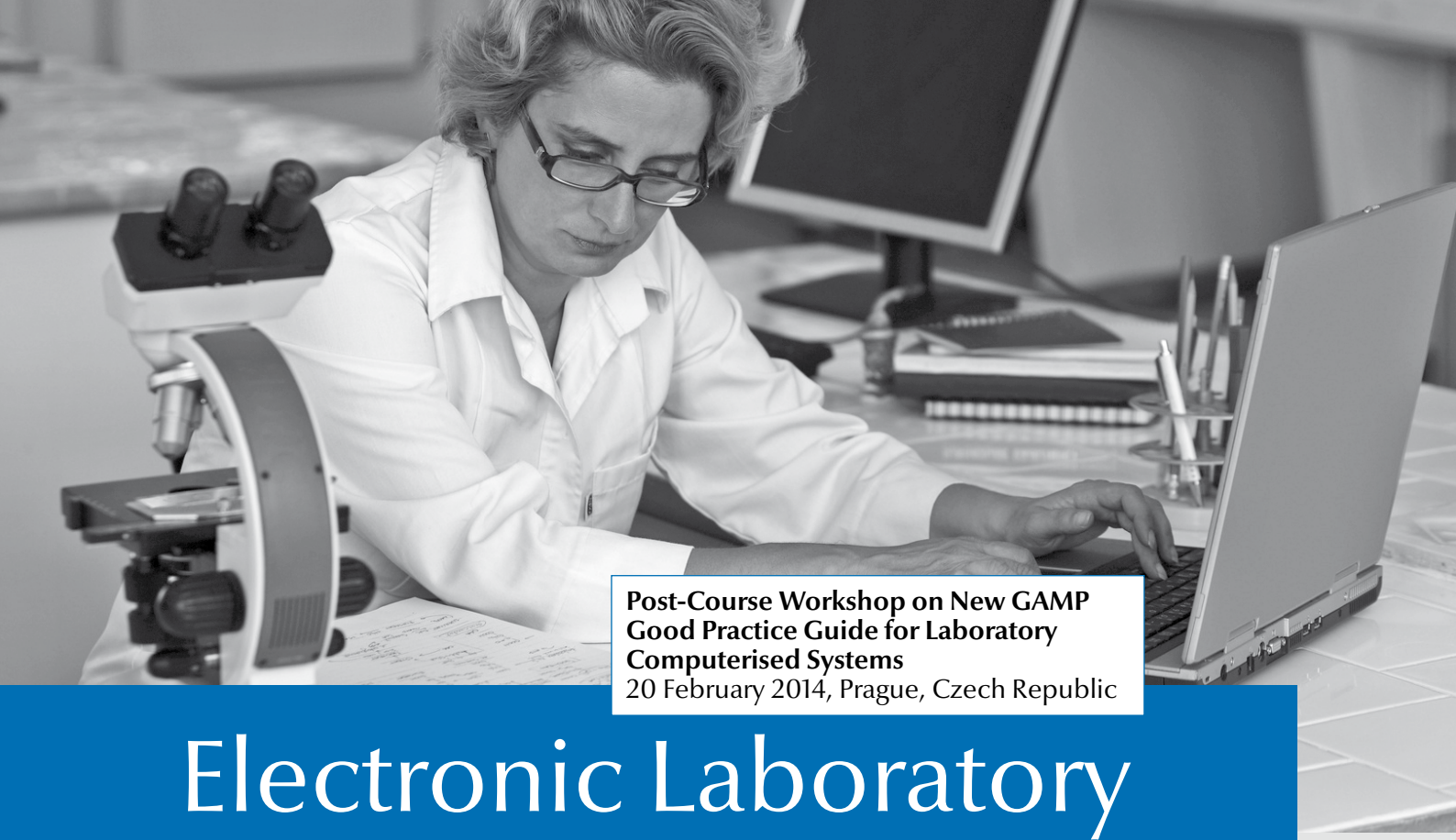


Post-Course Workshop on New GAMP Good Practice Guide for Laboratory Computerised Systems
20 February 2014, Prague, Czech Republic

Electronic Laboratory Notebooks

Implementing and Integrating ELNs in GMP Laboratories – Business Benefits, Data Integrity and Compliance

18 – 19 February 2014 Prague, Czech Republic

SPEAKERS:

Dr Markus Dathe
F. Hoffmann-La Roche, Switzerland

Dr Bob McDowall
McDowall Consulting

LEARNING OBJECTIVES:

- Strategic Plan of How Electronic Laboratory Notebooks (ELN) Interact Inside and Outside the Laboratory
- How to Specify, Select and Implement an ELN
- ELN in R&D versus ELN in QC
- Involving Users in an ELN Project
- Handling Convergence of Functions Between Instrument Data Systems, ELN, SDMA and LIMS
- Integrating an ELN with other Informatic Solutions
- ELNs to Improve Quality and Regulatory Compliance with Faster Data Analysis
- Data Integrity and Compliance with EU Annex 11 and 21 CFR Part 11
- ELN Validation – Leaner and Faster?
- ELNs for Knowledge Management

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager". Please find details at www.gmp-certification.eu

Electronic Laboratory Notebooks

18 – 19 February 2014 Prague, Czech Republic

Objectives

The purpose of this ECA course is to provide the attendees with the information to:

- Develop a strategic plan of how informatics applications including an Electronic Laboratory Notebook (ELN) interact inside and outside the laboratory
- Identify the functions that an ELN could automate within their laboratories
- Interfacing the ELN with other informatics applications to develop an electronic laboratory
- How to specify, select, implement and cost-effectively validate an ELN
- Handling convergence of functions between instrument data systems, ELN, SDMS and LIMS
- Involving users in an ELN project

Background

Most automation in a GMP laboratory requires the effective implementation of informatics solutions to generate business benefits and improve both data integrity and regulatory compliance. One such informatics application is an Electronic Laboratory Notebook (ELN). There are many questions that can be posed when considering an ELN e.g.:

- If I already have LIMS and instrument data systems, why do I need an ELN?
- What functions inside and outside a laboratory does an ELN automate?
- Where does an ELN fit in today's GMP laboratory?
- Does the application comply with current regulatory requirements?
- Can QC and R&D use the same system?

This ECA meeting has been designed to answer these and many other questions.

Target Audience

The education course is aimed at the following attendees: Laboratory managers and analytical scientists, Quality Assurance and IT professionals involved in ELN and related laboratory informatics projects.

Social Event

On 18 February 2014, 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

Programme

Electronic Laboratory Notebooks and the Laboratory Informatics Jig saw Puzzle

There are many laboratory informatics applications that could be used in the GMP laboratory to automate processes inside the laboratory and communicate with customers outside of it.

- Understanding the laboratory informatics available
- Main functions of an ELN
- Looking outside the lab – communication with other solutions e.g. SAP
- Cloud computing and lab informatics

It's Not a Technology Problem – It's about the Users

You may have the best technical solution but it will be worthless if the users are not involved with the project and the implementation of the system. This presentation will look at how the potential users can be involved in a project and how to handle issues such as change of working practices.

- Human issues in an ELN and informatics projects
- Ways of involving the users
- Roll-out styles for a project with advantages and disadvantages

Understanding and Improving the Laboratory Process

You cannot implement an ELN or any other informatics application on a manual process as this will not obtain any tangible business benefits. Furthermore you will implement a hybrid solution, which from a records management perspective is the worst possible situation to be in. Therefore the underlying processes need to be designed to work electronically.

- Mapping the current laboratory processes
- Understanding the problems and soliciting improvement ideas
- Designing an electronic process
- Improving quality and regulatory compliance with faster data analysis

Specifying Requirements and Selecting an Electronic Laboratory Notebook

The most important document in any validation is the user requirements specification which has two functions. The first is to define user and system needs so that an objective selection of a suitable ELN can be made rather than be seduced by technology (i.e. investment protection), the second is to validate the system and a second stage URS is required after system selection has been made.

- Defining initial user requirements in a first stage URS
- Selecting the system
- Updating the user requirements in a second stage URS for validation

WORKSHOP 1:
Optimize a Manual Analytical Process

One key to the successful implementation of an ELN is to map and analyse the current manual or hybrid processes in the laboratory and optimise them for electronic working. This workshop will require the attendees to take an existing manual process and redesign it to work electronically.

- What features need to be present to ensure compliance with GMP regulations?
- How will you ensure improved quality and faster data acquisition and analysis?

Convergence of Laboratory Informatics Functions: When is an SDMS an ELN?

As many laboratory informatics solutions can perform similar functions (convergence), how does a laboratory select which function is performed by which application?

- Functions able to be performed by LIMS, ELN, instrument data systems and SDMS
- Options for working
- Identifying advantages and disadvantages of each

WORKSHOP 2:
Integrating an ELN with Other Informatics Solutions

Attendees will be presented with a laboratory scenario where two informatics solutions have already been implemented. Which functions will the ELN automate and how will it be linked to the existing applications?

One Size Fits All? Meeting Analytical Development and Quality Control Needs

One approach to keeping costs contained is to have the corporate ELN where R&D and QC use the same system. Can this be done and is it wise?

- QbD and Flexibility is the requirement of R&D
- Constraint and control are the requirements of QC
- Which department wins?

Leaner and Faster Validation of ELNs

Validation is always said to make an ELN project longer but is this true or are your organisation's validation processes not risk based and lean?

- Which life cycle model to use?
- Leveraging the suppliers development work
- Effective risk assessment
- Focussed user acceptance testing

WORKSHOP 3: Validating an ELN

To reinforce the lean risk based validation presentation, attendees working in teams will be presented with a scenario and asked to outline the validation approach to be taken. Solutions generated will be discussed with the teaching team and the rest of the course.

Ensuring Quality, Data Integrity and Compliance with Annex 11 and Part 11

What are the drivers for ELN validation and what do the regulations require when automating a process? The presentation will look at the 21 CFR 11 and EU GMP Annex 11 technical controls required to ensure quality and data integrity of the process and hence to be compliant with the regulations.

- Data inputs and verification of critical data entry
- Data integrity
- Data transfer between systems
- Audit trail requirements
- Do I need an electronic signature or will identification of user action be adequate?

WORKSHOP 4:
Implementing Controls for Data Integrity

Based on the improved process from workshop 1 and the information from the previous presentation, teams will discuss and identify the technical controls required to ensure the compliance with the regulations.

The Electronic Laboratory – Trending and Knowledge Management

As the laboratory becomes more automated more data will be captured and managed electronically. A new requirement of GMP following ICH Q10 is the trending of data and proactive identification of potential issues as well as information and knowledge management.

- Regulatory requirements for data trending
- Identifying what data to trend and how to trend it
- Use in identifying problems and issues e.g. out of expectation and out of trend
- Abstracting information from data and knowledge management e.g. laboratory and resource management.

Speakers

Dr MARKUS DATHE,
F. Hoffmann-La Roche, Basel, Switzerland
Analytical and Process Chemist, more than 20 years of practical experience in laboratory, quality and informatics functions. Markus held several positions in life science and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP and CSV coordinator in the chemical development and supply of Hoffmann-La Roche in Basel since 2011. He has been successfully leading global projects like CDS, LIMS, QMS.

Dr BOB MCDOWALL,
McDowall Consulting, Bromley, Kent, UK
Analytical chemist with over 40 years experience including 20 years working in the pharmaceutical industry and 18 years working for the industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 20 years and is the author of a book on the validation of chromatography data systems. Bob is also the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

Implementing the New GAMP Good Practice Guide for Laboratory Computerised Systems

20 February 2014, Prague, Czech Republic

On 20 February 2014, i.e. on Thursday of the same week, there will be the Post-Course Workshop on Validation of Laboratory Computerised Systems – Implementing the New GAMP Good Practice Guide for Laboratory Computerised Systems in Prague.

Objectives and Background:

The second edition of the GAMP Good Practice Guide entitled A Risk-Based Approach to GXP Compliant Laboratory Computerised Systems had been published. This replaces the Good Practice Guide on Validation of Laboratory Computerised Systems published in 2005. There are major differences between this and the first edition of the guide.

The purpose of this one day ECA course is to provide the attendees with the information to:

- Understand the differences between the second edition and the first edition of the Good Practice Guide and identify the advantages that the second edition offers.
- Map and understand the approaches to harmonise USP <1058> on Analytical Instrument Qualification updates and the new Lab Guide but also to identify and manage the differences between the two documents.
- Apply an effective risk based approach to the validation of laboratory computerised systems.

This ECA course has been designed to help you implement the new GAMP Good Practice Guide for risk-based validation of laboratory computerised systems.

Programme

Overview of the 2nd Edition of the GAMP Good Practice Guide for Laboratory Computerised Systems

- Structure of the 2nd Edition: main chapters and appendices
- Highlights of the new edition
- Differences between the 2nd and 1st editions of the guide
- Advantages of the 2nd over the 1st edition

Approaches to Harmonisation between USP <1058> and the Laboratory Guide

- Background to the revision of the GAMP Good Practice Guide and USP <1058> for Analytical Instrument Qualification (AIQ)
- Update of the Good Practice Guide
- USP <1058> Stimulus to the Revision Process – January 2012
- Status of the update to USP <1058>
- Mapping the GPG to <1058>: similarities and differences

Scaleable Approach to Validation: from Simple to Complex Systems

- Definition of simple, medium and complex systems
- Definition of intended use is important
- Qualification of a simple system
- Validation of a medium system
- Validation of a complex system
- Impact of interfacing on the approach taken to validation

Defining Electronic Records and Raw Data – Facilitated Discussion

Using the information from the presentation, attendees will define the electronic records / raw data for two systems used in a GMP laboratory.

Data Integrity and Security Issues for Laboratory Systems

- Problems with data integrity: warning letter citations
- Technical controls for laboratory computerised systems for ensuring data integrity
- Ways of ensuring the security of lab systems
- Facilitated Discussion: Applying technical controls to specific examples in the regulated laboratory

Leveraging Supplier Information and Documentation

- How can we use supplier information to reduce the amount of validation we do?
- Role of the supplier audit
- Evaluating supplier IQ and OQ documentation: is it right for you?
- Leveraging the supplier's internal testing in your validation

Target Group

Laboratory managers and analytical scientists, Quality Assurance and IT professionals involved in validation and support of laboratory computerised systems.

Moderator

Dr Bob McDowall, McDowall Consulting, UK

Participants who register simultaneously for both courses will receive a **350€ discount** (not valid for EU GMP Inspectorates).

Conference Language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany,
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 84
info@concept-heidelberg.de,
www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director)
at ++49-62 21 / 84 44 40 or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager)
at ++49-62 21 / 84 44 51 or per e-mail at
strohwald@concept-heidelberg.de.

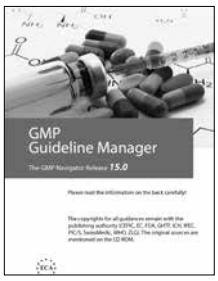
What are The ECA Foundation and the ECA Academy?

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.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "Certified Quality Control Manager". 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-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.

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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Electronic Laboratory Notebooks,** 18 - 19 February 2014, Prague, Czech Republic

☐ **Implementing the New GAMP Good Practice Guide for Laboratory Computerised Systems**
20 February 2014, Prague, Czech Republic

☐Mr ☐Ms

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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 %
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Dates

Electronic Laboratory Notebooks
Tuesday, 18 February 2014, 09.00 - 18.15 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 19 February 2014, 08.30 - 16.00 h

Implementing the New GAMP Good Practice Guide for Laboratory Computerised Systems
Thursday, 20 February 2014, 08.30 - 16.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
10069 Prague, Czech Republic
Phone: + 420 261 191 111
Fax: + 420 261 225 011

Fees

Electronic Laboratory Notebooks
ECA Members € 1,490.-*
APIC Members € 1,590.-*
EU GMP Inspectorates € 845.-*
Non-ECA Members € 1,690.-*
The course 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.

Implementing the New GAMP Good Practice Guide for Laboratory Computerised Systems
ECA Members € 790.-*
APIC Members € 845.-*
EU GMP Inspectorates € 445.-*
Non-ECA Members € 890.-*
The course fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

*per delgate plus VAT

Do you want to save money?
If you register for both ECA Education Courses at the same time, you will receive a 350 € discount. This is not valid for EU GMP Inspectorates.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.