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Integrating Analytical Instrument Qualification and Computerised System Validation

An Integrated Approach to Analytical Instrument Qualification (AIQ) and Computerised System Validation (CSV) for the GMP Regulated Laboratory

19 – 20 October 2015, Berlin, Germany

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Bob McDowall
McDowall Consulting, UK

PROGRAMME:

- Analytical Equipment Qualification: Where Are We Now?
- Computerised System Validation: Where Are We Now?
- AIQ and CSV: A Risk-based Approach
- An Integrated Approach to AIQ and CSV:
  - Process Workflows
  - How to Minimise the Validation/ Qualification Effort
  - Key Documents to be Written
  - Component Installation
  - User Configuration
  - User Acceptance Testing
- Applying Integrated Approach Principles in Practice to
  - Analytical Balance
  - Stand Alone Spectrometer
  - HPLC with a Networked CDS Data System

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

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Learning Goals

Analytical instrumentation used within GMP analytical laboratories is computerised either via firmware inside the instrument or via a workstation with software loaded on to a workstation that is situated next to the instrument. However, the **current situation** regarding the qualification of analytical instrumentation and validation of computerised systems **is unsatisfactory; qualification and validation are typically considered as separate activities** with little if any interaction between the two disciplines.

For example, the AAPS have produced guidance on analytical instrument qualification (AIQ) that has been incorporated as **General Chapter <1058>** within the United States Pharmacopoeia **(USP)**. This focuses on the instrument with little emphasis on computerised system validation. In contrast, the **GAMP Good Practice Guide for Validation of Laboratory Computerised Systems second edition** looks exclusively on the computerised system and ignores the instrument qualification aspects entirely.

The major problem is that you cannot validate the computer system without qualifying the instrument and vice versa.

The teaching team have been actively involved in bringing AIQ and CSV together during 2011 - 3: they have written a stimulus for revision paper for USP <1058> that was published in the January-February 2012 issue of Pharmacopoeial Forum. Also they have been involved with input and writing sections of the second edition of the GAMP Good Practice Guide for Validation of Laboratory Computerised Systems published in November 2012. In addition they have redrafted USP <1058> and are co-authors of an article published in Pharmaceutical Engineering mapping the GAMP and USP <1058> approaches together. The course will include material from these publications.
In addition there is now the new version of Annex 11 in combination with Chapter 4 in Europe: what is the impact of these regulations on laboratory systems?

This workshop will address these current concerns and present an integrated approach to analytical instrument qualification (AIQ) and computerised system validation (CSV) for laboratory systems including the latest information with USP and GAMP. This will be achieved by presentations coupled with workshops and discussions to reinforce the presentation principles. The number of participants is limited.

Note: This workshop will not discuss user training and the writing of SOPs for operating the instruments or systems.

Target Group

Analytical scientists, laboratory managers, validation personnel working with laboratory equipment and systems, quality assurance personnel and any IT personnel involved with systems such as chromatography data systems and LIMS.

Programme

Introduction to the Course

- Aims and objectives of the course
- Course process (presentations / workshops)
- Road map for the course

A Risk-based Approach - Working Smarter not Harder

- Quality Management Systems in the analytical laboratory; implications of ICH Q10
- Traditional approaches to calibration, qualification & validation
- Impact of new technology changes on instruments & systems
- New and novel regulatory expectations
- Equipment, Apparatus, Instrument or System?
- Establishing 'fitness for purpose' and 'suitability for intended use'
- Terms and definitions; the role of a technical glossary

Analytical Instrument Qualification: Where Are We Now?

- Calibration or Qualification?; Modular & holistic approaches
- USP <1058> Analytical Instrument Qualification
- USP <1058> Stimulus to the revision process paper
- Establishing risk-based criteria based on user ways of working
- Software linking in USP <1058> now and future: the new sub groups proposed
- Applying the principles of USP <1058> in practice to an
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

Computerised System Validation: Where Are We Now?

- Regulators
  - FDA; Part 11, Predicate Rules & 2002 software validation guidelines
  - EU; the New Annex 11 and Chapter 4 requirements
  - PIC/S Good practices for computerised systems in regulated "GXP" environments
- Industry
  - GAMP 5: risk based approach
  - GAMP Good Practice Guides: Laboratory computerised systems 2nd Edition
- Applying CSV principles to
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

An Integrated Approach to AIQ and CSV for Analytical Systems – Part 1

- Do I have to qualify or validate?
- The new USP <1058> proposed risk assessment process:
  - Define intended purpose
  - Record impact
  - Software classification
  - System categorisation
- If I do how much do I do?

WORKSHOP I
Risk Assessment of Laboratory Instruments and Systems – Application of the Proposed <1058> Risk Assessment

Attendees will be given a short inventory with intended use defined and taken through the proposed <1058> risk assessment to classify the instruments and systems. This will be facilitated group work.

WORKSHOP II

Risk Assessment with Process Workflows – Exploring the Integrated Approach to AIQ and CSV

An integrated approach for qualifying instruments and validating software will use the proposed <1058> risk assessment for three examples: .

- Analytical Balance
- Stand alone spectrometer
- HPLC with a networked CDS data system

This will be working in teams.

An Integrated Approach to AIQ and CSV for Analytical Systems – Part 2

- How can I minimise the validation/qualification effort?
- Threads and Phases of the Integrated Model of AIQ & CSV
- Applying integrated approach principles to
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

WORKSHOP III
Turning the Principles of the Integrated Approach into Practice

Attendees will be given three examples and asked to adapt the integrated AIQ – CSV process for each one:

- Analytical Balance
- Stand alone spectrometer
- HPLC with a networked CDS data system

Documenting the Qualification and Validation Effort

- How much do I really need to do?
- Key documents to be produced
- "Validation Lite" a simplified approach for low risk systems
- Paper or electronic documentation
- Traceability of the validation/qualification effort
- Supporting documentary evidence
- Managing sign off and operational release
- Linking with a Quality Management System (QMS)

Component Installation and Integration

- Nomenclature & mapping; the USP <1058> 4 Qs & GAMP
- Factory acceptance testing; strengths and weaknesses
- Vendor documentation; pros & cons
- Vendor installation & commissioning
- Leveraging vendor activities to reduce user testing
- Configuration management and the change control baseline
- Managing the IT interface
- Applying the principles to
  - Analytical balance
  - Stand alone spectrometer
  - HPLC with a networked CDS data system

WORKSHOP IV
Risk Assessment of Vendor IQ and OQ Documentation

Attendees will review examples of vendor qualification documentation from the examples below to identify where time can be saved or where there is little value add from the vendor approach:

- Analytical balance
- NIR spectrometer
- Networked CDS

Configuring the Application to Meet User Needs

- Establishing laboratory work flows & SOPs
- How good is the fit with vendor materials?
- Prototyping to determine/ensure the fit to the business process
- Defining mandatory user requirements as a consequence of the workflow
- Operational ranges & conditions
- Calibration procedures and reference standards
- Do you need a configuration document for
  - Analytical balance,
  - Stand alone spectrometer,
  - HPLC with a networked CDS data system?
- What are the implications for change control?

WORKSHOP V
Documenting the User Configuration

The attendees will identify where user configuration is required for a real life scenario of an implementation of an automated dissolution system connected to an automated HPLC and networked data system.

User Acceptance Testing – Instrument, Software and System

- What to test and what not to test
- What has the vendor to offer?
- Risk assessment and the URS
- Typical aspects to test
- Test plans and test scripts

- Assumptions exclusions and limitations of testing
- White box and black box testing
- Testing approaches
- Setting sound acceptance criteria
- Integrating calibration and qualification

WORKSHOP VI
How to Focus on Critical Areas for User Acceptance Testing
Based on the outputs from workshop 5, the attendees will decide how to focus on the critical areas of the system for user acceptance testing.

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy, Barnard Castle, UK
Dr Burgess is a Chartered Chemist and has more than 40 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.

Dr Bob McDowall
McDowall Consulting, Bromley, Kent, UK
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK for over 20 years. He has been involved with the validation of computerised systems for over 25 years and is the author of a book on the validation of chromatography data systems. 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.

Moderator

Dr Bob McDowall, McDowall Consulting, UK

Social Event

At the evening of the first course day all participants and speakers are invited to a dinner in a nice restaurant, where the topics of the course can be further discussed in a relaxed atmosphere.

ECA Education Course
FDA-Compliance in Analytical Laboratories
21 - 23 October 2015

On 21 - 23 October 2015, i.e. from Wednesday to Friday of the same week, there will be another ECA GMP Education Course in Berlin about **FDA Compliance in Analytical Laboratories**. The objective of this course is to give the participants comprehensive insight into the key laboratory compliance issues for laboratories in an FDA-regulated environment.

Topics that will be covered are:

- Regulatory Requirements and FDA Inspections
- Documentation in the Pharmaceutical Quality Control
- Sampling in Compliance with FDA Requirements
- Qualification of Analytical Instruments in the QC
- Calibration for FDA Inspected Analytical Laboratories
- Reference Standards and Reagents for FDA-inspected Laboratories
- Validation of Analytical Procedures
- Stability Testing
- Out of Specification Results
- Practical Computer Validation in Analytical Laboratories
- Transfer of Analytical Procedures
- Validation of Excel Spreadsheets
- Training Case Study

In addition, **Workshops** are offered about:

- Method Validation
- Out of Specification Results
- Validation of Excel-Spreadsheets
- Method Transfer

Speakers:
Dr Manfred Fischer, SkyePharma AG, Switzerland
Dr Christopher Burgess, Burgess Analytical Consultancy, UK
Dr Joachim Ermer, Sanofi, Germany
Dr Bob McDowall, McDowall Consulting, UK

The course on **Integrating Analytical Instrument Qualification and Computerised System Validation** (19-20 October 2015) is an ideal precursor to the Education Course **FDA-Compliance in Analytical Laboratories** (21-23 October 2015). Further information about the course FDA Compliance in Analytical Laboratories can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses will receive a **350€ discount** (not valid for EU GMP Inspectorates).

Organisation and Contact

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Dr Günter Brendelberger (Operations Director) at +49-62 21 / 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at +49-62 21 / 84 44 46, or per e-mail at weidemaier@concept-heidelberg.de

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates.

Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

Reservation Form:
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☐ **Integrating Analytical Instrument Qualification and Computerised System Validation,**
19 – 20 October 2015, Berlin, Germany
☐ **FDA Compliance in Analytical Laboratories,** 21 – 23 October 2015, Berlin, Germany
Please tick if you want to register for this course, too.

☐ Mr. ☐ Ms.

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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 %,
- until 1 weeks prior to the conference 50 %
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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)

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Date

Monday, 19 October 2015, 09.00 - 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 20 October 2015, 08.30 - 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
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Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845,-
The course 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.

Do you want to save money?

If you register for the ECA Education Course "FDA Compliance in Analytical Laboratories" from 21-23 October 2015 at the same time, you will receive a 350 € discount.
This is not valid for EU GMP Inspectorates.

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. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.