ECA Certified Computer Validation Manager Course*

Save up to € 490.- by booking both courses

Computer Validation: Leveraging Suppliers
Computer Systems Validation Master Class

Qualify as an expert for the validation of computerised systems

19 June 2012 and 20-22 June 2012, Hamburg, Germany

SPEAKERS:

Frank Behnisch
CSL Behring, Germany

Dr David Selby
Selby Hope International, UK

Dr Rob Stephenson
Rob Stephenson Consultancy, UK

PROGRAMME:

- Regulatory Update
- Leveraging Suppliers
  - Managing Quality
  - Leveraging Test Activities
  - Supplier Assessment
- Good Validation Practices
- Scaleability of Validation
- Advanced Risk Management
- IT Governance
- Change Control and Configuration Management
- Upcoming Challenges in IT
- Learning by doing: up to 11 Workshops
- Interactive sessions

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: Leveraging Suppliers

19 June 2012, Hamburg, Germany

Learning Goals

- Learn what activities and deliverables you should expect to see from your IS/IT supplier to demonstrate Supplier Good Practice
- Learn how to verify your supplier's capabilities so that there are "no surprises".
- Learn how to plan validation (verification) activities, leveraging the expertise of your supplier
- Learn how to minimise duplication of effort between the supplier and your regulated company in order to achieve lean and effective processes throughout the system lifecycle
- Learn how to work with your supplier in order to build a strong and lasting client-supplier relationship

Background

Recognising the potential savings available, regulated companies are increasingly withdrawing from 'in-house' developed solutions and looking to their external system suppliers to provide them with innovative and compliant products and services which fulfil their operational and business needs.
The recently released Annex 11 on Computerised Systems states that 'the competence and reliability of a supplier are key factors when selecting a product or service provider'; 'Leveraging Supplier Involvement' is also one of the 5 key concepts of the GAMP®5 guidance 'A Risk-Based Approach to Compliant GxP Computerized Systems'.
This course aims to provide attendees with the knowledge and a chance to practice the skills required to achieve successful partnerships with their IS/IT suppliers in order to improve the efficiency of the validation (verification) process.

Target Group

This ECA course is directed at employees from Production, Quality Control/Quality Assurance, Engineering and IS/IT, who have to assess, manage or work with computerised system or service providers.
The course will also be of value to representatives from supplier organisations that are working or seeking to work with Regulated Companies in the Life Sciences Sector.

Programme

Introduction – What the Participants Expect

An open session capturing the expectations of the delegates

Leveraging Suppliers Expertise: An Overview of Good Practice

- What is current Good Practice?
- Optimising Supplier involvement
- Integrating the Supplier's expertise and deliverables into your validation process
- How to do more with less

An overview of current good practice approaches to getting effective engagement with IT Systems suppliers throughout the full lifecycle of a system; from initial concept, through the project phase and into operation.

Performing a Supplier Assessment

- Why Assess the Supplier?
- The Overall Process
- Assessment Topics
- Types of Assessment
- Corrective Actions & Follow Up Audits

Effective supplier assessment is a critical process which ensures that the customer's requirements will be met and that any potential inadequacies are identified and addressed effectively. This session will look at the assessment process – in particular assessing the supplier's QMS (Quality Management System).

Workshop 1: Selecting a Supplier

Delegates will plan an assessment of a software supplier using GAMP®5 principles:

- What factors to take into account?
- How to focus the assessment?
- How to engage with the supplier?
- How to report and manage the findings?
- The regulatory expectation

Identifying Leveraging Opportunities 1: Quality Planning

- Quality Planning
- Assuring Quality
- Quality Controls

This session will focus on the development of a Quality Plan which can facilitate the successful development and implementation of a system. Delegates will learn how the findings from the supplier assessment can be used to achieve cost-effective compliance

Workshop 2: Quality Planning within a Supplier's QMS - Developing a Quality Plan that Delivers

Delegates will follow a case study with practical exercises to identify how the Quality Plan can be modified to address weaknesses identified in the Supplier Assessment:

- Quality Management System
- Establishing Requirements
- Producing Specifications
- Testing and Release
- Support and Maintenance
- QA

Identifying Leveraging Opportunities 2 : Leveraging Testing Activities

- What must the supplier do
- What must the regulated company do
- Which Supplier Tests can be accepted

Effectively involving the supplier in system testing activities provides significant opportunities for gaining efficiencies and reducing costs. This session will discuss strategies for success and how to avoid the pitfalls.

Workshop 3: Leveraging Supplier Testing

Delegates will consider what steps are required to ensure that the supplier's testing results can be accepted without the need for re-execution:

- Test script development
- Test script execution
- Test script review and approval

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Managing Quality within an Outsourced IS/IT Environment

Increasingly IT services and systems are being outsourced. Annex 11 states that internal IT departments 'should be considered analogous'. This session considers the controls required to ensure that patient safety, product quality and data integrity are not compromised.

- Making a Business Case
- Outsourced Supplier Specification and Selection
- Implementation
- Monitoring
- Contract Change and Exit

Workshop 4: Developing Service Level Agreements

In this workshop session delegates will get the opportunity to develop a simple Service Level Agreement:

- What Services are being provided?
- Responsibilities of the Provider?
- Service Level Targets?

Speakers of both courses

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.

Objectives

As a specialist for the validation of computerised systems, this event will provide you with

- Suggestions on how the current regulatory developments have to be put into practice
- Real-life examples of how the validation efforts can be controlled by means of risk analysis
- Answers to specific questions, like e.g. on source code review or on drawing up design specifications
- The opportunity to bring questions from your own practice up for discussion

The event is interactive and encourages the active participation of all attendees. Lectures alternate with workshops and discussion sessions.

Background

The V model has become a worldwide standard in the validation of computerised systems. Regulatory requirements as well as industry standards, like e.g. GAMP®, are orientated towards this model. In practice, you as a validation specialist will often wonder in how far this model can be applied to your own validation projects.

Target Audience

The Master Class is directed at employees from

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

The participants should already have experience in the validation of computerised systems and preferably to have attended the Basic CSV Course.

Programme

Introduction – Gain Understanding of Delegate Experience and Background

An open tutor-led session to introduce everyone and enable the tutors to understand the background and experience of the delegates.

Workshop 1: What the Delegates expect

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

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

GAMP® 5 Overview

Introduction to what is new and what has changed in GAMP® 5

- Overview of the changes
- Full life cycle approach
- Science and risk-based approach built into CSV
- Scalability
- Leveraging supplier activities

Roles, Responsibilities and Governance

In GAMP® 5 the emphasis on Good Engineering practices has shifted some responsibilities especially in relation to QA

- Activities for Effective Governance
- Process and System Ownership
- The role of Subject Matter Experts
- The role of QA

Workshop 2: Implications for your Organisation

How does the GAMP® 5 approach change the way we carry out and control our validation/verification activities? Who will be impacted by the changes?

- What is the role of
- IT
- Engineering
- Subject matter experts
- QA

Writing Requirements Documents

An introduction to writing requirements documents, particularly the do's and don'ts.

- What goes into a requirements document?
- What are the considerations for systems?
- Characteristics of good and bad requirements documents
- Sources of requirements information

Workshop 3: Writing a Requirement Specification

- A short exercise to create a working URS and a review of the output
- Delegates will work on a simple requirements scenario
- Output will be discussed with the tutors
- The feedback will be combines and fed back to the delegates
- Lessons learned will be summarised

Practical Use of Scaleability

GAMP® 5 emphasises the importance of "Scaleability of approach" in planning validation activities, and particularly the documentation, to the size of the project and the risk to the patient. This presentation will discuss a scaled approach

- What do we mean by scaleability?
- How does it work in practice?
- How can we combine documents successfully?
- How much is enough?

Workshop 4: Scaleability of Validation

Delegates will be asked to work out what is work a scaled approach to a multi-component system to minimise the cost and time required for validation

- How should the system be sub-divided?
- How can risk management be applied?
- What sub-projects are appropriate?
- Who is involved in each?
- What will the validation plan look like?

Advanced Risk Assessment - FMEA

A review of the finer points of FMEA and the implications of the different approaches that are possible from the GAMP® 5 perspective

- How are assessment scales defined?
- How do you set the "threshold of acceptable risk"?
- Which technique is most appropriate?
- What are the pitfalls?

Workshop 5: Application of GAMP® Risk Management Methodology to a Control System (HVAC)

Delegates will work on a case study using risk management to reduce the validation effort.

- Setting assessment scales
- Assessment of risks
- Formulation of an approach
- Response to regulatory criticism
- Feedback on the outcome of the case study

Workshop 6: Application of GAMP® Risk Management Methodology to a Computer System

Delegates will work on a different case study using risk management to reduce the validation effort.

- Assessment of risks
- Formulation of an approach
- Impact on the validation effort
- Feedback on the outcome of the case study

Design Specification, Design Review and Risk Mitigation

Design specification and review is key to keeping costs under control. This lecture describes good practices for design specifications and reviews and how to manage the outcome.

- Creating design specifications
- Planning and executing design reviews
- Recording design reviews
- Controlling actions arising from design reviews
- Creating traceability matrices

Workshop 7: Application of Risk Mitigation and Challenge Testing

An exercise to mitigate risks for given functionality and to determine rigour of testing

- Delegates will determine mitigation strategies
- Determine the necessary testing
- Design test cases
- Feedback on the outcome

Infrastructure Management / ITIL

The qualification of the IT Infrastructure is a key process in validation activities. The delegates will be informed on the recent trends and the integration of the qualification approach into IT Infrastructure Library processes (ITIL)

- Validation or qualification?
- Configuration Items and Management
- Data Center
- Network
- The ITIL processes

Change Control and Configuration Management

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

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

Interactive Session: Change Control examples

Delegates will work on a variety of change management scenarios

- Evaluating the magnitude and impact of the change
- Application of the principles of risk management
- Leveraging supplier and SME (Subject Matter Expert) expertise
- Minimising the workload whilst maintaining compliance

Interactive Session: Good Validation Practices

Open session in which delegates score their CSV system themselves s against 12 good validation practices

- Each good practice introduced
- Delegates score themselves
- Results consolidated and fed back
- Allows delegates to compare their CSV system against best practice and other practitioners
- Minimising the workload whilst maintaining compliance

Upcoming Challenges in IT

IT is a fast developing industrial sector. What is the impact of new developments on GMP / on computer systems validation?

- Open source software
- Global systems
- Paperless Production: EBR with Vertical Integration
  - Introduction & system description
  - Vertical integration
  - Process control through MES
  - EBR & batch release
  - Challenges, Chances Conclusion

Validating Spreadsheets

A review of the approaches to the validation of spreadsheets, including their development

- Why are spreadsheets high risks?
- Design considerations
- What is important (risk again)!
- How to document spreadsheet validation

Risk Management applied to Electronic Record Controls

An introduction to the application of the science- and risk-based approach to the control applied to electronic record. The presentation will emphasise the principles to be applied and the methods to decide on the most appropriate controls to apply.

- An introduction to GAMP® Guide
- An overview of the principles of risk management applied to electronic records
- Examples of the application of controls
- Impact of the approach on validation or e-record systems

Code Review

- Principles of code review
- Regulatory expectations of code review
- Carrying out code reviews
- Recording and documenting code reviews

Case Study – GAMP® 5 approach

A case study will be presented to illustrate how, using the principles in GAMP® 5, the cost of validation was more than halved

- The simplification of the validation system
- The leverage of supplier expertise
- The use of the risk-based approach
- The financial and other benefits of the GAMP® 5 approach- Minimising the workload whilst maintaining compliance

Handover – the Process and Package

This final session will look at the issues associated with handover and the maintenance of the validated state when the system is in the productive environment.

- What is the handover process?
- Who is the system owner?
- What does the system owner have responsibility for?
- How can we persuade the system owners to accept responsibility?

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.
The ECA will provide 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.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a 200 € discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**

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.

Conference Folder

You cannot take part in this event? Just order the documentation at the price of € 180.- + VAT + postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, The conference folder will not be available until 2 weeks after the event.

The Three Most Important Guidelines and Comparison Matrix in One Booklet

"FDA cGMP, EC GMP and ISO 9001 Matrix for a pharmaceutical Quality System - A GMP Roadmap".

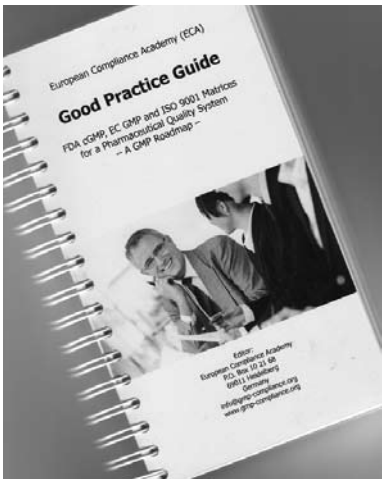
The revised ECA Good Practice Guide is a comprehensive juxtaposition containing the requirements laid down in FDA's cGMP Guide, the EU GMP Guide and ISO 9001. The Matrix has 21 pages as well as more than 530 pages for the following three regulations

- FDA cGMP Guide
- EU GMP Guide Part I, II, and III incl. all Annexes
- ISO 9001 Quality Management Systems

In addition, the current Good Practice Guide contains the revised introduction to the EC GMP Guide as well as the new Part III to the EC GMP Guide containing:

- Explanatory Notes on the preparation of a Site Master File
- Quality Risk Management (ICH Q9
- Pharmaceutical Quality System (ICH Q10)
- Internationally harmonised requirements for batch certification

You can purchase the booklet that is printed in an easy-to-use format together with the conference registration. If you do so, you will be granted the ECA Members price of 99.- € (plus VAT and shipping costs). The regular price is 149.- € (plus VAT and shipping costs).



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 "7148" to receive the specially negotiated rate (single room € 100,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 May 2012. 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.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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www.concept-heidelberg.de

For questions regarding content:
Dr Andreas Mangel (Operations Director) at +49-62 21 / 84 44 41, or per e-mail at mangel@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:Marion Grimm (Organisation Manager) at +49-62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

Social Event

On 20 June 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.

Special offer with Lufthansa – up to 20% discounted travel for all ECA Events Attendees

Lufthansa Mobility Partner

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

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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P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
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e-mail:
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Internet:
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☐ **Computer Validation: Leveraging Suppliers,** 19 June 2012, Hamburg, Germany
☐ **Computer Systems Validation Master Class,** 20-22 June 2012, Hamburg, Germany

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General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- 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)!

Dates

Computer Validation: Leveraging Suppliers
Tuesday, 19 June 2012, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computer Systems Validation Master Class
Wednesday, 20 June 2012, 09.00 h – 18.15 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 21 June 2012, 08.30 h – 18.00 h
Friday, 22 June 2012, 08.30 h – 13.00 h

Venue

InterCityHotel Hamburg Hauptbahnhof
Glockengießerwall 14/15
20095 Hamburg, Germany
Phone +49(0)40 24870 0
Fax +49(0)40 24870 11

Fees

Computer Validation: Leveraging Suppliers
ECA Members EUR 790.- per delegate plus VAT
APIC Members EUR 840.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 890.- per delegate plus VAT
EU GMP Inspectorates EUR 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 Systems Validation Master Class
ECA Members EUR 1,790.- per delegate plus VAT
APIC Members EUR 1,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 1,990.- per delegate plus VAT
EU GMP Inspectorates EUR 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.

Save money and book both courses
ECA Members EUR 2,190.- per delegate plus VAT
APIC Members EUR 2,290.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 2,390.- per delegate plus VAT
EU GMP Inspectorates EUR 1,195.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, 3 lunches, social event including dinner on June, 20h, and all refreshments. VAT is reclaimable.