Participate in 5 Workshops!

Maintaining Laboratory Computer Validation

How to Maintain the Validated Status of Computerised Systems in Analytical GMP Laboratories

19 – 20 June 2012, Prague, Czech Republic

SPEAKER:

Dr. Bob McDowall
McDowall Consulting, UK

LEARNING GOALS:

- Regulations and Guidelines (US and EU)
  - Impact of EU GMP Annex 11 and Chapter 4
  - New FDA Requirements for Data Integrity
- Practical Approach to Configuration Management
- Change Control Processes for Laboratory Computerised Systems:
  - Impact of Changes, Managing the Risk, Revalidation
- Integrating the IT Department – Qualified IT Infrastructure
- How to Revalidate a Chromatography Data System (CDS)
- Electronic Records and Raw Data
  - Definition
  - Backup
  - Options for Archiving
- User Account Management: Security and Access Management
- What is a Periodic Review and what Systems should it cover?

ECA
EUROPEAN COMPLIANCE ACADEMY

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

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Objectives

The objectives of this course are:

- To provide guidance through presentations and experience through workshops for attendees to understand the GMP regulatory requirements and practical steps required to maintain the validation status of computerised analytical systems including the requirements of Annex 11 and Chapter 4.
- To provide the latest information on the updates of USP <1058> and the GAMP Good Practice guide for Laboratory Computerised Systems to be published in early 2012.
- To highlight approaches to ensure compliance with the FDA's initiative on laboratory data integrity under Compliance Program Guide 7346.832.

Background

Computerised systems are everywhere in a GMP Analytical Laboratory from networked systems such as LIMS and chromatography data systems to standalone systems that control and acquire data from instruments such as spectrophotometers or thermal analysis to embedded software with balances and pH meters. In addition there are software applications including spreadsheets. If they perform GMP relevant work then they must be validated and the validation status must be maintained throughout the operational life until decommissioning.
Most analytical scientists think that validating a computerised analytical system is difficult but they are wrong as it is the easiest part of the life cycle. The most difficult part of computer system validation is trying to maintain the validation status of a computerised analytical system throughout the whole of its operational life.

After a review of the regulations, this short course will look at the main areas involved in maintaining the validation of any computerised laboratory system e.g. change control, security and access control, backup of electronic records and the periodic review.

There are many areas that need to be considered when maintaining the validation status of a computerised analytical system within a GMP analytical laboratory but the most important of these is change control. Therefore a large part of this education course will look at the change control and configuration management of computerised laboratory systems.

The short course will consist of presentations and five workshops with time for discussion on points specific to an attendees needs.

Participants will receive **a comprehensive listing covering regulations and guidance for change control as a handout.**

Note: the course will not be covering disaster recovery or business continuity management as this is typically outside of the laboratory remit and lies with the IT Department.

Target Audience

This course will be of significant value to:

- Process Owners of laboratory computerised systems
- System Owners supporting networked laboratory computerised systems
- Quality Control managers
- Analytical scientists who are system administrators of standalone or networked laboratory systems
- Quality Assurance professionals with computerised system responsibilities
- Information Technology staff responsible for supporting networked laboratory systems

Moderator

Dr Bob McDowall, McDowall Consulting, Kent, UK

Programme

Introduction

- Introduction to the course
- Scope of the two days and the workshops

Regulations and Guidelines for Maintaining Validation of Laboratory Computerised Systems

- US and EU GMP and GLP regulations
- Impact of the new EU GMP Annex 11 and Chapter 4 regulations
- Regulatory guidance documents
- Industry guidance for maintenance of validation status
- Laboratory data integrity under the FDA's Compliance Program Guide 7346.832
- Defining the key areas for maintaining the validation status of computerised systems in the laboratory

Understanding the Change Control Processes for Laboratory Computerised Systems

- What are the main change control processes?
- Linkage of change control with incident management
- Is it a change or maintenance?
- Process flows involved with change control including risk assessment
- Who are the key people involved with change control?

WORKSHOP 1: Review of a Change Control SOP

Attendees will be provided with a change control procedure for computerised systems and they will review the document against regulatory criteria from the earlier presentation. They will feed their comments back to the course for discussion and comment.

Understanding Configuration Management for Laboratory Computerised Systems

- What is configuration management?
- How does configuration management link with change control?
- Practical approach to defining configuration items

WORKSHOP 2: Review of Change Control Requests for Laboratory Systems

Using the change control process developed earlier, attendees will be given change requests for GMP regulated laboratory computerised systems to review and analyse if the correct course of action was chosen.

Revalidating Your Application and Managing the Risk

- One key requirement of any change control process is to ensure that the amount of revalidation is undertaken is appropriate. A short introductory presentation will look at the risk assessment in some system upgrades and discuss with the course options for revalidation
- What will change when the request is implemented?
- What is the impact of these changes?
- How do we manage the risk of the change?

WORKSHOP 3: Revalidating a CDS after Upgrades

Using the principles of the previous presentation, a facilitated discussion will look at risk management when upgrading a validated networked chromatography data system (CDS). As part of the change control request the amount of revalidation will need to be determined, the course will develop the principles to determine the amount of revalidation to be performed for any application.

How the IT Department Can Impact the Validation Status of Networked Systems

- Is the IT infrastructure qualified and the impact this can have on a validated application
- Managing change to the infrastructure to ensure control
- Integrating IT and GMP changes and understanding why this is important
- Assessing the impact of change on infrastructure and its impact on GMP laboratory systems
- How will IT changes impact laboratory systems

Data Integrity

- Annex 11 and Chapter 4 requirements for data integrity
- New FDA requirements for data integrity
- Procedural and technical controls to meet the regulatory requirements

Electronic Record & Raw Data Definition and Management of Records

- Defining electronic records and raw data as required by Part 11 and Chapter 4
- What are the compliance requirements for backup – regardless of who performs the activity?
- Who performs the backup? IT (networked systems) or the laboratory (standalone systems)?
- Is the backup done and are there records of the work?
- Can you recover your data?
- Archive of electronic records – considering some of the options

WORKSHOP 4: Options for Archive & Retention of Electronic Records

When upgrading a laboratory computerised system what should be considered for the archive of existing records from the current system? The course will look at the options facing laboratories based on case study examples based on chromatography data systems.

User Account Management: Security and Access Control

- Data integrity issues with security and access control
- Users and password maintenance
- Authorised users: defining access privileges
- How to maintain security and access control records

Periodic Evaluation (Review or Audit) of Laboratory Computerised Systems

- What is a periodic review and what systems should it cover?
- Who performs a periodic review and how often should they take place?
- How to do undertake a periodic review
- Findings and the classification of severity
- Drafting the corrective action plan and the periodic review certificate

WORKSHOP 5: Generating Findings from Periodic Review Observations

Attendees will be given the observations from a periodic review of a laboratory computerised system from a GMP laboratory. Are there any findings or non-compliances? If so, how severe are they? This will be followed by a review and discussion.

Review of the short course and final discussion

- Key learning points of the course
- Final discussion and close

Speaker

Dr BOB McDOWALL,
McDowall Consulting, UK
Analytical chemist with over 30 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK for 19 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.

Social Event

On 19 June 2012 you are cordially invited to a social event in Prague. 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

Maintaining Laboratory Computer Validation,
19 – 20 June 2012, Prague, Czech Republic

☐ Mr. ☐ Ms.

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Date

Tuesday, 19 June 2011, 09.00 – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 20 June 2011, 08.30 – 16.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Praha 4
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Phone + 420 261 191 111
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Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- 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 course. Please use this form for your room reservation or be sure to mention booking code "XCON18062012" to receive the specially negotiated rate (single room € 137,50 per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 21 May 2012. Early reservation is recommended.

Conference language

The official conference language will be English.

Registration

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

Organisation and Contact

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