Computer Validation:

Save up to € 490.- by booking both courses

- Leveraging Suppliers
- Computer Systems Validation Master Class

Qualify yourself as an expert for the validation of computerised systems

7 June 2016 & 8 - 10 June 2016, Barcelona

SPEAKERS:

Frank Behnisch
CSL Behring, Germany

Maik Guttzeit
GEA Lyophil, 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
- Scalability of Validation
- Advanced Risk Management
- IT Governance
- Change Control and Configuration Management
- Upcoming Challenges in IT
- Learning by doing: up to 12 Workshops
- Interactive sessions

ECA ACADEMY

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

Computer Validation: Leveraging Suppliers

7 June 2016, Barcelona, Spain

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 EU-GMP 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

Computer Systems Validation Master Class

8 - 10 June 2016, Barcelona, Spain

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 for "Small Systems".

Maik Guttzeit,
GEA Lyophil GmbH, Germany
Maik is Team Leader Validation at GEA Lyophil which provides customized GMP Lyophilizer systems. He is member of the GAMP® D-A-CH and member of a GAMP® Special Interest Group "Leveraging Supplier Effort".

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 more than 30 year experience in Pharmaceutical and Personal products industries (Boots, Lilly, Unilever, Pfizer). 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

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 Scalability

GAMP® 5 emphasises the importance of "Scalability 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 Scalability?
- How does it work in practice?
- How can we combine documents successfully?
- How much is enough?

Workshop 4: Scalability 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?

More about Risk Management

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

- What is really important in managing risk?
- How do you set the "threshold of acceptable risk"?
- The importance of Risk Registers
- How to document risk management for benefit

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

Upcoming Challenges in IT

IT is a fast developing industrial sector. What is the impact of new developments on GMP / on computer systems validation? Attendees can select 3 of the following topics which will be discussed intensively

- Open source software
- Global systems
- Paperless Production: EBR with Vertical Integration
- Cloud Computing / Virtualisation
- Infrastructure Qualification / ITIL
- Outsourcing

Workshop 7: Design Review

Design Review is a process which ensures that all requirements have been addressed, identifies issues and proposes corrective actions. Delegates will perform a Design Review over extracts from a real life set of requirements and specification documents in order to confirm that all deliverables have been identified and to confirm traceability. There will also be an opportunity to discuss what corrective actions might be required

- Review of User Requirements, Functional Specifications and Design Specifications
- Completion of a Requirement Traceability Matrix
- Reporting of corrective actions
- Links to verification activities

Workshop 8: 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

Computer Systems Validation Master Class

8 - 10 June 2016, Barcelona, Spain

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

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 and Electronic Records

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.

- A clear definition of electronic records with examples
- An overview of the principles of risk management applied to the classification of electronic records
- When is an audit trail needed
- Do we need to keep chromatographic (and other) raw data?
- Examples of the application of controls
- Impact of the approach on validation of 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?

Social Event

On 8 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.

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

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Computer Validation: Leveraging Suppliers,** 7 June 2016, Barcelona, Spain
☐ ☐ **Computer Systems Validation Master Class,** 8 - 10 June 2016, Barcelona, Spain

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GERMANY

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Dates

Computer Validation: Leveraging Suppliers
Tuesday, 07 June 2016, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)

Computer Systems Validation Master Class
Wednesday, 08 June 2016, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 09 June 2016, 08.30 h – 17.30 h
Friday, 10 June 2016, 08.30 h – 13.00 h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
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Fees (per delegate plus VAT)

Computer Validation: Leveraging Suppliers
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
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 € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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 up to € 490 and book both courses:
ECA Members € 2,190 / APIC Members € 2,290
Non-ECA Members € 2,390 / EU GMP Inspectorates € 1,195
The conference fee is payable in advance after receipt of invoice and includes conference documentation, 3 lunches, social event including dinner, and all refreshments. VAT is reclaimable.

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. 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.

Organisation and Contact

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