



## Speakers



**Frank Behnisch**  
CSL Behring GmbH



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# Computer Validation: - Leveraging Suppliers - Computer Systems Validation Master Class

12 & 13 - 15 May 2020 | Barcelona, Spain



Qualify yourself as an expert for the validation of computerised systems

## Highlights

- Regulatory Update
- Leveraging Suppliers
  - Managing Quality
  - Leveraging Test Activities
  - Supplier Assessment
- Good Validation Practices
- Scalability of Validation
- Advanced Risk Management
- IT Governance
- Data Integrity
- Change Control Management
- Upcoming Challenges in IT
- Learning by doing: up to 10 Workshops
- Interactive sessions



Save money and  
book both courses!

## Objective

- 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 life cycle
- 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 Audience

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

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An open session capturing the expectations of the delegates

### Leveraging Suppliers Expertise: An Overview of Good Practice

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- 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

### Performing a Supplier Assessment

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



#### 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



#### 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

### Identifying Leveraging Opportunities

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- Define the role of the supplier
- What must the supplier do?
- What must the regulated company do?



#### 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

### Managing Quality within an Outsourced IS/IT Environment

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

## 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 have attended a basic CSV Course.

## Programme

### Introduction – Gain Understanding of Delegate Experience and Background

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#### 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

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- 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

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- 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 combined and fed back to the delegates
- Lessons learned will be summarised

### Practical Use of Scalability

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- What do we mean by Scalability?
- 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?

### Making Use of Risk Information

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- Generation a process risk register
- Using the risk register to:
  - Identify the range of risk-based controls necessary for the effective management of the process
  - Identify critical tests for qualification or verification
  - Help manage change, incidents, the focus for audits etc.
  - Identify the residual risks to be managed
  - Show embedding of risk management within the Quality Management System



## Workshop 5: 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 Review – A Critical Process

- When to perform a Design Review?
- Who should participate?
- How to document the Review
- How to manage the findings



## Workshop 6: Design Review

The delegates will be presented with the typical findings from a Design Review and, in a team-based exercise, will develop a set of risk-based corrective actions to address the issues

## Upcoming Challenges in IT

- Open source software / Agil
- Global systems
- EBR / MES
- Cloud Computing / Virtualisation
- Infrastructure Qualification / ITIL

## Interactive Session: Good Validation Practices

- Open session in which delegates score their CSV system themselves 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

## Change Control and Configuration Management

- Responsibilities
- Planned/unplanned changes
- Classification

## 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

## Validating Spreadsheets

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

## Risk Management and Electronic Records

- 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

## Data Integrity – Formulating a Company Strategy

- Management accountability
- Incorporation of data governance in the Quality Management System
- Defining appropriate metrics
- Auditing the data integrity processes
- Reviewing progress



## Workshop 7: Data Integrity

The delegates will be presented with an audit observation about deficiencies in the management of data. They will be asked to devise a programme to improve data integrity governance as part of the response to the regulatory observation.

## 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

## Handover – the Process and Package

- 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?

## Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG  
 P.O.Box 10 17 64  
 69007 Heidelberg, Germany  
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 www.concept-heidelberg.de

### For questions regarding content please contact:

Dr. Andreas Mangel (Operations Director) at  
 +49(0)62 21/84 44 41, or at  
 mangel@concept-heidelberg.de.

### For questions regarding reservation, hotel, organisation etc. please contact:

Ms Marion Grimm (Organisation Manager) at  
 +49(0)62 21/84 44 18, or at  
 grimm@concept-heidelberg.de.

## Social Event

On 13 May, 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 (SIG) for “Small Systems”.



Maurice Kerens  
 Rescop BV, Netherlands

Maurice is CTO of Rescop BV. He is working in IT for over 30 years and built up an extensive knowledge and experience in the areas of business information management, Enterprise Architecture, supply chain management and IT compliancy.



Yves Samson, Kereon AG  
 Basel, Switzerland

Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group „IT Infrastructure Compliance and Control“.



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.



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

Reservation Form (Please complete in full)

- Computer Validation: Leveraging Suppliers, 12 May 2020, Barcelona, Spain
- Computer Systems Validation Master Class, 13 - 15 May 2020, Barcelona, Spain

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

Country

ZIP Code

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg  
GERMANY

**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.
  2. If you have to cancel entirely we must charge the following processing fees:
    - Cancellation until 2 weeks prior to the conference 10 %
    - Cancellation until 1 week prior to the conference 50 %
    - Cancellation within 1 week prior to the conference 100 %
- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at [http://www.gmp-compliance.org/eca\\_privacy.html](http://www.gmp-compliance.org/eca_privacy.html)). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

## Date

Computer Validation: Leveraging Suppliers  
Tuesday, 12 May 2020, 09.00 h – 18.00 h  
(Registration and coffee 08.30 h - 09.00 h)

Computer Systems Validation Master Class  
Wednesday, 13 May 2020, 09.00 h – 17.30 h  
(Registration and coffee 08.30 h - 09.00 h)  
Thursday, 14 May 2020, 08.30 h – 17.30 h  
Friday, 15 May 2020, 08.30 h – 13.00 h

## Venue

Barceló Sants Hotel  
Plaça dels Països Catalans, s/n  
08014 Barcelona, Spain  
Phone +34 (93) 503 53 00  
Email [sants@barcelo.com](mailto:sants@barcelo.com)

## 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 money and book both courses:

ECA Members € 2,390

APIC Members € 2,490

Non-ECA Members € 2,590

EU GMP Inspectorates € 1,440

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 HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. 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](http://www.gmp-compliance.org).

## Conference language

The official conference language will be English.