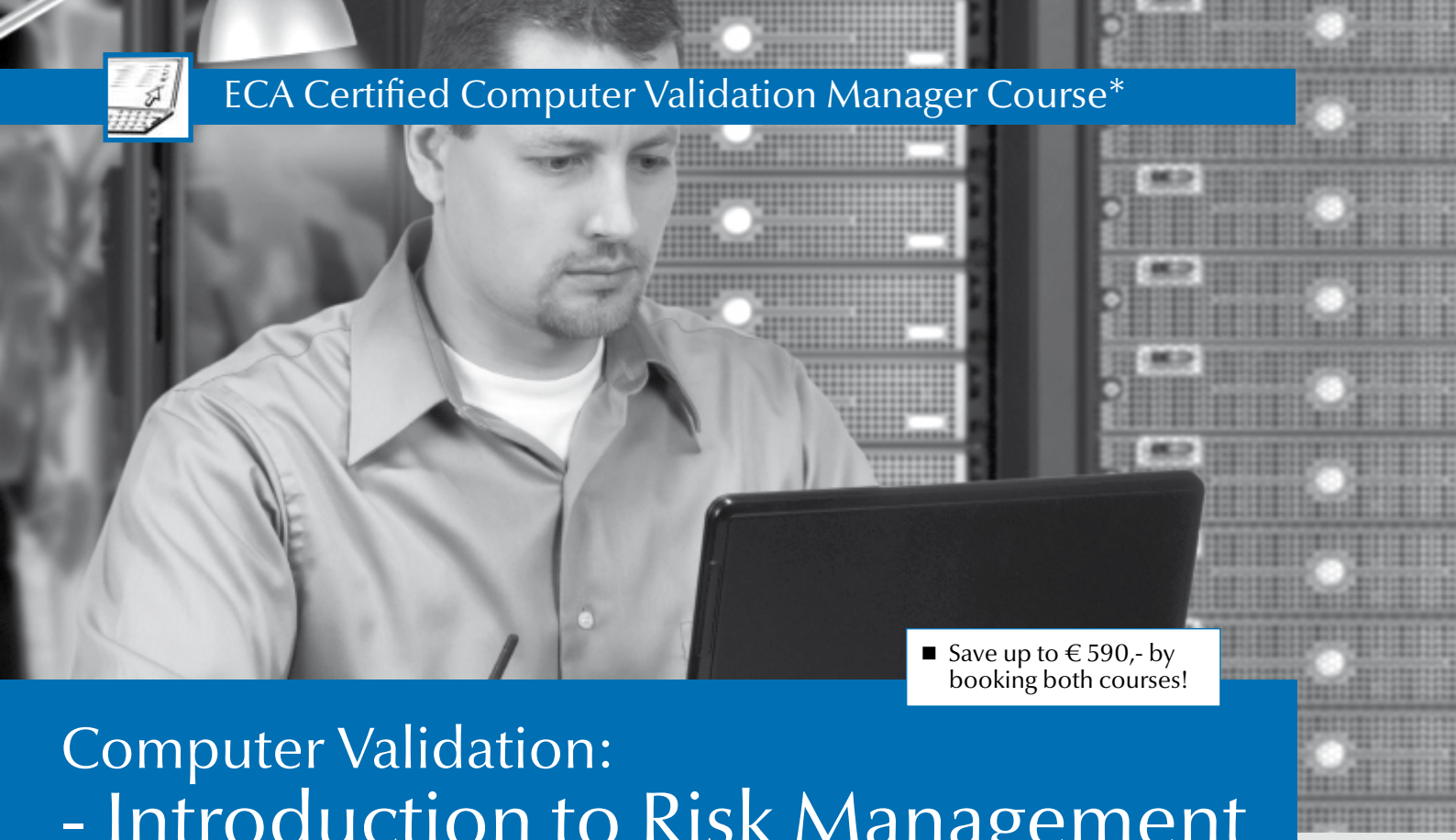

ECA Certified Computer Validation Manager Course*

■ Save up to € 590,- by booking both courses!

Computer Validation:
- Introduction to Risk Management
- Maintaining the Validated State

Introduction to Risk Management
26 October 2010, Prague, Czech Republic

Maintaining the Validated State
27-28 October 2010, Prague, Czech Republic

SPEAKERS:

Frank Behnisch
CSL Behring GmbH, Germany

Kate Samways
KAS Associates Ltd, UK

Dr David Selby
Selby Hope International, UK

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

Computer Validation: Introduction to Risk Management

26 October 2010, Prague, Czech Republic

Learning Goals

- You get to know the current risk management approaches of ICH Q9 and the 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, draft EC-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 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 life cycle. The regulatory expectations for risk management will be discussed.

GAMP® 5: M 3 FMEA Methodology

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

An introduction to GAMP® 5 for delegates to see how important risk management is for successful CSV. The principles of risk management are applied to the validation life cycle and delegates will be introduced to the GAMP® methodology for risk management.

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.

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: 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: Maintaining the Validated State

27-28 October 2010, Prague, Czech Republic

Learning Goals

3 good reasons why you should attend:

- You will get to know methods for maintaining the validated state of a computerised system in a GMP-compliant way.
- You will learn how to ensure the security of your data in the short, medium and long term.
- In 4 workshops, you will implement the theoretical knowledge practically and discuss suitable solution strategies with your colleagues.

Background

Today, the validation of computerised systems is a required and lived practice in the pharmaceutical industry. Even though the first validation only takes a short time in the life cycle of a system, the current regulations and industry guides deal above all with this phase. However, the greatest part of the life cycle is represented by daily operation.

How can the validated state be maintained during routine operation? What is required and how can these requirements be put into practice? Experts from the pharmaceutical industry and from the GAMP® Committee will give you answers to these questions. Besides, you will learn to establish a GMP-compliant change control system for your computerised system.

Target Group

This Education Course is directed at employees from

- Production
- Quality Control
- Quality Assurance
- Engineering
- IT

who have to deal with the validation and operation of computerised systems and the maintenance of the validated state.

Programme

Introduction – Understanding of Delegate Experience and Background

Workshop 1: What the Delegates Expect

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

Working in groups delegates derive their requirements from the training event and share them with tutors

How well do you Maintain the Validated State

- Each good practice introduced
- Delegates score themselves
- Results consolidated and fed back
- Allows delegates to compare their maintenance against best practice and other practitioners

Open session in which delegates discuss how well they maintain the validated state of their systems against current best practices.

Handover, Establishing Support Services and Ownership

- What does ownership include?
- Who is the system owner?
- Who does the work?
- What is periodic review?
- The importance of a risk-based approach
- How can it be managed cost-effectively?

A detailed look at what system ownership means, who is responsible for what, and who actually does it. A practical way to approach periodic review will be described.

Keep the system running smoothly

- Incident Management
- CAPA
- Establishing and Managing Support Services
- Performance Monitoring

A look at some of the processes that will assist in keeping the system running smoothly.

Record and Document Management

- Who makes it happens?
- Who ensures it is to the appropriate standard and regulatory expectation?
- What documentation?
- Where is it?

As well as maintaining the systems, the supporting documentation must be maintained. This session looks at the documentation supporting the maintenance of the validated state.

Security and Training
- Scope of security measures
- Roles and responsibilities
- Security measures available
- System security requirements
- Training for everyone!
- Training records

A review of the importance of security when creating, managing and maintaining GxP records and a discussion of the different requirements. A brief look at the need for training and the importance of training records.

Workshop 2: Security Hierarchy
- What is a security hierarchy?
- What security controls are available?
- What are the risks?
- How should they be applied?

The participants will choose a list of appropriate controls for different types of e-records and justify their selection

Periodic Review and Priority Setting
- What is a periodic review?
- Which systems are most important?
- How do I decide?
- How do you do a periodic review?

This presentation discusses what periodic review includes and how it may be carries out.

Workshop 3: Planning a Periodic Review
- Organise the team
- Communicate the requirements/scope
- Define the process
- What is the difference between a periodic review and a surveillance audit?

Delegates will work on two different scenarios to work out the differences between an internal periodic review and the surveillance audit of a supplier.

Operational Change Control and Configuration Management
- Regulatory requirements
- Configuration management
- Responsibilities
- Planned/unplanned changes
- Classification
- Sources of changes

The session will provide practical guidance on the set-up of an operational change control procedure covering computerised systems.

Change Management for Infrastructure
- What are IT Infrastructure changes?
- Minor / Major changes
- Standard Changes
- Control the Configuration Items
- Archiving Configuration Items

IT infrastructure can have a considerable influence on the validated state of computerised systems. Changes have to be documented, their consequences for GMP compliance, evaluated.

System/Data Migration, Back-up and Restore
- Regulatory expectations for record retention
- What are the considerations for migration?
- It will not be perfect process!
- Which techniques are most appropriate?
- The importance of back-up and its management
- The difficulties encountered

The value of e-records generally decreases with age. The issues surrounding data or system migration will be discussed. Then the process of back-up and restore will be reviewed. It is a key area of regulatory interest.

Workshop 4: Data Migration
- What are the issues with data mapping?
- What is the sequence of a migration?
- Must all the data be migrated?
- Impact of data migration on interfaces

Record Archiving and Retrieval
- When is archiving necessary?
- It will not be a perfect process!
- How should it be indexed?
- What are the security issues?
- Periodic electronic regeneration

Archiving is appropriate once data volumes are high or the records need to be consulted infrequently. The process needs to be controlled so that the records can still be located and still need to be accessible sometimes at quite short notice in case of emergency.

Decommissioning, Retirement and Disposal Legacy Systems Validation
- Withdrawal from active service
- Shutting down the system and transfer of data
- Disposal of the system

At the end of the operational life, the system must be withdrawn from service and the records managed. This session will look at the phases of retirement, decommissioning and disposal.

Business Continuity Planning
- How do you survive a business interruption?
- What should you plan for?
- What options are available?
- Managing the short and long term
- Maintaining regulatory credibility

Every business is dependent , many almost totally, on the availability of their system to operate. There needs to be plan in place to manage this situation which takes account of both short and long term interruptions to the business and to key suppliers.

Registration

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

Accommodation

CONCEPT 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 "VA 6309 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 28 September 2010. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at
+49-62 21 / 84 44 18, or per e-mail at
grimm@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

Social Event

On 27 October 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"

Kate Samways

KAS Associates Ltd, UK
Kate Samways qualified as a pharmacist and has more than 25 year's experience in the pharmaceutical industry. For the last six years, she has been consulting within the industry on computer systems validation. Kate joined the GAMP® Forum in 1994 and currently serves as the **Secretary to the GAMP® Europe Steering Committee**.

Dr David Selby

Selby Hope International, UK
David Selby, BSc., PhD., was with Glaxo for many years in different positions. He is a **founder member 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.

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 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

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P.O. Box 10 17 64
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Germany

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+ 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

☐ **Computer Validation: Introduction to Risk Management,** 26 October 2010, Prague, Czech Republic
☐ **Computer Validation: Maintaining the Validated State,** 27-28 October 2010, Prague, Czech Republic

☐ Mr ☐ Ms

Title, first name, surname

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GERMANY

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If you cannot attend the conference you have two options:
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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 %
- within 1 week prior to the conference 100 %.

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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 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)!

Date

Computer Validation: Introduction to Risk Management
Tuesday, 26 October 2010, 09.00 h – 18.15 h
(Registration and coffee 08.30 h – 09.00 h)

Computer Validation: Maintaining the Validated State
Wednesday, 27 October 2010, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 28 October 2010, 08.30 h – 16.15 h

Venue

Dorint Novotel Don Giovanni
Vinohradská 157A
130 20 Prague 3
Czech Republic
Phone +420 – 2 6703 111
Fax +420 – 2 6703 6717

Fees

Introduction to Risk Management on 26 October 2010
Non-ECA Members € 890.- per delegate plus VAT
ECA Members € 811.- per delegate plus VAT
EU GMP Inspectorates € 445.- per delegate plus VAT
APIC members € 845,- per delegate plus VAT (does not include ECA membership)

The fee is payable in advance after receipt of invoice and includes conference documentation, lunch, and all refreshments. VAT is reclaimable.

Maintaining the Validated State, 27-28 October 2010
Non-ECA Members € 1,690.- per delegate plus VAT
ECA Members € 1,521.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
APIC members € 1,605,- per delegate plus VAT (does not include ECA membership)

The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on 27 October, lunch on both days and all refreshments. VAT is reclaimable.

Save up to 590.- € and book both courses:
Non-ECA Members € 1,990.- per delegate plus VAT
ECA Members € 1,791.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
APIC members € 1,890,- per delegate plus VAT (does not include ECA membership)
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on 27 October, lunch all 3 days and all refreshments. VAT is reclaimable.