ECA Academy
Your GMP/GDP Information Source

Speakers

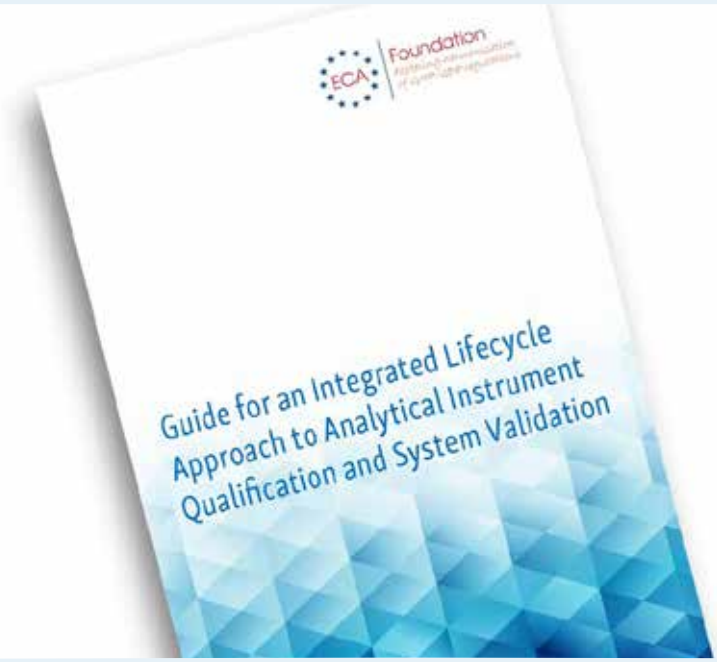
Dr Christopher Burgess
Burgess Analytical Consultancy Limited, UK

Dr Amanda Guiraldelli-Mahr
Scientific Affairs Manager at United States Pharmacopoeia

Dr Bob McDowall
R D McDowall Limited, UK

Introduction to the AQCG's new ECA Guide for an Integrated Lifecycle Approach to Analytical Instrument Qualification and System Validation

Live Online Training on 29 April 2024



Includes USP Speaker Update on the Analytical Procedure Lifecycle

Highlights

- Introduction to the ECA AIQSV Guide
- Analytical Instrument Qualification and System Validation (AIQSV) Lifecycle and AIQSV Risk Assessment
- Evolution of Analytical Procedure Validation: The Analytical Procedure Lifecycle
- Update on the revision of USP <1058>
- Overview of Qualification of Chromatographs and Validation of Chromatography Data Systems
- Q&A Sessions
- For free download: The new AIQSV Guide and other Guides developed by the AQCG

50% discount for participants of the ECA course "Analytical Instrument Qualification" from 14 – 16 May 2024 in Vienna, Austria.

ECA Analytical Quality Control Group
An ECA Foundation Interest Group

Programme

Objective

The objectives of this Live Online Training are:

- Understand the rationale for the lifecycle approach for new ECA AIQSV Guide
- Learn the risk-based risk assessment approach to determine 'fitness for use'
- Overview of these principles to specific examples for analytical instruments and systems
- Provide an insight into the ECA AQCG collaboration with the USP

Background

Although qualification of analytical instruments has been a regulatory requirement in the GMP regulations since the 1970s, it was only the publication of United Stated Pharmacopoeia (USP) General Chapter <1058> on Analytical Instrument Qualification in 2008 that provided a formal requirement. This is still the only pharmacopoeial general chapter on the subject. In 2017, <1058> was updated and currently there are Stimuli to the Revision Process articles about moving from the 4Qs Model to a three phase lifecycle model to be congruent with USP <1220> on Analytical Procedure Lifecycle.

The ECA Analytical Quality Control Group (AQCG) Guide for an Integrated Lifecycle Approach to Analytical Instrument Qualification and System Validation (AIQSV) was written to be a practical guide for risk-based instrument qualification and system validation. It adopts a three-phase lifecycle and not the 4Qs model similar to proposals for update of USP <1058>. The Guide has six appendices outlining how to qualify and validate common instruments and systems used in GMP regulated laboratories.

All participants receive a free copy of the new Guide and the other guides developed by the AQCG for download.

Target Audience

This Live Online Training is aimed at the following:

- Managers and staff from Quality Control and Analytical Development Laboratories of pharmaceutical companies, Contract Research Organisations and Contract Manufacturing Organisations involved in qualifying analytical instruments and systems
- CSV staff involved in validating laboratory computerised systems
- Quality Assurance staff involved in reviewing laboratory qualification and validation documents
- Auditors (internal and external) responsible for auditing qualification and validation of analytical instruments and systems

Moderator

Dr Markus Funk (CONCEPT HEIDELBERG and Administration Manager of the ECA AQCG)

Programme

Introduction to the Live Online Training and the AQCG

Dr Markus Funk (CONCEPT HEIDELBERG and Administration Manager of the ECA AQCG)

- Overview of the structure and activities of the ECA Foundation
- Introduce the ECA AQCG Board
- AQCG Aims & Objectives
- ECA AQCG Published Guidelines

Introduction to the new AQCG ECA AIQSV Guide

Dr Chris Burgess, Burgess Analytical Consultancy Ltd, UK

- Rationale for the Guide and the development process
- Acknowledgements
- What's in and what's out of the AIQSV guide
- Collaborative 2-day meeting with USP on practical implementation at PharmaLab on 26/27 November 2024 in Düsseldorf/Neuss

An overview of the AIQSV Lifecycle

Dr Chris Burgess, Burgess Analytical Consultancy Ltd, UK

- Why the 4Qs model is inadequate for most analytical instruments and systems
- IQ, OQ and PQ dropped by FDA in 2002 and GAMP in 2008
- Lifecycle phases and threads
- Phase 1: Specify and Select
- Phase 2: Qualification / Validation of Instruments and Systems
- Phase 3: Continued Performance Verification
- Who does what; Roles and Responsibilities

Evolution of Analytical Procedure Validation: The Analytical Procedure Lifecycle

Dr Amanda Guiraldelli-Mahr, United States Pharmacopoeia

- USP's journey in the creation of compendial approaches incorporating QbD principles
- Introduction to the Analytical Procedure Lifecycle Framework described in USP <1220>
- USP Analytical Instrument Qualification (AIQ) Joint Subcommittees and collaborative efforts
- Stimuli Articles on AIQ, update on the revision of USP <1058> and collaborative 2-day Workshop to allow broader stakeholder input & debate
- Planned two-day AQCG/USP session at PharmaLab 2024

AIQSV Risk Assessment; an Integrated Approach
Dr Bob McDowall, R.D.McDowall Limited, UK

- Overview of the AIQSV Guide risk assessment
- Understanding why a different intended use defines a different USP <1058> Group and sub type for the same make and model of instrument/system
- Analytical computerised systems are not created equal: validation approaches vary from a single integrated validation document to a networked CDS

Overview of Qualification of Chromatographs and Validation of Chromatography Data Systems
Dr Bob McDowall, R.D.McDowall Limited, UK

- Laboratory specification of liquid chromatographs versus supplier specifications
- Supplier's qualification protocols and qualification data
- Risk based validation of a chromatography data system
- Specifying testable or verifiable user requirements
- How to leverage the supplier software development and testing
- Practical user acceptance testing

Wash Up Session & Close of Meeting
Dr Chris Burgess, Burgess Analytical Consultancy Ltd, UK

- Review and feedback on Guide
- Soliciting topics for the two-day AIQSV Guide meeting at PharmaLab 2024

Dr Christopher Burgess
Burgess Analytical Consultancy Limited, UK

Qualified Person, USP Council of Experts 2010 to 2025 and Chairman of the AQCG Board

Dr Christopher Burgess is a Chartered Chemist and has more than 49 years' experience in the pharmaceutical industry initially with Glaxo in Analytical R&D, Quality Control and Quality Assurance followed by 29 years in international consultancy. He is a "Qualified Person" in the European Union. He was appointed to the United States Pharmacopoeia's Council of Experts and Expert Committees 2010 to 2025 revising and reviewing spectroscopic general chapters <85x> and <185X> series and is a visiting professor at 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 was a member of the USP Expert Panel which developed General Chapter <1220> and is chairman of the JSC revising General Chapter <1058>.

Dr Amanda Guiraldelli-Mahr
Scientific Affairs Manager at United States Pharmacopoeia

Dr Amanda Guiraldelli has been with USP since 2012 and holds the position of scientific affairs manager. She is also the scientific liaison for the USP chapters <1220> Analytical Procedure Life Cycle and <1039> Chemometrics in the compendial science group-general chapters. She is visiting professor at the University of Campinas (UNICAMP) in Brazil at the Institute of Chemistry and is a frequent speaker and instructor on topics related to analytical procedure life cycle and Analytical Quality by Design (AQbD). Amanda is specialist in chromatography, mass spectrometry and chemometrics and has more than 15 years of experience in pharmaceutical R&D areas. Amanda is a graduate in pharmacy & biochemistry and holds a Ph.D. in analytical chemistry from the University of São Paulo.

Dr Bob McDowall
R D McDowall Limited, UK

Member of the AQCG Board and Member of the ECA IT Compliance Interest Group

Dr Bob McDowall is an Analytical chemist with over 50 years experience including 15 years working in the pharmaceutical industry and over 30 years as a consultant. He is Director of R D McDowall Ltd., UK. He has written and taught extensively on compliance within analytical laboratories including qualification of instruments and validation of informatics solutions. Bob is the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several journals. He is the author of Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories.

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GERMANY

Reservation Form (Please complete in full)

Introduction to the AQCG's new ECA Guide for an Integrated Lifecycle Approach to Analytical Instrument Qualification and System Validation
Live Online Training on 29 April 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Monday, 29 April 2024, 10.00 – 16.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

Non-ECA Members EUR 790,-
ECA Members EUR 690,-
APIC Members EUR 740,-
EU GMP Inspectorates EUR 395,- per delegate plus VAT

50% Discount
Participants of the ECA course "Analytical Instrument Qualification" from 14 – 16 May 2024 in Vienna, Austria pay only EUR 395.-

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.
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