6th European GMP Conference

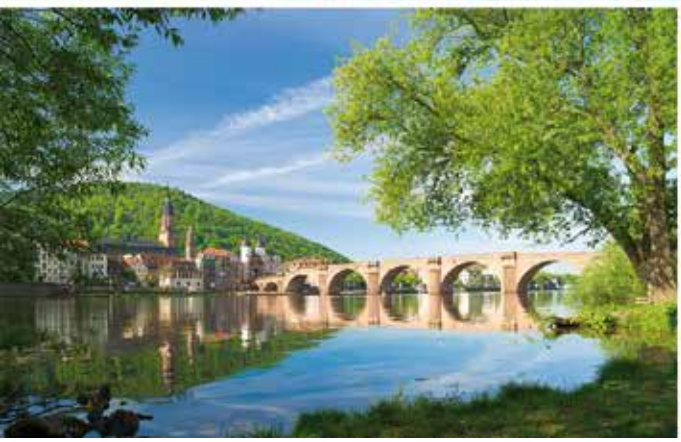
The biennial No. 1 Event in Europe

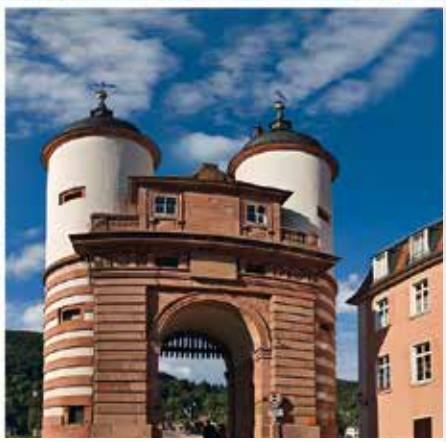
Heidelberg, Germany
9 - 10 June 2015

- Current initiatives in EU and FDA
- Trending of GMP Data
- Building a bridge from GMP to GDP
- The new EU and FDA Validation Requirements
- Interest Group Meetings – Get involved in the next steps

Pre-Conference Workshop on 8 June 2015: „How to establish Quality Metrics“

Special bonus for each participant: Receive the new ECA GMP Matrix plus three additional ECA Guidance documents (see programme for more details)





Speakers and Moderators

RICHARD BONNER
Qualified Person and Chairman ECA, UK

DR CHRISTOPHER BURGESS
Qualified Person and Chairman of ECA's Quality Control Working Group

KLAUS EICHMÜLLER
GMP Inspectorate, Germany

DR AFSHIN HOSSEINY
Qualified Person and Chairman of ECA's GDP Interest Group

DR AJAZ HUSSAIN
Insight, Advice & Solutions, LLC. Former FDA Deputy Director

DR JEAN-DENIS MALLET
NNE Pharmaplan, France and ECA Advisory Board Member

GERT MOELGAARD
NNE Pharmaplan and Co-Chair of ECA's Working Group on Validation

DR BERND RENGER
Qualified Person and Immediate Past Chair of the EQPA

DR FRANZ SCHÖNFELD
GMP Inspectorate, Germany

DR WOLFGANG SCHUMACHER
F. Hoffmann-La Roche Ltd., Switzerland, and ECA Board Member

LANCE SMALLSHAW
UCB Biopharma sprl, Belgium, and ECA Board Member

DR INGOLF STÜCKRATH
sanofi-aventis, Germany

Pre-Conference Workshop: How to establish Quality Metrics

8 June 2015, Heidelberg, Germany

This pre-conference session is designed to discuss the implementation of Quality Metrics in the manufacture of medicinal products and APIs. In the centre will be challenges and possible solutions to identify, measure and report meaningful Quality Metrics. For that purpose the ECA Foundation and its interest group, the European Qualified Person Association, have invited stakeholders from industry and authorities.

Speakers from EMA, FDA, MHRA, ECA Foundation, European QP Association and Industry.

Programme

The EMA view on Quality Metrics
- What are the potential benefits of Quality Metrics
- Risk-based Inspections: The role of Quality Metrics and other risk factors
- Drug Shortages and Quality Metrics: Is there a link?

The FDA Quality Metrics Initiative
- What triggered the Initiative
- Potential Quality Metrics from FDA perspective
- How to collect the data
- Advantages for industry

Developing, Establishing and Monitoring of Meaningful Quality Metrics in Quality Control
- What are the challenges and risks associated with Quality Metrics
- Comparison from different data sets
- What is Good Quality Control Practice
- What are meaningful Quality Metrics for Lab activities

How to use Quality Metrics to control the Supply Chain and the Supplier
- How to oversight the Supply Chain?
- Is a complex supply chain always a risk?
- How to control and measure the supplier in the supply chain
- Supply Chain and Supplier Metrics

Inspection based on Compliance Information
- How to anticipate supply chain and compliance risks
- How to improve compliance-related communication with industry
- Implementation a risk-based escalation process regarding inspection results

Quality Metrics and Management Review
- Quality Culture as the basis for quality improvements
- How to involve the management in Quality Metrics
- Set up of a practical review system
- Follow up actions on management reviews

Case Study: Quality Metrics
- Industry Quality Metrics – typical data sets and reports
- How to measure Quality Metrics in daily practice
- Lessons learned from implementation
- Comparison of Quality Metrics – potential risks and challenges

6th European GMP Conference

Objectives
The EU GMP Conference is only offered every two years. This unique conference will discuss current and planned changes to the GMP regulation. All experts and managers involved in GMP compliance activities will have the opportunity to get a comprehensive GMP update and to talk to the leading experts from industry and authority

Although EU GMP is in the center of attention, a harmonized approach with cGMP from FDA will also be an important aspect of the agenda. For international operating companies both EU GMP and FDA compliance is important and the corporate quality systems need to cover the regulation of both regions.

The agenda will therefore focus on key GMP compliance developments. Attention will be paid on the implementation of these requirements into pharmaceutical quality systems. The ECA Foundation's objective is to support industry, and therefore current activities as well as guidance documents and SOPs are presented during this conference.

Each Session will have speakers from industry and inspectorates to discuss both expectations and implementation aspects.

We wish you a successful and interesting conference.

Yours sincerely,

Richard M. Bonner
Chairman of the ECA Advisory Board

Target Group
The conference is of particular interest for GMP experts of pharmaceutical companies (e.g. QA, QC, production, distribution, regulatory affairs), of GMP inspectorates and Regulatory Authorities.

Each participant will receive a set of documents developed by ECA working and interest groups such as:
- Latest version of the GMP Matrix (comparison of EU GMP, FDA cGMP and ISO 9001)
- OOS SOP developed by the Analytical QC Group
- Validation Good Practice Guide developed by the Validation Group
- Current chapters of the GDP interpretation developed by the GDP Group in cooperation with PQG

Important Information!
The presentations can be downloaded shortly before the conference. You also will receive a USB stick containing all lectures when you register in Heidelberg.

Note: there will be **no print-outs** available during the conference.

WELCOME

Introduction – Update ECA

Richard Bonner, Chairman ECA

Session I Current Initiatives in EU and FDA

Moderator: Richard Bonner

This session will discuss the latest changes and current initiatives in EU GMP and FDA GMP regulation

Update from recent EU GMP changes

- Latest Changes in EU Regulations
- Latest Revisions of the EU GMP Guide and its Annexes
- New EMA Guidelines with impact to GMPs
- Look over the pond - Important GMP developments in the US

Dr Bernd Renger, QP and immediate past chair of the EQPA

FDA´s focus on Data Integrity

- What are the reasons behind the new inspection focal point?
- Data integrity concerns in the US, India and Europe – are there any differences?
- The culture of error – how to avoid data integrity problems

Dr Ajaz HussainInsight, advice and solution, former FDA deputy director

Formalized Risk Assessment for Excipients – a new task for every pharmaceutical company

- What does a QP require of an excipient manufacturer?
- Do excipients pose a risk to GMP? What could go wrong?
- Are there ways to assess and mitigate the risks?
- Is a Technical Agreement and Supplier Audit required?
- What are the acceptable standards to apply to excipient manufacturers?

Dr Jean-Denis Mallet, nne pharmaplan

Session II Trending of GMP Data

Moderator: Lance Smallshaw

Trending of GMP data is under discussion in the pharmaceutical industry and in authorities. What kind of data should be used for trending? What is a trend in a set of data? What are the consequences of a trend? This will be discussed in presentations covering trends in production and analytical data.

Trending from the regulators point of view

- Trending requirements
- Authorities' expectations
- Inspection findings

Dr Franz Schönfeld, GMP inspectorate

Case Study: Trending in production

- SPC as trending tool
- Case Study

Dr Ingolf Stückrath, sanofi-aventis

The new Out of Trend Guidance developed by the ECA Foundation Analytical QC Working Group

- Regulatory need for trending analysis
- Overview of Analytical QC Working Group
- Generation process of this guidance document
- Structure and content
- Current status and next steps

Dr Chris Burgess, QP and chairman of ECA's Quality Control Working Group

Session III Building a Bridge from GMP to GDP

Moderator: Dr Wolfgang Schumacher

The new EU GDP Guide will not only have a huge impact on Logistic Service providers but will also require from pharmaceutical Industry to establish a system to control and monitor the distribution supply chain of its medicinal products.

The enhanced GMP and GDP Inspection activities from the point of view of an EU GMP/GDP Inspector

- Authorities requirements
- What changed with the EU GDP Guideline revision?
- Inspection findings

Dr Franz Schönfeld, GMP inspectorate

New GDP Guidance Documents and their implementation

- Implementation of the EU GDP Guide for medicinal products
- The new GDP Guide for APIs
- Track and Trace – what will come next?

Dr Afshin Hosseiny, QP and chairman of ECA's GDP interest group

The new PQG/ECA Guidance Documents on GDP implementation

- Current status of the documents
- Lessons learned from interpretation
- Next steps

Dr Afshin Hosseiny, QP and chairman of ECA's GDP interest group

Session IV The new EU and FDA Validation Requirements

Moderator: Dr Jean-Denis Mallet

This session will highlight the recent draft Annex 15 to the EU GMP Guide and the relating EMA and FDA Guidance documents.

The new EU GMP Annex 15 from the point of view of an EU GMP inspector

- History of validation guidelines in the EU
- The EU GMP Annex 15 revision
- Links to EMA Process Validation Guideline
- What´s really new?

Klaus Eichmüller, GMP inspectorate

Process validation regulations at a crossroad: What should you do tomorrow?

- Comparing FDA Process Validation Guidance and EU Annex 15
- Equipment qualification: EU and US approaches
- Continued Process Verification challenge and opportunities
- Continuous manufacturing today and in the future

Gert Moelgaard, NNE Pharmaplan and co-chair of ECA's working group on validation

Session V Interest Group Meetings – Get involved in the next steps

Moderators: Dr Afshin Hosseiny, Richard Bonner, Dr Chris Burgess

Get involved in the ECA Working Groups. Each delegate will be invited to discuss the upcoming developments with the Chair/Co-Chairs of the working groups.

Agenda

You can address topics of interest for you and you can provide feedback on the currently planned activities. It is the aim of the Working Group to provide a platform of discussion with both colleagues from industry and regulatory authorities.

Parallel-Sessions:

Working Group GDP	Working Group Validation	Working Group OOT/OOE

Speakers and Moderators

Richard Bonner
Qualified Person, UK
Dick has been working with Eli Lilly and Company, UK, for many years and is currently Chairman of ECA and the European QP Association.

Dr Christopher Burgess
Qualified Person, UK
Chris has been working in the pharmaceutical industry (e.g. Glaxo) for many years and is currently among others Chairman of ECA's Quality Control Interest Group.

Klaus Eichmüller
Regional GMP Inspectorate, Germany
Klaus is working in the field of GMP Inspections of manufacturer of medicinal products and importers since 1996 he. He is Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse.

Dr Afshin Hosseiny
Qualified Person, UK
Afshin looks back to many years with Glaxo Smith Kline in the UK and is Chairman of ECA's GDP Interest Group. Today, he works as Qualified Person and Consultant.

Dr. Ajaz Hussain
Insight, Advice & Solutions, LLC, USA
Ajaz' career at US FDA spanned 10 years; from 2000-2005 he served as the Deputy Director of the Office of Pharmaceutical Science (OPS) in the Center for Drug Evaluation and Research (CDER). Ajaz is now management consultant in the lifescience sector.

Dr Jean-Denis Mallet
NNE Pharmaplan, France
Jean-Denis was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps) and is now working for NNE. He is an ECA Advisory Board Member.

Gert Moelgaard
NNE Pharmaplan,Denmark
Gert is Vice President at NNE Pharmaplan, Denmark and Co-Chair of the ECA Working Group on Validation.

Dr Bernd Renger
Qualified Person, Germany
Bernd worked for many years in the pharmaceutical industry. Immediate Past Chair of the EQPA.

Dr Franz Schönfeld
Regional GMP Inspectorate, Germany
Franz works for the centralised inspectorate for medicinal products of the government of upper Bavaria. He is head of the experts working group 7 for APIs and deputy head of the Radiopharmaceutical expert working group.

Dr Wolfgang Schumacher
F. Hoffmann-La Roche Ltd. , Switzerland
Wolfgang is currently Head of the department of Quality Computer Systems at F. Hoffmann-La Roche and a member of the ECA Advisory Board.

Lance Smallshaw
UCB Biopharma sprl, Belgium
Lance is Global Director of Analytical Strategy for NBEs at UCB in Belgium and Member of ECA's Advisory Board.

Dr Ingolf Stückrath
sanofi-aventis, Frankfurt, Germany
Ingolf is Six Sigma Black Belt at sanofi-aventis. Today, he is responsible for a major insulin production facility in Frankfurt.

Social Event at the Heidelberg Castle

On 09 June, participants and speakers are cordially invited to a social event at the Heidelberg Castle. We will have a guided tour of the Castle followed by a dinner at the Castle Restaurant. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Heidelberg – Optimal Accessibility via Frankfurt

Airport Shuttle Service PCS
http://www.pcs-hd.de/
Phone: +49 (0)6221 – 16 46 64, pcs@pcs-hd.de

TLS Airport Shuttle Service Heidelberg
www.tls-heidelberg.de
Phone +49 (0)6221 77 00 77, info@tls-heidelberg.de

Lufthansa Bus Airport Shuttle
http://www.transcontinental-group.com/en/frankfurt-airport-shuttles
Tel. +49 (0)6152 – 97 69 099,
info@frankfurt-airport-shuttles.de

Train
You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. www.bahn.de

For your return transfer to the Frankfurt Airport, ECA will provide a **free of charge shuttle service**. The bus will leave the Marriott Hotel to the Airport on **10 June at 14:00 h**.

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-conference.org

6th European GMP Conference

Date
Tuesday, 9 June 2015, 9.00 – appr. 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 10 June 2015, 9.00 – appr. 13.00 h

Venue
Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49 (0)6221 908-00
Fax +49 (0)6221 908-660

Fees
ECA/EQPA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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.

Pre-Conference Workshop

Date
Monday 8 June 2015, 9.00h – 17.00h
(Registration and coffee 08.30h – 09.00h)

Venue
Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49 (0)6221 908-00
Fax +49 (0)6221 908-660

Fee
Regular Fee € 890
Special rate for participants of the 6th European GMP Conference: € 690

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

Conference Language
The official conference language will be English.

Registration
You can either register via the attached reservation form, by E-Mail or by fax, or you can register online at www.gmp-conference.org. Your registration will be confirmed by E-Mail.

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
Phone +49 (0) 62 21/84 44-0
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info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Sven Pommeranz (Operations Director) at +49-62 21 / 84 44 47, or per e-mail at pommeranz@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at +49-62 21 / 84 44 22 or per e-mail at bach@concept-heidelberg.de.

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

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

☐ **6th European GMP Conference,** 9-10 June 2015, Heidelberg, Germany +49 6221 84 44 34
I want to take part in the following **Working Group Session** (please tick only one)
☐ GDP
☐ Validation
☐ OOS

☐ Pre-Conference Workshop "How to establish Quality Metrics" on 8 June 2015

☐ **6th European GMP Conference,** 9-10 June 2015, Heidelberg, Germany
AND Pre-Conference Workshop "How to establish Quality Metrics" on 8 June 2015
I want to take part in the following **Working Group Session** (please tick only one)
☐ GDP
☐ Validation
☐ OOS

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

Street / P.O. Box

City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

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 %.

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 HEIDELBERGwill 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).

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.

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