

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Trevor Coomber
Pharmaceutical Development Consultant, UK

Dr Xaver Schratt
LAT GmbH Dr . Tittel, Germany

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

ECA ACADEMY

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

Validation of Analytical Test Procedures and Measurement Uncertainty

6 – 8 May 2014, Berlin, Germany

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 discuss the scope of validation necessary to obtain approval by the Registration Authorities (EMA, FDA, MHRA, etc.)
- to become familiar with the statistical parameters to be applied
- to understand the qualification of laboratory equipment as a precondition of reliable analytical testing
- to outline the documentation (SOPs, Validation Protocols and Reports, etc.) which you should have in your lab.

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

Background

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 the FDA investigator's approval, the qualification of all critical laboratory equipment should be performed in standard IQ/OQ/PQ format. 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.

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

Free brochure "Validation of Analytical Test Procedures"
Each participant gets a brochure containing over 200 pages of examples and validation protocols on analytical methods validation for free.

Programme

Validation in Context

- Components of data quality
- Integrated Approach to Qualification and Validation
- Conclusion

Basics of Measurement Uncertainty

- Why is measurement uncertainty important?
- Relationship between uncertainty and confidence
- Uncertainty of measurement
- What is a measurand
- Error sources in analysis and testing

Analytical Instrument Qualification

- Guidance
- Validation Master Plan
- Definition of DQ, IQ, OQ and PQ
- Examples of protocols and documents
- Change Control
- Risk assessment

Measurement Uncertainty in Calibration and Qualification of Analytical Instruments

- Qualification, Calibration & Validation
- Measurement uncertainty
- Propagation of Errors
- Measurement uncertainty of a CRM
- Detection and quantitation limits
- Noise & drift
- Statistical aspects

New Developments in Instrument Qualification - The USP Proposals

Statistical Aspects of Analytical Methods Validation

- The use (and misuse?) of statistics to support validation data
- Basic theory of the common statistical techniques
- Merits, pitfalls and underlying assumptions of particular tests
- The meaning behind
- Standard deviation - F-test - t-test
- ANOVA - Correlation Coefficient
- Linear regression
- Exploration of more sophisticated statistical techniques such as interval hypothesis testing and experimental design

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 Lifeycle

- Product Development Life Cycle
- Sources of Guidance
- 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
- ransfer 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

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., UK*
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and 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 30 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.

Dr Xaver Schratt, *LAT GmbH Dr. Tittel, Graefelfing/Munich, Germany*
Dr Schratt studied Chemistry at the University of Bayreuth, where he specialized in HPLC and HPLC/MS. In 2005 he joined LAT and since 2006 he is head of department R & D 2. 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.

Social Event

On 6 May 2014, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Validation of Analytical Test Procedures and Measurement Uncertainty,
6 – 8 May 2014, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

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City Zip Code Country

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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.
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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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)! (as of January 2012)

Date

Tuesday, 6 May 2014, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 7 May 2014, 8.30 – 17.30 h
Thursday, 8 May 2014, 8.30 – 16.30 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Phone +43 (0)30 288 755 0
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Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

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