The biennial No. 1 Event in Europe

Speakers/Moderators

RICHARD BONNER
Chairman ECA, UK

DR CHRISTOPHER BURGESS
Chairman of ECA's Working Group on Quality Control

KLAUS EICHMÜLLER
District Government of Upper Bavaria Munich, GMP Inspectorate, Germany

DR MATTHIAS HEUERMANN
European GMP Inspector, Germany

IAN HOLLOWAY
Head of the Defective Medicines Report Centre at MHRA, UK

DR AFSHIN HOSSEINY
Chairman of ECA's GDP Interest Group

DR JEAN-DENIS MALLET
SNC Lavalin and ECA Advisory Board Member

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

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

DR RENATE SCHENK-GRÖNINGER
Boehringer Ingelheim Pharma, Germany and Co-Chair of ECA's Working Group on Validation

DR THOMAS SCHNEPPE
Bayer Pharma, Germany and Co-chair of ECA's Working Group on Validation

Supporting Organisations

QP Association

ECA
European Compliance Academy

5th European GMP Conference

50th Anniversary of GMP

Heidelberg, Germany
6-7 June 2013

Three GMP Sessions "Industry meets Authorities"

- The Good Distribution Practice Guideline
- Version 2 of ECA's SOP on OOS
- New ECA Good Practice Guide on Validation

Additional Documents for all participants:

- New Good Practice Validation Guide
- New Version 2: ECA SOP on OOS
- ECA's GMP Matrix (US GMP vs.EU GMP)

5th European GMP Conference

Objectives

Dear Colleagues,

In 2013, GMP will celebrate its 50th anniversary. The first GMP rule was published in 1963 by the FDA to protect the health of drugs' consumers. Since then, the development of the GMPs has been tremendous. GMP is the accepted worldwide "gold standard" for the manufacturing and control of medicinal products.

For APIs, a global harmonised GMP guideline is available (ICH Q7).However, for medicinal products, Europe, USA, Japan and the rest of the world continue to use different guidelines as the basis for GMP inspections.

To harmonise the interpretation of GMP worldwide, the ECA has set up Working Groups amongst others about Good Distribution Practice, Process Validation and Quality Control. Additionally the ECA runs a website to promote the harmonization of GMPs for Medicinal Products.

The ECA is dedicating the fifth biennial European GMP Conference to recognise the 50th anniversary of the first published GMP regulations and further the work towards a harmonized set of GMP regulations for medicinal Products.

In addition to Key Notes about 50 years of GMP, the conference will include parallel sessions for interest group meetings that will allow concrete discussions about how we could promote a harmonization set of GMP regulations.

We wish you a successful and interesting conference.

Richard M. Bonner
Chairman of the ECA Advisory Board

5th European GMP Conference

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.

About the 1st European GMP Conference

In the US, Asia and Europe, GMP Conferences have established themselves as meeting places for the pharmaceutical industry. Therefore, the University of Heidelberg and ECA organised the first biennial European GMP Conference in June 2005, focusing on harmonisation, ICH Q8 and ICH Q9.

About the 2nd European GMP Conference

The international GMP harmonisation was covered in detail at the 2nd European GMP Conference in 2007.

About the 3rd European GMP Conference

GMP initiatives to meet globalisation was covered in detail at the 3rd European GMP Conference in 2009. Therefore, sessions with the slogan "authority meets industry" were hold.

About the 4th European GMP Conference

The forth biennial European GMP Conference was focussed on GMP harmonisation. Five parallel sessions under the motto „Authority meets Industry - Industry meets Authority" contributed to the concrete discussion and showed solution approaches.

High level speakers included:
Grace McNally, FDA, USA
Dr Janice Soreth, FDA, USA
Grace Yi-Ni Ye, SFDA, China
Ian Thrussel MHRA,
Lionel Viornéry, AFSSAPS, France
Julie Maréchal-Jamil, EGA, Belgium

WELCOME

Activities of the ECA Foundation to support Harmonisation and Compliance

Richard Bonner, chairman eca

Part I Key Note
50 years GMP - Harmonisation of the GMPs

Since the first GMP guide has been developed 50 years ago the GMP requirements have been developed further and further.

However, compared with GMP for APIs the manufacture and control of Medicinal Products is not globally harmonised. There are three different regulations in the ICH Region 21 CFR 210/211 in the USA, the EU GMP Guide in Europe and tekisei seizo kihan in Japan.

- Which requirements need to be updated?
- Which requirements are interpreted differently by inspectors?

To support the harmonisation process the ECA has established an internet new platform. The current status of this project and the proposed changes to the GMP requirements will be discussed in this key note

- The current GMP Guidelines in place
- Structure of E-Workshop: Harmonisation of GMP
- Results
- Next steps

NEW:
ECA's revised GMP Matrix (US GMP vs. EU GMP)

Dr Jean-Denis Mallet, SNC Lavalin and ECA Advisory Board Member

Part II Sessions
Industry meets Authorities

SESSION 1
GOOD DISTRIBUTION PRACTICE
Moderator:
Dr Afshin Hosseiny

3 Sessions

For the following 3 sessions, the organiser invited the major stakeholders from authorities and industry. It is the objective of the sessions to discuss current developments in order to identify strategies to meet the new challenges.

This session will discuss the consequences of the new EU GDP Guideline. GDP will be closely linked to the GMP environment. Wholesalers, Distributors, Agents, Transportation and Distribution Service Providers deal with the Medicinal Products. How to track the shipment? How to guarantee the quality? What level of supervision is necessary and what can be outsourced? A number of questions need to be answered. The ECA Working Group is currently developing a Good Practice Guide with the PQG Group

Agenda

The new EU GDP Guideline and its impact on the Pharmaceutical Industry

- Content of the EU GDP Guideline
- What are the challenges for the industry in implementing the new requirements?
- How best to proceed and become compliant?

Dr Afshin Hosseiny, chairman of eca's GDP interest group

Regulatory GDP Inspection

- GDP Inspections
- Frequent findings
- Expectations regarding the Responsible Person

NEW:
GDP Good Practice Guide

Ian Holloway, Head of the Defective Medicines Report Centre at MHRA, UK

SESSION 2
THE ROLE OF THE QUALITY UNIT IN OOS HANDLING: ECA´S NEW OOS SOP VERSION 2

Moderator:
Dr Christopher Burgess

FDA's final Guidance for Industry titled "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production" was already published in 2006. However, the incorrect handling and investigation of OOS results is still a continuing source of 483 citations and Warning Letters since 2006. And the investigation of OOS results is still a hot topic in FDA inspections. With the support of 100 ECA Members a Working Group developed a harmonised SOP on OOS handling. This first version was launched in June 2012 at the international OOS Forum. Based on the feedback received from industry and authorities the Working Group developed a version 2. Two new SOPs on OOS/OOE and OOS in Microbiology are currently under development.

Agenda

OOS Findings in recent FDA Warning Letters
- Why is OOS still a problem
- Frequent 483 citations and Warning Letters
- Frequent misconceptions

Dr Bernd Renger, qualified person, immediate past chair of the european qualified person association

ECA's SOP on Out of Specification Results (Version 2)
- Key elements and process flow of version 1
- Changes to SOP version 2
- Alternative Approaches discussed with ECA's OOS Review team
- The role of the Quality Unit in OOS handling

Dr Christopher Burgess, chairman of eca's working group on quality control

OOS Results – European Requirements and Expectations of a European GMP Inspector
- Definition of in-spec and out-spec Results
- OOS Investigation phases
- Batch disposition
- Surveillance of the release decision
- Comparison ECA OOS SOP and MHRA approach

NEW:
Version 2 of ECA's SOP on Out-of-Specification Results

Dr Matthias Heuermann, european gmp inspector at the center of health, germany

Current status of new ECA activities regarding OOT
- New SOP dealing with Out of Trends and Out of Expectations
- New SOP dealing with OOS in Microbiology

Dr Christopher Burgess, chairman of eca's working group on quality control

SESSION 3
ECA VALIDATION GOOD PRACTICE GUIDE

Moderator:
Richard Bonner

The ECA Working Group has developed a Version 1 of a Good Practice Guide on Validation. This document is intended to provide support to both regulators and industry. On one hand the Guide contains the main elements of the new approach ("what to do") but on the other hand it also serves as supporting guide for the implementation ("how to do").

Agenda

Insight from ECA´s Validation Good Practice Guide (Part 1): Risk-based Qualification
- What does risk-based qualification mean?
- Costs of (unnecessary) qualification
- Are DQ, IQ, OQ, PQ obsolete?
- Case Study

Gert Moelgaard, nne pharmaplan and co-chair of eca's working group on validation

Insight from the new Guide (Part 2): Case Study: Process Validation and Statistical Trending in Biopharmaceutical Manufacturing
- Introduction in Biopharmaceutical Processes
- Process development, reevaluation of commercial processes and definition of parameters
- Parameters and control
- Process Performance Validation Approach
- Trending program and choice of parameters
- Case study

NEW:
ECA Good Practice Guide on Validation

Dr Renate Schenk-Gröninger, boehringer ingelheim and co-chair of eca's working group on validation

SESSION 3
cont'd

Insight from the new Guide (Part 3): "Case Study legacy products"

- Key Messages
- How to align the 3 batch evaluation" and "continuous verification"?
- General Process Flow to implement process capability indices and control charts
- Specifics on identification of Control Charts
- Case study and Implementation Support

Dr Thomas Schneppe, bayer pharma ag and co-chair of eca's working group on validation

Process Validation - view of a European GMP Inspector

- Process Validation in EU and PIC/S guidelines - what is new?
  - Revision of Chapter 1 EU GMP Guide
  - EMA´s Draft Guidance Process Validation
  - Concept Paper revision of Annex 15
- Future developments.

Klaus Eichmüller, District Government of Upper Bavaria Munich, GMP Inspectorate, Germany

Part III Interest Group Meetings
Get involved in the next steps

Moderators:
Dr Afshin Hosseiny
Richard Bonner
Dr Christopher Burgess

Get involved in the ECA Working Groups. Each delegate will be invited to discuss the upcoming developments with the Chair and 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 author

Parallel-Sessions:

Working Group GDP	Working Group Validation	Working Group OOS

Social Event

On 06 June, participants and speakers are invited to a unique evening.

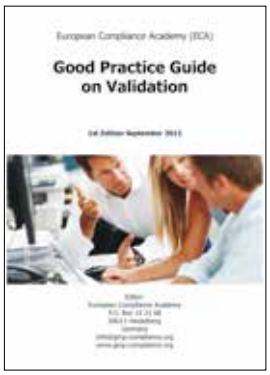
We will visit Heidelberg's picturesque old town and have dinner in a fraternity's fencing hall from the early 1900's.

The Heidelberg Marriott Hotel

Set in a natural environment, the Heidelberg Marriott Hotel is the perfect location for incentives and events due to its central location in Germany and the activities on offer in the city.

Many of the rooms offer ideal views of the Neckar valley and the famous castle.
Go for a swim in the indoor pool or ask for a treatment or a massage at the 'Unique Spa'.

Good Practice Guide on Validation



The European concept to modern process validation is not clear yet. The ECA has therefore set up an Expert working group to develop a Good Practice Guide. This document is intended to provide support to both regulators and industry. On one hand the Guide should contain the main elements of a new approach ("what to do") but on the other hand it should also serve as supporting guide for the implementation ("how to do").

The document contains information and examples on
- Risk-based Approach to Process Validation
- Risk-based Qualification
- Statistics in Process Validation and Continuous Process Verification
- Process Validation and Statistical Trending in Biopharmaceutical Manufacturing
- Special Case: Legacy Processes

Members of the ECA Expert Working Group:
Richard Bonner, ECA Chairman
Dr Jean-Denis Mallet, ECA Board Member
Dr Thomas Schneppe, Bayer Pharma AG
Gert Moelgaard, NNE Pharmaplan
Dr Renate Schenk-Gröninger, Boehringer Ingelheim Pharma GmbH & Co. KG
Sven Pommeranz, Concept Heidelberg GmbH

Special offer with Lufthansa – discounted travel for 5th European GMP Conference attendees

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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; otherwise the booking platform window will not open.

Heidelberg – Optimal Accessibility via Frankfurt

Lufthansa Shuttle Bus: Even if you do not fly, you can take this bus. It leaves Frankfurt Airport approximately once an hour. Contact: www.ics-logistik.de, phone +49 (0)621 - 651620. The TLS Airport Shuttle Service Frankfurt can be booked directly at the Marriott Hotel: Germany's most experienced Airport Shuttle-Service TLS brings you promptly and reliably from the airport to your hotel. You will receive the details when you have registered for the event.
Train: You can get on the train at the Airport Station. A train leaves up to three times per hour and usually takes less than an hour to get to Heidelberg.

About the Supporting Organisations

ECA
European Compliance Academy

The European Compliance Academy (ECA) was founded in 1999. The ECA is an independent organisation chaired by a Scientific Advisory Board with 10 members of the pharmaceutical industry and regulatory authorities. With nearly 4,000 members from 60 countries, ECA has become the leading European association with regard to pharmaceutical Quality Assurance and GMP compliance.

QP Association

The Qualified Person Association was founded in 2006 with the objective to represent qualified Persons in Europe. More than 200 QPs and individuals preparing to become a QP from all over Europe already signed up for membership. The members represent all major pharmaceutical companies as well as small and medium-sized businesses.

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

Date
Thursday, 06 June 2013, 09.00 – approx. 18.00 h
Registration and coffee 08.30 – 09.00 h
Friday, 07 June 2013, 08.30 – approx. 16.00 h

Venue
Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49 (0)6221 908-00
Fax +49 (0)6221 908-698

Conference Fees
ECA and QPA Members EUR 1,590*
APIC Members EUR 1,690*
Non-ECA / Non-QPA Members EUR 1,790*
EU GMP Inspectorates EUR 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.

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.

*per delegate plus VAT. VAT is reclaimable

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.

Conference Language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
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For questions regarding content:
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+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
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Reservation Form (Please complete in full)

5th European GMP Conference - 50th Anniversary of GMP
6-7 June 2013, Heidelberg, Germany

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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.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
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