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Validation of Analytical Test Procedures & Measurement Uncertainty

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy Limited, UK

Trevor Coomber
Pharmaceutical Development Consultant, UK

Dr Xaver Schratt
GBA Pharma GmbH, Germany

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

Validation of Analytical Test Procedures and Measurement Uncertainty

2 – 4 April 2019, Vienna, Austria

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 precondition 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

Programme

Validation in Context

- Practical components of data quality
- Assessment of data quality
- Analytical Procedure Lifecycle Management; the future direction
- Course road map

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

- USP <1058> Guidance
- USP revision process and GAMP
- 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

Analytical Procedure Lifecycle Management; the future direction

- Validation; the changing regulatory climate
- FDA Process Validation Paradigm shift
- Analytical Procedure Lifecycle Management
- Data governance in a regulated laboratory
- ICH Q12
- USP <1220>
- ECA APLM guideline

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
  - Linear regression; Correlation Coefficient & Coefficient of Determination
- 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
- 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 Pharmacopoeia'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.

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

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ 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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I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 2 April 2019, 9.00 – 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

Venue

Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
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Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event on the first day, lunch on three 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/POG 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.

Social Event

In the evening of the first course day, 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.

Organisation and Contact

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