



Academy
*Your GMP/GDP
Information Source*

Speaker



Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Confidence in Analytical Results and Measurement Uncertainty



Live Online Training on 30 September 2021



Highlights

- Basic Understanding of Measurement Uncertainty
- Calibration/Qualification of Analytical Instrumentation and Measurement Uncertainty
- Validation of Analytical Methods and Measurement Uncertainty
- Monte Carlo Simulation
- Method Performance
- Transfer of Analytical Procedures
- Method Performance and Reportable Values

Objectives

In this new online Training Course, the principles of measurement uncertainty and error budgets will be discussed. You will get to know how to apply these principles in your analytical laboratory. The purpose of course is to

- Describe the basic principles of measurement uncertainty and error budgets
- Apply these basic principles to the calibration and qualification of analytical instruments
- Allow participants to gain experience in applying the techniques to analytical method validation and method transfer.
- Introduce the Monte Carlo simulation approach for more complex systems

Background

For many years, measurement uncertainty calculations have been a requirement in ISO 17025 accredited laboratories. The USP has introduced these ISO concepts into USP General Chapter <1010> *Analytical Data—Interpretation And Treatment*. Measurement uncertainty is of key importance in analytical instruments qualification as well as in analytical methods validation and transfer. Therefore everyone who is involved in generating and evaluating analytical results in GMP controlled laboratories or bears the responsibility for these activities must have a thorough understanding of the principles of measurement uncertainty and error budgets.

Target Audience

This training is recommended for Laboratory Managers, Supervisors and Analysts in pharmaceutical quality control departments who have responsibility for the validation of analytical test procedures as well as the Calibration and Qualification of Analytical Instruments. Furthermore, this Course will be of interest to personnel from Quality Assurance, Regulatory Affairs and Contract Laboratories.

Programme

Introduction to the Course

Basics of Measurement Uncertainty

- Definition of measurement and uncertainty
- Analytical Procedures (Methods) as Processes
- Error sources and statistical descriptions
- Accuracy and Trueness under ISO definitions
- ICH Q2(R1) and revision in 2021 to (R2) & Q14
- Approaches to quantifying MU and Error budgets
- Quantifying uncertainties with a very simple example; a reference standard solution
- Shape of errors
- Statistical assumptions for Error budgets

Measurement Uncertainty in Calibration and Qualification of Analytical Instrumentation

- Qualification, Calibration & Validation (QCV)
- Experimental errors
- Calibration example of a UV spectrophotometer
 - Wavelength accuracy
 - Sensitivity; DL & QL

Measurement Uncertainty in the Validation of Analytical Methods

- Holistic approach of MU
- Case study example; Error Budget Process
 - Step 1: Description of the measurement process
 - Step 2: Specification of the measurand
 - Step 3: Identification of uncertainty sources
 - Steps 4 & 5: Quantification and combination of uncertainties

Measurement Uncertainty without the Maths; an Introduction to Monte Carlo Simulation

- Monte Carlo Simulation (MCS) modelling
- Principles behind MCS for MU
- Example 1: Making a standard solution of a certified reference material (CRM)
- Example 2: Leachable cadmium determination by Atomic Absorption Spectrometry (AAS)
- Pros & Cons for MCS



Method Transfer; Success or Failure?

Case Study with interactive workshop

Process Performance and Reportable Values

- What is a reportable value?
- OOS, OOE & OOT
- Process performance and process capability
- ICH precision approach
- USP <1010>

Speaker



Dr Christopher Burgess
Burgess Analytical Consultancy, UK

He is a Chartered Chemist and has more than 45 years' experience in the pharmaceutical industry initially with Glaxo in Quality Control, Quality Assurance and Analytical R&D and then 25 years in international consultancy. He is a "Qualified Person" in the European Union. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2020 (re-elected for the 2020-2025 cycle) 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 Extended board of European Compliance Academy Foundation. He is also a member of the USP Joint Sub-Committee (JSC) on Validation and Verification entrusted to develop a new General Chapter<1220> on Analytical Procedure Lifecycle and the USP JSC for the revision of General Chapter<1058> on Analytical Instrument Qualification.

Your Benefit:
Internationally Acknowledged Certificate from
ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.



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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)



Confidence in Analytical Results and Measurement Uncertainty Live Online Training on 30 September 2021, 09.00 - 16.45 h CEST

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

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 %
 - Cancellation within 1 week prior to the conference 50 %
 - Cancellation 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. 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.

Important: This is a binding registration and above fees are due in case of can-

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).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at <https://www.gmp-compliance.org/privacy-policy>). 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 of the Live Online Training

Thursday, 30 September 2021,
09.00 – 16.45 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 890

APIC Members € 950

Non-ECA Members € 990

EU GMP Inspectorates € 495

The fee is payable in advance after receipt of invoice.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG

P.O. Box 10 17 64

D-69007 Heidelberg

Telefon +49(0) 62 21/84 44-0

Telefax +49(0) 62 21/84 44 34

E-Mail: info@concept-heidelberg.de

www.concept-heidelberg.com

For questions regarding content:

Dr Gerhard Becker (Operations Director) at
+49(0)62 21/84 44 65, or per e-mail at
becker@concept-heidelberg.de.

For questions regarding organisation please contact:

Ms Julia Grimmer (Organisation Manager) at
+49(0)62 21/84 44 44, or per e-mail at
grimmer@concept-heidelberg.de.