Save up to € 490.- by booking both courses

Computer Validation

- Introduction to Risk Management
- The GAMP® 5 Approach

Learn How to Plan, Implement and Document Effectively Computer Validation Activities

20 November 2012, Copenhagen, Denmark

21-23 November 2012, Copenhagen, Denmark

SPEAKERS:

Frank Behnisch
CSL Behring GmbH, Germany

Dr David Selby
Selby Hope International, UK

Dr Robert Stephenson
Rob Stephenson Consultancy, UK

LEARNING OBJECTIVES:

- The New EU GMP Guide Annex 11
- 21 CFR Part 11
- The GAMP® 5 Lifecycle
- Practical Risk Management – ICH Q9 and FMEA Methodology
- Validation Planning
- Change Control
- Validation Documentation
- Presentation to Inspectors
- **Learning by doing: up to 10 Workshops**

ECA
EUROPEAN COMPLIANCE ACADEMY

GAMP® is a trademark of ISPE - http://www.ispe.org/gamp5

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

Computer Validation: Introduction to Risk Management

20 November 2012, Copenhagen, Denmark

Learning Goals

- You get to know the current risk management approaches of ICH Q9 and GAMP®5
- You become familiar with the latest methods and tools for risk analysis and can assess their relevance to practice in the validation of computerised systems
- You learn how the activities involved in the validation of computerised systems can be controlled efficiently by means of risk management
- In 4 workshops you can apply the procedures and discuss them

Background

The current GMP regulations and guidelines (ICH Q9, GAMP®5, EU GMP Guide Annex 11 "Computerised Systems") focus more and more on the topic of risk management. However, the regulations do not offer much concrete advice on how its principles should be translated into practice during the validation and operation of computerised systems. Therefore, it is the aim of this course to provide you with practice-oriented guidance in performing this task.

Target Group

This Education Course is directed at employees from Production, Quality Control / Quality Assurance, Engineering, IT who have to deal with risk assessment and risk management in the field of computer validation.

Programme

Introduction – What do you want from this day?

- Capturing delegates expectations
- Sharing and reducing to key points in groups
- Sharing with all delegates and tutors

An open session capturing the expectations of the delegates. Working in groups delegates derive their requirements from the training event and share them with the tutors.

An Introduction to Risk Management (including ICH Q9)

- Definition of "Quality Risk Management"
- Principles of Quality Risk Management
- Application of the principles in validation
- Methods of assessing and controlling risk
- Regulatory expectations for risk management

An introduction to the principles and terminology used in ICH Q9, Quality Risk Management. The principles will then be applied to the validation life cycle. The regulatory expectations for risk management will be discussed.

Risk Management the GAMP® 5 Way

- The GAMP methodology for risk management
- Where to apply risk management in validation
- Methods of assessing risk

The GAMP® 5 approach to science-based quality risk management is described for delegates to see how important effective risk management is to successful CSV. Scalability of risk identification and risk controls based on system complexity and business process analysis is also discussed.

Workshop 1: Risk Assessment in Validation
Risk management applied to a computer system

- Evaluating identified risks
- Classification of risks into H, M, L
- Controls to mitigate unacceptable risks
- Links to the validation plan and protocols

In this workshop, delegates will use the GAMP methodology. The participants will work on a case study in which the risks associated with a computer system are assessed and managed to reduce the testing workload in validation.

Workshop 2: Risk Management in Validation
Risk management applied to a control system

- What are the conclusions from the risk assessment?
- What options do you have to mitigate (reduce) the higher risks?
- How will the output affect the protocol?

Based on a real case study, delegates will use the same risk assessment techniques to determine where to focus the qualification of a packaging line.

Assessing and Selecting a Supplier

- What are the criteria to use to select a supplier?
- Why does supplier selection matter?
- How should the selection process be conducted?

Delegates will understand the value of identifying a good supplier, the importance of having a good supplier selection procedure and what to look for when selecting the most appropriate supplier for your project

Workshop 3: Assessing and Selecting a supplier

- What factors influence supplier assessment?
- What risks are associated with supplier selection?

Delegates will assess supplier selection information to choose between two possible suppliers for an application

An Introduction to Risk Ranking

- What is risk ranking
- How is it carried out
- How is it documented?
- A few useful applications

This presentation presents the principles of risk ranking and shows how it may be used in a number of applications relating to the compliance of computer systems.

Workshop 4: Applying Risk Ranking to determine periodic review priorities

- How is severity determined?
- How can scales be created?
- Ranking the risks
- Developing a risk-based action plan.

Delegates will apply the techniques of risk ranking to determine which systems present the highest risk to the patient and should therefore be reviewed first.

Computer Validation: The GAMP® 5 Approach

21-23 November 2012, Copenhagen, Denmark

Learning Goals

This is why you should attend this course:

- You will systematically be introduced to the principles and methods of the validation of computerised systems (according to GAMP®)
- You will learn the skills to plan, implement and document effectively validation activities for computerised systems and to assess them with respect to their GxP compliance
- You have the opportunity to practically apply the theoretical foundations in 6 workshops

Background

Computerised systems are a central factor determining work sequences in the pharmaceutical industry. Their use increases product safety and saves time and costs of manual intervention. This creates the requirement and necessity, however, to validate all computerised systems which can influence the quality of pharmaceutical products. The basis of the education course will be the current requirements for the validation of computerised systems like GAMP® and their GxP-oriented application in practice. Experts from the pharmaceutical industry and from the GAMP® Committee will show you efficient ways to validate your computerised systems.

Target Group

This course is directed towards specialists and executives in the pharmaceutical industry entrusted with the planning, implementation and evaluation of the validation of computerised systems.

Programme 1st Day

Introduction –What the Participants Expect

An open session capturing the expectations of the delegates

Laws, Regulations and Guidelines for Computer Validation

- The historical perspective
- Current regulations and regulatory guidelines from US
- New regulatory guidance (GAMP® 5, GAMP® Good Practice Guides, ASTM)
- New industry guidance
- Regulatory training
- Harmonisation

A review of the laws, regulations and guidelines from both the regulators and industry, right up to the present day, and anticipating new developments.

Electronic Records and Signatures

- What Part 11 means – Now!
- Identify e-records in predicate rules
- Identify risks to records
- Identify appropriate controls for records

This session will show how to identify electronic records and review the most common issues arising from the recent FDA regulation. It will show how the risks to the record, will determine the controls to be applied, based on the GAMP® Guidance, published in 2005.

The EU Annex 11 "Computerised Systems"

- What is new?
- What are the important points?
- How can you implement it?

The new versions of EU GMP Guide Chapter 4 Documentation and Annex 11 were published in 2011. You will get an overview about the important points.

The GAMP® 5 Approach to Computer Validation

- Validation needs structure
- The GAMP® approach
- What is new in GAMP® 5
- General validation activities
- The GAMP® Categorisation System
- Life Cycle cost reduction

An overview of all the processes in the computer validation lifecycle, including how the approach to validation can be modified to fit in with the GxP criticality of the application.

Workshop 1: Review of User Requirements Specifications

A short review of the URS and how to write specifications, as a prelude to a workshop in which delegates will evaluate a real requirements specification.

- What is a URS?
- Why is it important?
- Contents of a URS
- Characteristics of good specifications
- Testable specifications

An Introduction to Risk Management (including ICH Q9)

- Definition of "Quality Risk Management"
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- Application of the principles in validation
- Methods of assessing and controlling risk
- Regulatory expectation s for risk management

An introduction to the principles and terminology used in ICH Q9, Quality Risk Management. The principles will then be applied to the validation lifecycle. The regulatory expectations for risk management will be discussed.

Workshop 2: Risk Management in Validation

In this workshop, delegates will use the GAMP® methodology. The participants will work on a case study in which the risks associated with a computer system are assessed and managed to reduce the testing workload in validation.

- Risk management applied to a computer system
- Evaluating identified risks
- Classification of risks into H,M,L
- Controls to mitigate unacceptable risks

Programme 2nd Day

Validation Planning

- Why is a validation plan important?
- Definitions and regulatory expectations
- Building risk management into planning phase
- Structure and contents of validation plans
- Discussion of best approach
- The impact of scaleability

This session will focus on what is important in a Validation Plan. This will include the information required and the regulatory expectations.

Workshop 3: Validation Planning

Based on considerations of the type of application, knowledge of the supplier and how it will be used, delegates will work out the best approach to delivering the benefits of a GxP system

- What are the risks associated with delivering the system?
- What options do you have to manage the most critical risks?
- How can they best be managed?
- What are the key issues to monitor to ensure delivery of the project benefits?

Specifications, Design Review and Traceability

- What sorts of specifications are needed?
- How are they constructed?
- Can they be combined?
- How to carry out a design review?
- How to construct a traceability matrix?

This session will show the interconnectivity between specifications and the importance of getting them right before h/w and s/w are built. It will also introduce the concept of traceability and how it helps the project to stay focussed.

Protocols, Test Scripts and Deviation Management

- Principles of Risk-Based Qualification
- Leveraging the Supplier
- Commissioning vs Qualification
- Test Script Design
- Deviation Management

GAMP® 5 principles are applied to the development of effective testing protocols based on risk, how to get best value from the Supplier's documentation, good practice guidance when executing test protocols and how to document deviations to ensure compliance.

Workshop 4: Risk Management in Protocol Planning

Based on a real case study, delegates will use the same risk assessment techniques as in Workshop 2 to determine where to focus the qualification of a packaging line.

- Risk management applied to a control system
- Using FMEA to assess risks to be managed and controlled in validation
- Identifying options to mitigate (reduce) the higher risks
- Using the output in creating the testing protocol

Change Control

- Regulatory requirements
- Configuration management
- Responsibilities
- Planned/unplanned changes
- Classification
- Sources of changes

The session will attempt to provide practical guidance on the set-up of a change control procedure covering computerised systems.

Workshop 5: Change Control

The participants will work on a number of case studies and define the change control activities needed.

- Change Control forms
- Approval process
- Standard Changes
- Committees

Workshop 6: Managing Deviations

In this workshop examples of deviations will be examined and methods of resolution discussed. The examples are based on real-life protocols.

- Test failures found during IQ/OQ
- Manage the deviations
- Suggest solutions

Programme 3rd Day

Automation Aspects

- System Overview
- GAMP® and risk analysis
- Specifications
- Qualification / Validation

Process Control Systems (PCS) and Process Logical Controllers (PLC) are widely used. This session describes specific aspect of automation systems regarding computerised system validation.

Validation Reporting & Presentation to Inspectors

- The link between the plan and the report
- Key documents
- Validation summary reports
- Style and emphasis
- Managing the inspection

The relative importance of different validation documents will be discussed from the point of view of presenting a validation study to an inspector. The presentation and the key communication issues will be discussed.

Introduction to IT-Infrastructure Qualification

- The qualification lifecycle
- How to deal with user requirements
- Qualification documentation
- Critical issues
- Qualification summery report

The participants will be informed on the basic concepts, critical items and recent trends on the qualification of the Network, Platforms, Back-end and Front-end. This session will focus on the new requirements published in the GAMP® Good Practice Guide "IT-Infrastructure Compliance and Control"

Regulatory Comments

- Recent general trends
- Highlights from Warning Letters and 483s
- Lessons we must learn

We will give you the necessary overview and update of national and international regulations. Beside others you will hear about the "Hot Buttons" of Computer Validation and frequent misconceptions.

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.

Organisation and Contact

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For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager)
at +49-(0)62 21 / 84 44 51 or per e-mail at
strohwald@concept-heidelberg.de.

Social Event

On 21 November 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.

Speakers

Frank Behnisch, *CSL Behring GmbH, Germany*

Frank is Senior Manager Project Engineering at CSL Behring GmbH in Marburg, Germany. He is member of the GAMP® D-A-CH „steering committee" and chairman of a GAMP® Special Interest Group (SIP) for "Small Systems".

Dr David Selby, *Selby Hope International, UK*

David Selby, BSc., PhD., was with Glaxo for many years in different positions. He occupied the role of Site Quality Assurance Manager there and latterly, he was the Site Manager. He is a founder member and Chairman of the GAMP® Forum and 2004 Chairman on the International Board of ISPE. He has established his own consultancy, Selby Hope International, specialising in the compliance of computerised systems and automated equipment used in pharmaceutical manufacturing.

Dr Robert Stephenson, *Rob Stephenson Consultancy, UK*

Rob has had extensive experience with the implementation and operational control of a wide range of applications within the Pharmaceutical and Personal Products sector. He joined Pfizer Sandwich UK in 2000 as member of their Quality Unit operating within the IT group where his responsibilities included coordinating the manufacturing site's initiative to achieve 21 CFR Part 11 compliance and authoring their IT Quality Management System. As a long-standing member of the GAMP Europe Steering Committee Rob has contributed material to GAMP®5 and the ISPE GAMP Good Practice Guide on "A Risk-Based Approach to Operation of GxP Computerized Systems" for which he was co-leader. Rob now works as an independent IT Systems Validation Consultant.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme Module "Certified Computer Validation Manager". 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

On the internet at www.gmp-certification.eu 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:
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)

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☐ **Computer Validation: Introduction to Risk Management,** 20 November 2012, Copnehagen, Denmark
☐ **Computer Validation – The GAMP 5 Approach,** 21-23 Novemebr 2012, Copenhagen, Denmark

☐ Mr. ☐ Ms.

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Date

Computer Validation: Introduction to Risk Management
Tuesday, 20 November 2012, 09.00 h – 18.15 h
(Registration and coffee 08.30 h - 09.00 h)

Computer Validation – The GAMP® 5 Approach
Wednesday, 21 November 2012, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 22 November 2012, 09.00 h – 17.30 h
Friday, 23 November 2012, 08.30 h – 13.00 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 00

Fees

Computer Validation: Introduction to Risk Management
ECA Members € 790.- per delegate plus VAT
APIC Members € 840.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 890.- per delegate plus VAT
EU GMP Inspectorates € 445.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Computer Validation – The GAMP® 5 Approach
ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event including dinner on the first day, two lunches and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotels. 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 "COHE" to receive the specially negotiated rate (Single room DKK 1,445.- per night, excl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 23 October 2012. Early reservation is recommended.

Save Money and book both courses
ECA Members € 2,190.- per delegate plus VAT
APIC Members € 2,290.- per delegate plus VAT
Non-ECA Members € 2,390.- per delegate plus VAT
(does not include ECA Membership)