8th European GMP Conference

The biennial No. 1 Event in Europe

Heidelberg, Germany, 6-7 June 2019

ECA's 20th Anniversary Event

ECA's 20th Anniversary Treat
400,- € Discount for ECA Members

20 YEARS | ECA Academy
Your GMP/GDP Information Source

Speakers and Moderators:

IB ALSTRUP
GxP IT Medicines Inspector,
Danish Medicines Agency DMA

DR CHRISTOPHER BURGESS
Qualified Person and Chairman
ECA Quality Control Group, UK

DR RAINER GNIBL
GMP Inspectorate of Upper Bavaria, Germany

DR AFSHIN HOSSEINY
Qualified Person and Chairman
ECA Foundation, UK

DR ULRICH KISSEL
Director Regulatory Affairs,
ECA Foundation, Germany

GERT MOELGAARD
Chair ECA Validation Group,
Denmark

DR BERND RENGER
Qualified Person and
EQPA Immediate Past Chair,
Germany

MERVI SAUKKOSAARI
Senior Pharmaceutical Inspector,
Head of Section,
Finnish Medicines Agency Fimea

MATTHEW SCHERER
Assistant Health Attache and
International Program and Policy Analyst
FDA Europe Office

DR WOLFGANG SCHUMACHER
Chairman ECA IT Compliance Group, Switzerland

LANCE SMALLSHAW
ECA Executive Board Member,
Belgium

Free of charge NEW ECA Guidance Documents

Each participant will receive a set of documents developed by ECA Working and Interest Groups such as:

- Data Governance and Data Integrity for GMP Regulated Facilities (Version 02)
- Analytical Procedure Lifecycle Management Guideline
- Out of Expectation (OOE and Out of Trend (OOT) Guidance Management Document
- Modern Qualification Guide – A guide to effective qualification based on Customer-Supplier Partnership
- Good Distribution (GDP) Interpretation Guide (ECA/PQG)
- Latest version of the GMP Matrix (comparison of EU GMP, FDA cGMP and ISO 9001)

The ECA Foundation Groups

QP Association | ECA Analytical Quality Control Group | GDP Association | ECA DI & IT Compliance Group | ECA Pharmaceutical Microbiology Group | ECA Validation Group | ECA Visual Inspection Group | ECA ATMP Interest Group

8th European GMP Conference – Industry meets Inspectorates

Dear Colleagues,

The 8th European GMP Conference coincides with the ECA's 20th anniversary. We would therefore like to invite you to join us celebrating this milestone.

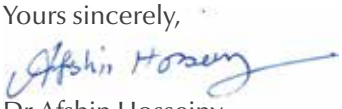
As always at this unique conference we will focus on key GMP compliance developments. Thus, as an expert and manager involved in GMP compliance activities you will get a comprehensive GMP update. You will also have the opportunity to discuss the current and new regulatory expectations and how to implement them in pharmaceutical quality systems with the leading experts from industry and authority.

Further, you will also benefit from the ECA Foundation Interest Groups' guidance documents such as the latest "Modern Qualification Guide" which will be presented, and you will receive free copy at the conference.

Finally, as a delegate you are invited to an evening dinner at the beautiful Heidelberg Castle to celebrate the ECA's 20th anniversary. In addition, ECA members will a receive 400,- € special discount on the registration fee.

We look forward to seeing you in Heidelberg and celebrating ECA's 20th anniversary with you.

Yours sincerely,



Dr Afshin Hosseiny
Chairman of the ECA Advisory Board

Target Group

The conference is of particular interest to GMP experts of pharmaceutical companies (e.g. QA, QC, production, distribution, regulatory affairs), of GMP inspectorates and regulatory authorities.

Programme

WELCOME
Introduction – Update ECA
Dr Afshin Hosseiny, Chairman ECA

Session I – Current Initiatives worldwide

Moderator: lance smallshaw

This session will discuss the latest changes and current initiatives in EU GMP and FDA GMP regulations. In addition, the Mutual Recognition Agreement between the EU and US (FDA) will be discussed.

GMP Update 2019 and Outlook 2020 – current Trends and Developments in Europe, US

- Major GMP developments and their impact for pharmaceutical industry
- The revised EU & PIC/S GMP Annex 1 – implications and experiences
- The new EU GMP Annex 21 on Importation and its implication
- Additional GMP developments from EMA and FDA
- Brexit and its consequences for the European GMPs

Dr Bernd Renger, QP And Immediate Past Chair of the EQPA

The Mutual Reliance Initiative on EU-FDA Inspections: Current Status and next Steps
Matthew Scherer, FDA

Brexit and increasing Drug Shortages: What does this mean for QA in Practice?

- European Pharma Industry post Brexit
- Impact on the product supply across Europe
- GMP compliance – are we compromising quality now that UK is a 3rd country?
- Long term impact on patient safety costs and supply

Dr Afshin Hosseiny, Chairman ECA

Session II – New and revised ECA Good Practice Guides – What QA needs to know and helpful tools

Moderator: dr afshin hosseiny

GMP requirements often lack concrete recommendations for implementation. Therefore ECA´s working and interest groups have been set up to develop so called Good Practice Guides. In this session you will get an update on the content of these Guides. Data Integrity has been the major GMP compliance issue in the past two years. Today, companies need to make sure that all sites, suppliers and contract labs comply with the regulatory requirements. This interactive session will discuss pragmatic approaches how this can be achieved. With the revision of FDA´s Process Validation Guidance and the Annex 15 a process validation life cycle became state of the art. Especially in the FDA guidance qualification and process validation are close together. How can this be achieved? This will be discussed, also referring to ECA´s Good Practice Guide on Modern Qualification. The ICH Q2 (R1) document about Analytical Method Validation will be revised. Why and the direction of the changes will be discussed. And how ECA´s Good Distribution Guide can be used for implementation and inspection will be presented too.

Data Integrity: How to manage Oversight over Suppliers, Service Providers, Contract Manufacturers and mutiple Sites

- Data Integrity implementation – Status of the industry 2019
- ECA Data Integrity Guide version 2.0
- ECA´s new Data Integrity Toolbox
- How to ensure compliance with Data Integrity requirements

Dr Wolfgang Schumacher, Chairman, ECA Data Integrity & It Compliance Group

Integrating Qualification and Validation from a QA Perspective – introduction into ECA´s Modern Qualification Guide

- What does "Modern Qualification" mean?
- ECA´s Modern Qualification Guide – and the link to Modern Process Validation
- Fast track facility projects using a modern qualification approach
- Teaming up with suppliers and other partners
- Subject matter experts and the modern role of QA in the future...?

Gert Moelgaard, Chairman, ECA Validation Group

What QA Needs to Know about Changes to ICH Q2(R1), Analytical Method Validation, and the proposed ICH Q14 on Analytical Procedure Development

- Reasons for the need to revise ICH Q2(R1) – Why the change from Method to Procedure?
- New lifecycle approach to the Validation for Analytical Procedures based on the FDA Process Validation model, 2011
- USP General Chapter <1220>, Analytical Procedure Lifecycle, 2017
- The ECA AQCG Guide to Analytical Procedure Lifecycle Management (APLM), 2018
- The aims & objectives of ICH Q14, Analytical Procedure Development using analytical quality by design methodology (AQbD)

Dr Christopher Burgess, Chairman ECA Analytical Quality Control Group

What QA Needs to Know About Good Distribution Practice Compliance Trends: The ECA/PQG Guide on Good Distribution Practice

- What is state of the art regarding GDP?
- What is the state of play regarding GDP implementation in industry
- Frequent findings during GDP inspections and audit
- The final version of the ECA and PQG Guide on the interpretation of GDP
- How to use the Guide for GDP implementation and GDP inspection

Dr Afshin Hosseiny, Chairman of the ECA Foundation and Head of ECA GDP Association

Session III – GMP Inspectors meet Industry – Urgent Non-Compliance Issues

Moderator: Dr Ulrich Kisssel

Recent FDA Warning Letters and GMP Non-compliance Reports in EMA´s EudraGMDP database show a great number of GMP findings. But what are most frequently observed GMP deviations at EU inspections? In this session you will learn from an inspector about recent inspection experience. An industry speaker will describe how companies with multiple manufacturing sites can prepare for successful GMP inspections.

Inspector's View: Non-compliance-issues – Is it all only about Data Integrity!?

- Which areas are critical to trigger Non-Compliance Statement
- What is critical with these areas?
- Improper Data-Management
- Deficiency examples from GMP inspections

Dr Rainer Gnibl, GMP Inspectorate

Industry view: How to Make Sure That all Sites and Suppliers are in Compliance

- Does industry make best use of the concepts laid down in the GMP rules?
  - The supply chain diagram
  - The Technical (Quality) Agreement
  - The product specification file
  - The QP declaration
  - Auditing by yourself or a third party
  - Product Quality Review

Dr Ulrich Kissel Director Regulatory Affairs, ECA and Chairman, European QP Association

Session IV – Parallel Sessions & Workshops with Inspectors

Moderators:
Dr Afshin Hosseiny/Mervi Saukkosaari
Gert Moelgaard/Dr Rainer Gnibl
Dr Wolfgang Schumacher/Ib Alstrup

Get involved in the ECA Interest and Working Groups. Each delegate will be invited to discuss the upcoming developments with the Chairs of the Groups and an EU Inspector.

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

ECA Validation Group

Option 1: Qualification & Validation: How to save time and money in Qualification & Validation but comply with GMP

This interactive session will offer opportunity for the participants to discuss some of new developments in qualification and validation activities:

- How can qualification and GMP interact?
- Integration of qualification into validation

ECA DI Task Force

Option 2: Data Integrity: How to manage oversight over suppliers, contract manufacturers and multiple sites

Data Integrity has been the major GMP compliance issue in the past two years. Today companies need to make sure that all sites and suppliers comply with the regulatory requirements. This interactive session will discuss how this can be achieved.

ECA GDP Association

Option 3: GDP: How to manage the interface between GMP and GDP

Complex supply chains require that the interface between GMP and GDP work correctly. Manufacturing and distribution of medicinal products need to comply with the regulatory requirements. Learn more about this important interface.

Social Event

On 6th June, participants and speakers are cordially invited to celebrate ECA´s 20th anniversary at the Heidelberg Castle. This is also an excellent opportunity to share your experience with colleagues from other companies in a relaxed atmosphere.

Speakers and Moderators

Ib Alstrup,
GxP IT Medicines Inspector with the Danish Medicines Agency (DMA)
Ib Alstrup is a GxP IT Medicines Inspector with the Danish Medicines Agency. With a background as a software designer and tester, he has specific focus and large experience in inspection of validation and operation of computerised systems throughout the GLP, GCP, GMP, GDP and GVP areas. He is a co-writer of the new PIC/S guide on Data Integrity and holds a B.Sc. in Electronic Engineering.

Dr Christopher Burgess,
Qualified Person, Chairman ECA Quality Control Group, UK
Chris has been working in the pharmaceutical industry for many years and is currently among others Chairman of ECA`s Quality Control Interest Group, member of ECA´s Extended Board and member of ECA´s Task Force on Data Integrity.

Dr Rainer Gnibl,
GMP Inspector, District Government of Upper Bavaria, Germany
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Afshin Hosseiny, Qualified Person, Chairman ECA Foundation, UK
Afshin looks back at many years with Glaxo Smith Kline in the UK and is Chairman of the ECA Foundation as well as Chairman of ECA´s GDP Association.

Dr Ulrich Kissel
Director Regulatory Affairs, ECA Foundation and Chairman, European QP Association
Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). Previous to his current role he held leadership positions in quality and supply chain and served for many years as QP for Roche.

Gert Moelgaard, Chairman ECA Validation Group, Denmark
Gert Moelgaard has more than 25 years of experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. Gert is Chairman of the ECA´s Validation Group and member of ECA´s Extended Board.

Dr Bernd Renger, Qualified Person and Immediate Past Chairman, European QP Association, Germany
Bernd worked for many years in the pharmaceutical industry and is Immediate Past Chairman of the European QP Association (EQPA).

Mervi Saukkosaari, Senior Pharmaceutical Inspector, Head of Section, Finnish Medicines Agency (Fimea)
Mervi Saukkosaari, pharmacist by profession, is currently Senior Pharmaceutical Inspector at FIMEA. She has more than 20 years of experience in the pharmaceutical industry (e.g. Scientist, Group and Project Manager in R &D and Consulting).

Matthew Scherer, FDA
Assistant Health Attache and International Program and Policy Analyst, FDA Office of International Programs – Europe Office.

Dr Wolfgang Schumacher, Chairman ECA Data Integrity & IT Compliance Group, Switzerland
He was Head of the department of Quality Computer Systems at F. Hoffmann-La Roche until July 2017. He is currently Head of ECA´s Data Integrity & IT Compliance Group, member of ECA´s Extended Board and member of ECA´s Task Force on Data Integrity.

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

Special offer with Lufthansa – discounted travel for 8th European GMP Conference 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.

This is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. This link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area. 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 you 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.

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

8th European GMP Conference

Date
Thursday, 6 June 2019, 9.00 – appr. 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 7 June 2019, 9.00 – appr. 13.00 h

Venue
Heidelberg Marriott Hotel
Vangerowstrasse 16
69115 Heidelberg
Phone +49 (0)6221 – 908 0
Fax +49 (0)6221 – 908 660
Mail: info.heidelberg@marriott.com

Fees
ECA Members receive a 400,- € anniversary discount.
ECA Members € 1,390.-
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.

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
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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.
Mr Oliver Schmidt (Operations Director) at +49-62 21 / 84 44 23, or per e-mail at schmidt@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.

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

☐ **8th European GMP Conference – Industry meets GMP Inspectorates**
6-7 June 2019, Heidelberg, Germany

☐ I also want to attend the Pre-Conference
GMP for Cannabis – What you need to know
5 June 2019, Heidelberg, Germany

☐ I want to take part in the Social Event on 6 June.

ECA's 20th Anniversary Treat
400,- € Discount for ECA Members

I want to take part in the following **Parallel Sessions & Workshops with Inspectors** (please tick only one):

☐ Qualification & Validation
☐ Data Integrity
☐ GDP

☐ 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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