

The European GMP & GDP FORUM



22-24 JUNE 2021

Face-to-Face

HEIDELBERG, GERMANY

Remotely

LIVE ONLINE



SPEAKERS & MODERATORS:

Ib Alstrup

GxPIT Medicines Inspector with the Danish Medicines Agency, DMA, Denmark

Dr Christopher Burgess

Qualified Person, Chairman ECA Quality Control Group, UK

Cheryl Chia

Lotus Phoenix Consulting, Netherlands

Prabjeet Dulai

GDP & Quality Matters, UK

Dr Rainer Gnihl

GMP Inspector, District Government of Upper Bavaria, Germany

Jochen Heinzel

F. Hoffmann-La Roche, Switzerland

Dr Afshin Hosseiny

Qualified Person, Chairman ECA Foundation and European GDP Association, UK

Saddam Huq

GlaxoSmithKline, U.K.

Dr Ulrich Kissel

Chairman, European QP Association, Germany

Gert Moelgaard

Chairman ECA Validation Group, Denmark

Helga Peters

Switzerland

Axel Radke

Trust Expertenservice, Germany

Jonathan Riley

Astellas Pharma Europe Ltd

Dr Bernd Renger

Qualified Person, Immediate Past Chairman European QP Association, Germany

Maria Sekamwa

Surgipharm, Uganda

Dr Franz Schönfeld

District Government of Upper Franconia, Germany

Dr Wolfgang Schumacher

Chairman ECA Data Integrity & IT Compliance Group, Switzerland

Lance Smallshaw

UCB Biopharma sprl, Chairman ECA Cannabis Group, Belgium

Dr Ingrid Walther

Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius

** ALL PARTICIPANTS RECEIVE AN EXCLUSIVE PACKAGE OF NEW ECA GUIDELINE DOCUMENTS | FURTHER INFORMATION INSIDE **

THE ECA FOUNDATION GROUPS

WELCOME

Dear Colleagues,



I would like to invite you to the European GMP & GDP Forum from 22 – 24 June 2021.

Our ECA members are familiar with biennial conferences on GMP and GDP we have been running for several years. However, we have now developed this unique Forum by combining the European GMP Conference and the European GDP Forum. I believe with this new event by

combining both GMP and GDP subjects, we have created a new opportunity for you to meet delegates and expert speakers from across the industry, and exchange views and learn about the whole Pharma supply chain challenges.

We have dedicated day 1 to GMP, day 2 will be a combination of both GMP, and GDP and the final day will be focussed on GDP topics only. This will allow you as a participant to take advantage of the event based on your personal needs and interest in the specific subject areas, you can now choose to attend the forum just for one of the three days, two days or all three days.

We intend to host the Forum every two years which I am sure will become a major European event for GMP and GDP professionals. For our first Forum in June 2021 we have invited speakers from Regulatory Authorities and Pharmaceutical Industry to share and discuss with you the latest GMP & GDP developments.

I look forward to meeting you either live online or in person in Heidelberg, Germany – one of the most beautiful cities in Europe!

Yours sincerely,

Dr Afshin Hosseiny, Chairman of the ECA Foundation Advisory Board

TARGET GROUP

The conference is of particular interest for GMP experts of pharmaceutical companies (e.g. QA, QC, production, regulatory affairs), of GMP inspectorates and Regulatory Authorities. It is also of interest for all personnel involved in GDP – pharmaceutical storage, transportation, cold chain and distribution activities and the control of these activities.

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

Reservation Form (Please complete in full) GMP & GDP FORUM 2021, 22-24 June 2021, HEIDELBERG, GERMANY & LIVE ONLINE

 PLEASE NOTE: You can already register now and decide later how you will participate – face-to-face in Heidelberg or remotely.

Participation: in Heidelberg Remotely I will decide later
I would like to attend on the following days: Day 1 Day 2 Day 3

- ONLY ON DAY 2: PARALLEL SESSIONS – PLEASE CHOOSE ONE**
- Qualification & Validation: Supplier integration - how does this fit with GMP?
 - Quality Control: How sure are you that your Laboratory Instrument/System is fit for its intended Purpose?
 - Data Integrity: Data integrity in the GMP area
 - GDP: How to Identify and Manage Falsified Medicines in the Supply Chain=
 - GDP: Risk Management in GDP Warehouse

Mr Ms

Title, first name, surname

CONCEPT HEIDELBERG

Postfach 10 17 64

Fax 06221/84 44 34

D-69007 Heidelberg

Company

Department

Important: Please indicate your company's VATID Number

P.O 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 %
 - Cancellation until 1 weeks prior to the conference 50 %
 - Cancellation within 1 week prior to the conference 100 %
- CONCEPT HEIDELBERG reserves the right to change the materials, instructions, 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.

refund of fees paid. CONCEPT HEIDELBERG will 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 (except if payment will not be confirmed). (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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 in relation with this order or similar ones. My personal data is stored and processed. Concept Heidelberg will only send me information (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.

WELCOME

Introduction – Update ECA
Dr Afshin Hosseiny, Chairman ECA

PROGRAMME 22 JUNE – GMP PART

Moderated by: Lance Smallshaw

SESSION

Current GMP Initiatives Worldwide

This session will discuss the latest changes and current initiatives in GMP and GDP regulations.

GMP Update 2021 and Outlook 2022 – Current Trends and Developments in Europe and the US

- Dr Bernd Renger, *QP and immediate past chair of the EQPA*
- Major GMP developments and their impact for pharmaceutical industry
- GMP Revisions – Annex 1 & 21
- GMP for Marketing Authorisation Holders
- The new EU GMP Annex 21 on Importation and its implication
- Analytical Procedure Development and Validation (ICH Q14/Q2)
- Other GMP Developments from EMA, FDA and others
- Brexit and its consequences for the European QPs

ICH Q 12: Views and Expectations of a GMP-Inspector

- Dr Franz Schönfeld, *GMP Inspector*
- Quality Risk Management
- Life Cycle Approach
- Views and Expectations

How to Implement ICH Q 12 into Daily Practice of Manufacturers – What QA (and QPs) needs to know?

- Dr. Ulrich Kissel, *Chairman European QP Association*
- What does QA (and QPs) need to consider?
- Some Quality systems become key
- Efficiency potential for Quality systems of manufacturing organizations
- ICH Q12 and key performance indicators
- Plan precisely, assess risks proactively, share transparently

SESSION

Industry Meets Inspectors

GMP Inspections from Russian Authority in Europe
To be named

Global Inspection Management: Cultural Differences to consider in hosting Competent Authorities from e.g. Arabic Countries, China, Korea, Taiwan, Mexico, Russia

➤ Helga Peters, *Basel, Switzerland*

- General Organisation
- Roles and Responsibilities
- Preparation
- Cultural Aspects

Annex 1 Revision: Comments from the Industry

➤ Dr Ingrid Walther, *Head of ECA's adhoc Task Force for comments to the Annex 1 revision*

- New requirements?
- New requirements!
- The role and importance of Quality Risk Management
- Contamination Control Strategy

Inspection – readiness for new Annex 1: Comments from the Inspector

➤ Dr Rainer Gnihl, *GMP Inspector*

- What is essential?
- What do I need to change or improve?
- Is it really such serious?

PROGRAMME 23 JUNE – GMP & GDP PART

Moderated by: Dr Ulrich Kissel

Brexit: Consequences for GMP and GDP Environment

➤ Dr Afshin Hosseiny, *Chairman ECA Foundation and European GDP Association*

- What is the impact of Brexit on Pharma Regulations?
- New GMP and GDP expectations from UK
- How Pharma Industry in EU should manage the UK business
- What impact all this has on the patients?

EU GMP Annex 21: Import of Medicinal Products

- ➔ Dr. Ulrich Kissel, *Chairman European QP Association*
- The meaning of importation within scope of Annex 21
- What is new in Annex 21 (draft)?
- What do we miss in Annex 21 (draft)?
- Conclusions and comments on the document

PARALLEL SESSIONS & WORKSHOPS WITH INSPECTORS

Moderated by: Dr Afshin Hosseiny / Dr Ulrich Kissel, Gert Moelgaard / Dr Rainer Gnibl, Dr Wolfgang Schumacher / Ib Alstrup, Dr Christopher Burgess / N.N., Saddam Huq / Prabjeet Dulai

Get involved in the ECA Interest and Working Groups. Each delegate will be invited to discuss the upcoming developments with the Chairs/ members of the groups and EU inspectors.

AGENDA

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

Parallel-Sessions

| | | | |
|------------------|-----------------------|--------------------------------------|-----------|
| Validation Group | Quality Control Group | Data Integrity & IT Compliance Group | GDP Group |
|------------------|-----------------------|--------------------------------------|-----------|

Option 1 (Validation Group): Qualification & Validation: Supplier integration – how does this fit with GMP?

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

- How can qualification and GEP interact?
- How can suppliers be integrated?
- Categorisation of equipment – a tool for streamlining qualification efforts
- Electronic qualification documentation

Option 2 (Quality Control Group): QC: How sure are you that your Laboratory Instrument/System is fit for its intended Purpose?

1. Introduction to the ECA AQC Group Guideline on Analytical Instruments and Systems Qualification Lifecycle
2. Overview of USP General Chapter <1058> and revision of spectroscopic General Chapters USP <85x> and <185x> and their relationship to the newly proposed analytical procedure lifecycle in USP <1220>
3. Reference standards for calibration and establishment of acceptance criteria for 'fitness for purpose'

Option 3 (Data Integrity & IT Compliance Group): Data Integrity: Data Integrity in the GMP area

This interactive session will offer the opportunity for the participants to discuss current Data Integrity issues

- How to prepare for a Data Integrity inspection – the industry view
- Data Integrity Risk Assessment
- Data Integrity Inspection findings

Option 4 (GDP Group): How to Identify and Manage Falsified Medicines in the Supply Chain

This workshop will offer the opportunity to discuss the following aspects:

- What is a suspected falsified medicine?
- How to identify falsified medicine in your workplace?
- How to approach the investigation of a suspected pack?
- What should the end user do with the pack?
- Routine monitoring of incoming goods
- Who should manage communication with the end users?

Option 5 (GDP Group): Risk Management in GDP Warehouse

The risk-based approach is a fundamental requirement for processes in the GDP environment. Risk management is one of the mandatory basic elements. It is applicable to a variety of activities and processes. This workshop will cover challenges and possible solutions concerning risk management in GDP warehouses. Different examples will be discussed.

SESSION

Inspections/Audits in Covid-19 Times

The corona pandemic causes unusual supplier qualification activities. Meetings face-to-face are reduced or not possible at all. This concerns supplier audits but also regulatory inspections. To fulfil GMP-requirements and to prevent travelling and meeting people personally is a balancing act. How to react?

Distant Assessments – GMP-inspector´s view

- ➔ Dr Rainer Gnibl, *GMP Inspector*
- Regulatory basis
- Requirements from guidelines
- Examples from inspections
- Reliability in "real life"

Supplier Management during Covid-19 Pandemic

- ➔ To be named

PROGRAMME 24 JUNE – GDP PART

Moderated by: Dr Afshin Hosseiny

It is of key importance that medicinal products are not only made to a high quality in accordance with Good Manufacturing Practice (GMP), but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where Good Distribution Practice (GDP) comes into play.

On day 3, challenges and possible solutions will be discussed and examples will demonstrate how the requirements can be put into practice.

GDP Update & Outlook

Dr Afshin Hosseiny, *Chairman ECA Foundation and European GDP Association*

- Major GDP developments

Case Studies: When Things go Wrong – What can Happen in the Real World?

➔ Axel Radke, *Trust Expertenservice*

- First plan, then start
- Hand in hand for safe transport
- Basis of all considerations “Worst Case Scenario”

Case Study: The Switch from Air-freight to Sea-Freight

➔ Saddam Huq, *GlaxoSmithKline*

- Challenges and Benefits
- Examples

GDP Challenges in Africa

➔ Maria Sekamwa, *Surgipharm*

- Background
- Evolution of GDP over the years
- Problems involved
- Steps taken to improve

Case Study: The Roche Quality Governance Model for Distribution to Direct Markets

➔ Jochen Heinzl, *F. Hoffmann-La Roche*

- Selection, implementation, operation and decommissioning of partners
- Key Performance Indicators (KPIs)
- Compliance score card

Master Data

➔ Cheryl Chia, *Lotus Phoenix Consulting*

- EU requirements
- Master Data framework for Medicines
- Impact to the Pharmaceutical Supply Chain
- QA/QP/RP oversight of the supply chain

GDP Responsibilities for Financial Trading Organisation

➔ Prabjeet Dulai, *GDP & Quality Matters &*

Jonathan Riley, *Astellas Pharma Europe*

- Involvement of Marketing Authorisation Holders in the distribution network
- The role of the Responsible Person when product handling is not involved
- Control of outsourced activities in integrated supply chains
- Processes used in financial distribution, and validation of computerised systems

SOCIAL EVENT

On 22 June 2021, participants and speakers are invited to a social event, followed by a dinner, where the topics of the course can be further discussed in a relaxed atmosphere.

SPECIAL OFFER WITH LUFTHANSA – DISCOUNTED TRAVEL



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.

SPEAKERS & MODERATORS

Ib Alstrup, *GxP IT Medicines Inspector with the Danish Medicines Agency, DMA, Denmark*

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 the ECA Quality Control Group, member of the ECA Foundation's Extended Board and member of the ECA Task Force on Data Integrity.

Cheryl Chia, *Lotus Phoenix Consulting, Netherlands*

Cheryl Chia is Consultant for GMP and GDP compliance in the pharmaceutical supply chain.

Prabjeet Dulai, *GDP & Quality Matters, UK*

Prabjeet Dulai is a Consultant at GDP & Quality Matters Ltd. Before working as a consultant she was the RP and Senior Supply Chain Pharmacist for the UK Ministry of Defence, and prior to this worked as a Pharmacist within the NHS/private hospital sector, retail and pharmaceutical industry.

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.

Jochen Heinzel, *F. Hoffmann-La Roche, Switzerland*

Jochen Heinzel is Global Quality Manager Supply Chain & Affiliate Quality EMEA Region.

Dr Afshin Hosseiny, *Qualified Person, Chairman ECA Foundation and European GDP Association, UK*

Afshin looks back to many years with Glaxo Smith Kline in the UK and is Chairman of the ECA Foundation and the European GDP Association.

Saddam Huq, *GlaxoSmithKline, U.K*

Saddam Huq is Senior Manager Quality for Distribution & Cold Chain Management Vaccines, Quality Assurance Shared Services.

Dr Ulrich Kissel, *Chairman European QP Association*

Ulrich Kissel is Qualified Person and Chairman 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 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 Validation Group and member of the ECA Foundation's Extended Board.

Helga Peters, *Switzerland*

Helga Peters held various positions in the Diagnostic and Pharmaceutical Industry. During the past years, she's been working for F. Hoffmann-La Roche Ltd in Global Quality Inspection Management where she is providing training, strategies and support during Health Authority Inspections. She is now self-employed.

Axel Radke, *Trust Expertenservice, Germany*

Axel Radke is Responsible Person and technical expert for investigations of issues in the storage and transport of pharmaceuticals.

Jonathan Riley, *Astellas Pharma Europe Ltd*

Jonathan Riley is a QA professional with over 18 years quality management experience including GMP, GDP, GLP and GCP in contract research, pharmaceuticals, clinical trials and chemicals manufacturing.

Dr Bernd Renger, *Qualified Person, 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).

Maria Sekamwa, *Surgipharm, Uganda*

Maria Sekamwa is Assistant Warehouse Manager and Qualified Person for Pharmacovigilance.

Dr Franz Schönfeld, *District Government of Upper Franconia, Germany*

Dr Franz Schönfeld is a GMP and GDP inspector at the local inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Dr Wolfgang Schumacher, *Chairman ECA Data Integrity & IT Compliance Group, Switzerland*

He was till July 2017 Head of the department of Quality Computer Systems at F. Hoffmann-La Roche. He is currently Head of the ECA Data Integrity & IT Compliance Group, member of the ECA Foundation's Extended Board and member of ECA's Task Force on Data Integrity.

Lance Smallshaw, *UCB Biopharma sprl, Chairman ECA Cannabis Group, Belgium*

Lance Smallshaw is Global Director of Analytical Strategy for NBEs at UCB in Belgium and member of the ECA Foundation's Executive Board.

Dr Ingrid Walther, *Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius*

Dr Walther was employed in various positions and has long years of experience in the fields of research and development, quality assurance/quality control, and the management of strategic projects and as head of a Business Unit Validation and GMP Compliance. Since July 2009 she runs her own business as consultant. She was Head of ECA's adhoc task force commenting the Annex 1 revision.

Date

Tuesday, 22 June 2021, 09.00 – approx. 17.30 h

(Registration and coffee 08.30 – 09.00 h)

Wednesday, 23 June 2021, 09.00 – approx. 17.00 h

(Registration for new participants and coffee 08.30 – 09.00 h)

Thursday, 24 June 2021, 09.00 – approx. 16.00 h

(Registration for new participants and coffee 08.30 – 09.00 h)

All times mentioned are CEST.

Venue

Heidelberg Marriott Hotel

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Conference Fees

ECA members and European GDP Association members receive a 200.- Euro discount.

APIC members receive a 100.- Euro discount.

EU GMP Inspectorates receive a 50% discount.

Day 1 or day 2 or day 3: EUR 990.- per delegate plus VAT

Day 1 and 2: EUR 845.- per day and delegate (total 1690,-) plus VAT

Day 2 and 3: EUR 845.- per day and delegate (total 1690,-) plus VAT

Day 1-3 EUR 665.- per day and delegate (total 1990,-) plus VAT

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all 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 not later than Early reservation is recommended.

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.



PLEASE NOTE: You can register now and decide later how you will participate – face-to-face in Heidelberg or remotely at your screen.

Conference Material

Important Information!

Just prior to the conference you will get access to a download area where you will find the presentations as PDFs. Presentations will be uploaded up to the Conference as they become available. We hope for your understanding, though, if individual presentations are not available for download due to restrictions from the authors.

Please keep in mind that the **conference materials will not be available as print outs** in a folder and there will be no on site opportunity to get presentations printed.

Conference Language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG

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For questions regarding content (GDP Part):

Dr Markus Funk (Operations Director) at +49-62 21 / 84 44 40,
or per e-mail at funk@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Mrs Nicole Bach (Organisation Manager) at +49-62 21 /
84 44 22 or per e-mail at bach@concept-heidelberg.de

AS A PARTICIPANT YOU WILL RECEIVE AN EXCLUSIVE PACKAGE OF NEW ECA GUIDELINE 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 (Version 1.0)
- Good Distribution (GDP) Interpretation Guide (ECA/PQG)
- Latest version of the GMP Matrix (comparison of EU GMP, FDA cGMP and ISO 9001)