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: Maintaining Control of Operation
7-9 October 2015, Prague, Czech Republic

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

City

Zip Code

Country

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 %,
- 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)! (As of January 2012)

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). 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

Wednesday, 7 October 2015, 09.00 h – 17.30 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 8 October 2015, 08.30 h – 17.30 h
Friday, 9 October 2015, 08.30 h – 12.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 261 191 111
Fax +420 261 225 011

Fees (per delegate plus VAT)

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, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG
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For questions regarding content:
Dr Andreas Mangel (Operations Director) at +49 (0)62 21 / 84 44 41, or per e-mail at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at +49 (0)62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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 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.

Social Event

On 7 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.

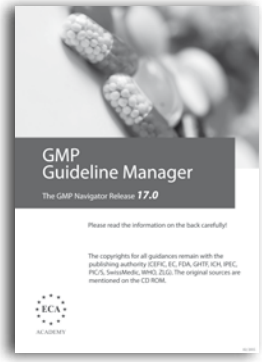
What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?



During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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.

Including new requirements on **Data Integrity**

Computer Validation: Maintaining Control of Operation

Keep your regulated systems and data in compliance throughout their operational life!

7-9 October 2015, Prague, Czech Republic

SPEAKERS:

Frank Behnisch
CSL Behring GmbH, Germany

Dr David Selby
Selby Hope International, UK

Dr Robert Stephenson
Rob Stephenson Consultancy, UK

HIGHLIGHTS:

- Requirements from the EU GMP Guide Annex 11
- The GAMP 5 Risk-Based Approach to Operation of GxP Computerized Systems
- Computer Systems in Use: Where are the Risks?
- Handover and Establishing Support Services
- Keeping the System Running Smoothly
- CAPA Management
- Record and Document Management
- Periodic Review
- Change Control and Configuration Management
- Business Continuity Planning
- System / Data Migration / Back-up / Restore
- Archiving and Retrieval
- Decommissioning / Retirement / Disposal

ECA 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: Maintaining Control of Operation

7-9 October 2015, Prague, Czech Republic

Learning Goals

Four good reasons why you should attend:

- Delegates will gain understanding of the controls needed to maintain validated systems in compliance throughout their operational lifecycle.
- Taking a risk-based approach, you will learn how these controls can be scaled across a wide range of computerised systems, allowing you to focus your resources on the most critical systems and the most critical parts of systems.
- You will learn the importance of role clarity and making best use of Subject Matter Experts and the Quality Unit.
- In workshops, you will get the chance to put the theory into practice and to discuss suitable solution strategies with your colleagues.

Background

The greatest part of the system life cycle is represented by daily operation. It is now a clear regulatory requirement that GxP computerised systems must be kept in compliance throughout their operational lifetime. Audit experience shows that companies struggle with this task. Once the implementation project is complete and the computerised system is handed over for use how can the validated state be maintained? What exactly is required and how can these requirements be successfully established and maintained?

The course reflects the requirements of the new EU Annex 11 and the approaches contained in the ISPE/GAMP Good Practice Guide 'A Risk-Based Approach to Operation of GxP Computerized Systems – A Companion Volume to GAMP®5'.

Experts from the GAMP® Committee will give you the answers to these questions and give you the opportunity to deepen your understanding by participating in a set of training workshops based on practical real-life examples.

Target Group

This Education Course is directed at anyone who has to deal with the validation and operation of computerised systems and the maintenance of the validated state. Typically delegates come from:

- Manufacturing and Production
- Quality Control /Quality Assurance /IT Compliance
- Engineering /Automation/IT
- Software Suppliers and IT Service Providers

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

Programme

Introduction – Understanding Delegate Experience and Background

Workshop 1: What Delegates want to know?

- 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.

Overview of the Operation Phase

- Regulatory Context and links with Annex 11
- Business process approach, Operational Activities and Information Flows
- Roles and Responsibilities, the RACI Model
- Periodic Assessment, checks and triggers
- Scalability and Risk Management
- Other Support Processes

How well do you maintain the Validated State?

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

Computer Systems in Use: Where are the Risks?

- What are the inspectors concerns?
- Where does the inspector believe the risks lie?
- What will his experience tell him to ask questions about?
- How will he assess the seriousness of any failings?

Workshop 2: Patient Risk in Maintaining Control over your Computer Systems

- Identify the patient risks in selected activities from computer system in use
- Identify the controls or checks to be made
- Suggest ways of implementing the checks and controls

Working in groups, delegates will be asked to discuss and answer specific questions related to the above and feed back their answers to the other delegates.

New requirements on Data Integrity

- What are the EU and FDA regulatory expectations?
- What are the consequences of data integrity failures – FDA Warning letters etc.
- What are the criteria for achieving consistent data integrity – ALCOA+
- What are the implications for systems in operation?
- How should Audits Trails be managed and reviewed?

Handover and Establishing Support Services

- Why does Handover go wrong?
- Roles and Responsibilities
- Handover Planning
- Handover Review and Reporting
- Putting Support Services in Place

Workshop 3: Establishing Responsibilities

- What tasks are required?
- What roles are involved?
- What are their responsibilities?

GAMP and RACI roles are applied to one of the Operational Support Processes

Keeping the System Running Smoothly 1 – Service Management and Performance Monitoring

- What Support services are required?
- How will Service Delivery be controlled?
- Defining Quality Requirements
- Performance Monitoring
- Periodic Review considerations
- Taking a risk-based approach

Keeping the System Running Smoothly 2 – Incident Management, CAPA and System Administration

- Dealing with unexpected events
- Capturing and Tracking Preventative Actions and Corrective Actions
- Preventing Failures and Driving Continuous Improvement
- Taking a risk-based approach

Workshop 4: Record and Document Management - Audit of System Documentation

- What procedures would you expect to see to confirm a system is under control?
- Which procedures must QA sign?
- What records would you expect to see to confirm a system is under control?
- What standards would you reference to support your arguments?

Delegates prepare to audit systems documentation, making an 'aide memoire' of documentation to check.

Workshop 5: Establishing a simple Service Level Agreement

- What are the customer requirements?
- What is the supplier specification?
- How is performance to be measured?

Delegates are given the opportunity to develop a simple Service Level Agreement for a specific Operational Control task

Security and Training

- The role of the System Administrator
- Security
- Training for everyone!
- Training records

Operational Change Control and Configuration Management

- Roles and Responsibilities
- Sources of changes
- Types of changes
- Scaling Change and Configuration Management based on Risk

Periodic Review and Assessment

- What is a periodic review?
- Which systems are most important?
- How do I decide?
- How do you perform a periodic review?

Workshop 6: Prioritisation for Periodic Review

- What are the important factors to consider?
- How can they be effectively assessed?
- How can this information be used to determine overall review priorities?

Typically resources for performing periodic reviews are finite; therefore regulated companies must prioritise their activities in order to focus on critical business and compliance issues. Using a Risk Ranking approach delegates will consider how to perform and report this task for a diverse range of regulated systems.

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

Workshop 7: 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

Change Management for IT Infrastructure

- Process flow diagram for change management
- How can this be modified for simple infrastructure changes?
- What is the involvement of QA in each of these processes?

Business Continuity Planning and Disaster Recovery – how are these processes integrated?

- How to develop a Business Continuity Plan and Disaster Recovery Plan for critical systems
- Taking a risk-based approach to disaster recovery testing

Workshop 8: Business Continuity Planning

- In a pharmaceutical manufacturing company what systems typically need 24/7 up-time
- Which of these systems has a regulatory requirement for 24/7 up-time?
- What are the key elements of a business continuity plan for IT?
- Whose responsibility is it to product the plan?
- How would you test it?

Decommissioning, Retirement and Disposal

- Withdrawal from active service
- Shutting down the system and transfer of data
- Disposal of the system

Decommissioning Case Study

- A Presentation of a real-life case study demonstrating a risk-based approach taken to decommissioning a group of operational systems whilst ensuring that regulatory records were retained for their specified retention periods.

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

Maintain Control in Operation: Regulatory Observations

- Regulatory observations
- understand the regulatory approach
- the way in which observations are written by regulators for maximum impact.