ECA Academy
Your GMP/GDP Information Source

GMP Forum
20 – 21 June 2023

GDP Forum
21 – 22 June 2023

Barcelona, Spain

Speakers of the GMP & GDP Forum

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

Peter Flury | CSL Behring, Switzerland

Ralf Gengenbach | Gempex, Germany

Dr Rainer Gnibl | GMP Inspector, District Government of Upper Bavaria, Germany

Thomas Højsholm Schmidt | CSL Behring, Switzerland

Dr Afshin Hosseiny | Qualified Person, Chairman of the ECA Advisory Board, UK

Alfred Hunt | European GDP Association Chairman, Ireland

Saddam Huq | GlaxoSmithKline, U.K.

Dr Rainer Kahlich | Local Government of Baden-Württemberg, Germany

Dr Ulrich Kissel | European QP Association, Switzerland

Dr Bernd Renger | Qualified Person, Immediate Past Chairman of the European QP Association, Germany

Dr Uwe Rettig | IDT Biologika, Germany

Dr Peer Schmidt | AbbVie Deutschland, Germany

Dr Torsten Schmidt-Bader | moveproTEC compliance advisory, Germany

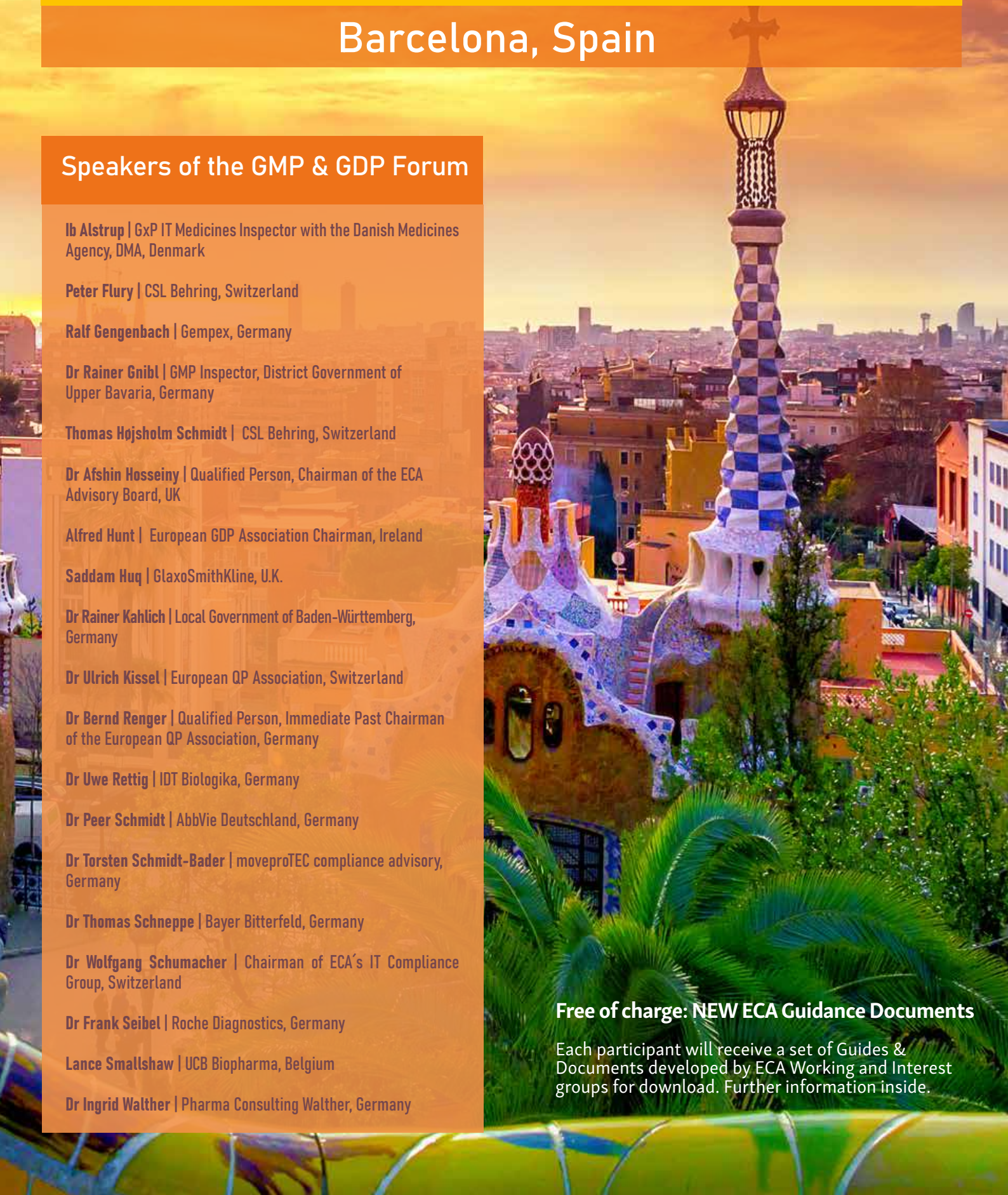
Dr Thomas Schneppe | Bayer Bitterfeld, Germany

Dr Wolfgang Schumacher | Chairman of ECA´s IT Compliance Group, Switzerland

Dr Frank Seibel | Roche Diagnostics, Germany

Lance Smallshaw | UCB Biopharma, Belgium

Dr Ingrid Walther | Pharma Consulting Walther, Germany



Free of charge: NEW ECA Guidance Documents

Each participant will receive a set of Guides & Documents developed by ECA Working and Interest groups for download. Further information inside.

Welcome

Dear Colleagues,

I would like to invite you to the European GMP & GDP Forum from 20 – 22 June 2023 in Barcelona, Spain.

Our ECA members are familiar with biannual conferences on GMP and GDP we have been running for several years. Since 2021 this unique Forum combines the European GMP Conference and the European GDP Forum. With this format by combining both GMP and GDP subjects, we have created a new opportunity for you to hear speakers from across the industry and authorities, and learn about the whole Pharma supply chain challenges.

And this year the Forum will be an on-site event that you can meet face-to-face.

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.

For our second Forum in June 2023 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 welcoming you to this event – on-site!

Yours sincerely,

Dr Afshin Hosseiny, Chairman of the ECA Advisory Board

Target Audience

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.

Speakers and 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 GxP areas. He is a co-writer of the new PIC/S guide on Data Integrity and holds a B.Sc. in Electronic Engineering.

Peter Flury
CSL Behring AG, Switzerland
Peter Flury has more than 35 years experience in the transportation logistics industry in numerous functions with manufacturers and logistics service providers. He is in the pharmaceutical industry since 2008 at CSL Behring and presently in the position as Senior Manager and Head Transportation Management EMEA.

Ralf Gengenbach
Gempex GmbH, Germany
Ralf Gengenbach is founder and managing director of gempex Co. Ltd., Germany. He is member of different organisations, among others DIN UA2 (Board for standards 'biotechnology'), of DECHEMA and ISPE. He is approved Quality Auditor according to DIN ISO 9000ff. Ralf is currently the Head of ECA´s Validation Group.

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. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Thomas Højsholm Schmidt
CSL Behring, Switzerland
Thomas Højsholm Schmidt is Associated Director and Lead Auditor at CSL Behring AG in Switzerland. Before that, he was a GMP Lead Auditor at LEO Pharma A/S in Denmark for over 12 years. Thomas is member of ECA´s Inspection Group.

Dr Afshin Hosseiny
Qualified Person, Chairman of the ECA Advisory Board, UK
Afshin looks back to many years with Glaxo Smith Kline in the UK and is member of ECA´s Executive Board.

Alfred Hunt
European GDP Association Chairman, UK
Alfred Hunt is a consultant. From 2008 until 2015 he was an Inspector with the Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board (IMB). He was also key member of the European Medicines Agency (EMA) drafting group which developed the revised EU GDP Guidelines (2013/C 343/01).

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

Dr Rainer Kahlich
Local Government of Baden-Württemberg, Germany
Dr Rainer Kahlich is pharmacist and GMP/GDP Inspector for the Local Government and the EMA and performs GMP/GDP inspections worldwide.

Dr Ulrich Kissel
European QP Association, Switzerland
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.

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

Dr Uwe Rettig
Vice President Supply Chain at IDT Biologika GmbH, Germany
Uwe Rettig has joined IDT 2011. With his current position as Head of Supply Chain Management Uwe Rettig is responsible for customer service, planning, and logistics and is in charge of the Sales- and Operations Plannig Process (S&OP).

Dr Peer Schmidt
AbbVie Deutschland GmbH & Co. KG, Germany
Peer Schmidt brings more than 20 years of experience in the development, manufacturing, registration and supervision of Medicinal Products, Medical Devices and Combination Products. As Director Global Quality Systems, he oversees the AbbVie Quality System Centers of Excellence. He also acts as EU Authorized Representative for AbbVie´s Medical Devices. Dr Schmidt holds a Ph.D. in Molecular Biology and was previously the Head of Quality Assurance at Abbott Biotechnology Germany. He is a member of the ICH Q9 Revision 1 Expert Working Group.

Dr Torsten Schmidt-Bader
moveproTEC compliance advisory, Germany
Dr Torsten Schmidt-Bader is Managing Director at moveproTEC and a GMP/GDP lead auditor and compliance advisor. Since 2010 he has been supporting the life science industries and pharma logistic providers with GDP implementation. For SGS ICS, he certified several providers against WHO and EU GDP standards.

Speakers and Moderators

Dr Thomas Schneppe
Bayer Bitterfeld GmbH, Germany
Thomas has more than 30 years GMP experience in Pharmaceutical Industry: Qualified Person, Mgmt. Training, GMP Projects, Operational Excellence in different functions at Klöckner Pentapack, Schering AG, Asche AG, Bayer AG and actually Bayer Bitterfeld GmbH.

Dr Wolfgang Schumacher
Chairman ECA´s IT Compliance Group, Switzerland
He was til July 2017 Head of the department of Quality Computer Systems at F. Hoffmann-La Roche. 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.

Dr Frank Seibel
Roche Diagnostics GmbH, Germany
Dr Frank Seibel is Quality Site Head at Roche Diagnostics in Mannheim. Before that he was, amongst others, Senior Vice President Corporate Quality & HSE at Aenova Holding and Director Global Manufacturing Quality Strategy at AbbVie.

Lance Smallshaw
UCB Biopharma S.A., Belgium
Lance Smallshaw is Global Analytical and Quality Expert – Head of Compendial Affairs at UCB in Belgium and Member of ECA´s Executive Board.

Dr Ingrid Walther
Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius, Germany
Dr Walther was employed in various positions and has long years of experience in the fields of research and development, QA/QC, 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.

Each participant will receive a set of PDF documents developed by ECA Working and Interest Groups for download:

- ECA Task Force on Contamination Control Strategy - Guide How to Develop and Document a Contamination Control Strategy
- ECA Good Practice Guide "Code of Practice for QPs – Duties and Responsibilities for Qualified Persons in the EU"
- ECA Guidelines for the Evaluation and Investigation of Microbiological Deviations
- ECA Standard Operating Procedure (SOP): Laboratory Data Management - Out of Specification (OOS) Results
- Laboratory Data Management Guidance: Out of Expectation (OOE) and Out of Trend (OOT) Results
- Laboratory Data Management Guidance - Analytical Procedure Lifecycle Management (APLM)
- Good Practice Guide "Integrated Qualification and Validation - A guide to effective qualification based on a Customer - Supplier Partnership"
- ECA Good Practice Guide on Validation
- ECA/PQG Guidance on the Interpretation and Implementation of European Good Distribution Practice & ECA/PQG Guidance on the Interpretation and Implementation of European Good Distribution Practice for Active Substances
- ECA Code of Practice for The Responsible Person for GDP
- Visual Inspection Group Guidance Documents & Best Practice Paper
- ECA Guidance Document - Data Governance and Data Integrity for GMP Regulated Facilities

Welcome

Introduction – Update ECA
Dr Afshin Hosseiny, Chairman of the ECA Advisory Board

Moderator
Dr Ulrich Kissel

Session 1: Current GMP Initiatives and Trends

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

GMP Update 2023 and Outlook 2024 – Current Trends and Developments in Europe and US
Dr Bernd Renger

- Regulation (EU) 2019/6 on Veterinary Medicinal Products – short feedback about the reduction of the use of antibiotics
- Revised Directive (EU) 2017/1572 on GMPs for Medicinal Products & Delegated Regulation (EU) 2017/1569 & revised Annex 13 – short feedback about the differences of „human use Medicinal Products" and „IMPs"
- Reflection Paper GMP and Marketing Authorisation Holder (MAH) – Experiences
- Revision of Annex 1 – Feedback from the industry
- New Annex 21 – Experiences
- Concept Paper Annex 11 – Goals of the revision
- ICH Q2(R2) und ICH Q14 – Life Cycle of Analytical Procedures – Current status and feedbacks from the industry
- Nitrosamines in Medicinal Products and APIs – Trouble for industry and authorities?

Session 2: Industry Meets Inspectors on Hot GMP Topics

Part A – The Revision of ICH Q9 Risk Management

ICH Q 9 Revision: Inspector´s View
Dr Rainer Gnibl

- Overview
- What is new?
- Consequences in practice

Industry View: What does the ICH Q9 Revision Mean for Manufacturers ?– What QA (and QPs) Need to Know?
Dr Peer Schmidt

- Background of guideline revision
- Key changes
- Impact on manufacturers
- Examples for application

Part B – EU GMP Annex 11 on Computer Validation – EU Concept Paper on the upcoming Revision

EU GMP Annex 11 – The EU Concept Paper
Ib Alstrup

- History of Annex 11
- Why now a new version
- Concept paper

EU GMP Annex 11 – Industry View
Dr Wolfgang Schumacher

- Importance of Annex 11 for the pharmaceutical industry
- Industry view on Annex 11 concept paper

Part C – The New EU GMP Annex 1 – Consequences for QA

Annex 1 Revision: What does Industry has to Expect? - GMP Inspector´s View
Dr Rainer Gnibl

- Contamination Control Strategy
- (Re-) Qualification
- Barrier Technologies &„old" clean air equipment
- News in material transfer
- Sterile filtration
- Worst case for Aseptic Process Simulation

Annex 1 Revision: Relevant Points for QA – Industry View
Dr Ingrid Walther

- Increasing relevance of Quality Risk Management
- Contamination Control Strategy
- Trending – the new Trend!

Moderator:

Lance Smallshaw

Part D – Inspection Trends

Hybrid Inspections
Thomas Højsholm Schmidt

- Definition of hybrid audits/inspections
- Planning for hybrid audits/inspections
- Conduct of hybrid audits/inspections

MHRA Audit – A System also for the EU?
Dr Afshin Hosseiny

- What is MHRA audit?
- Experiences with MHRA audit?
- A system also for the EU?

SESSION 3: Parallel Sessions & Workshops with Inspectors

Moderators:

Ralf Gengenbach | Dr Rainer Gnibl | Dr Thomas Schneppe | Dr Wolfgang Schumacher | Ib Alstrup | Saddam Huq | Alfred Hunt

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 working groups and EU inspectors.

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

Option 1 (Validation Group):

Qualification & Validation: Metrics in Validation/ Commissioning and Qualification
Ralf Gengenbach | Dr Thomas Schneppe | Dr Rainer Gnibl

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

- How to calculate cp/cpk, pp/ppk
- How to interprete cp/cpk, pp/ppk
- How can qualification and GEP interact?
- How can suppliers be implemented?

Option 2: (Data Integrity Group):

Annex 11 changes
Dr Wolfgang Schumacher | Ib Alstrup

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

- What will change?

Option 3 (GDP Group):

Mean Kinetic Temperature (MKT)
Saddam Huq

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

- What is MKT and conditions and rules when MKT could be applied

Option 4 (GDP Group):

Deviation Management
Alfred Hunt

During this workshop participants will learn and discuss how to ensure that the deviation system is being correctly used and implemented.

- Effective Root Cause Analysis
- Extending Impact Assessments
- CAPAs that work
- Example of deviations which will be worked on by the attendees

Part E – Regulatory Trends

FDA´s Quality Metrics Initiative – Current Status and what Industry can already Use to Supervise and Improve Qualty of Products
Dr Frank Seibel

- Regulatory Requirements
- Implementation into Pharmaceutical Quality Systems
- Meaningful working with metrics

Managing Medicines Shortages: Reducing the Impact on the Pharmaceutical Supply Chain
Dr Uwe Rettig

- Lesson learned after pandemic and other crises impacting global supply chain, e.g. looking at insecure markets, raw material / energy supply, uncertain customers / distributers or unreliable suppliers and the effects on the pharma supply chain
- Analysing the collaboration between all supply chain stakeholders
- Challenges, solutions, best practice and forecast for functioning supply chain for advanced therapy manufacturing

Agenda – Day 3: GDP Forum

22 June 2023

Moderator:

Alfred Hunt

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

Alfred Hunt

- Major GDP developments
- Current Trends in Europe and the US

GDP for Veterinary Medicinal Products

Dr Rainer Kahlich

- New regulatory framework for VET-GDP – the European Regulations
- GDP for veterinary / for human medicinal products – what are the similarities, what are the differences?
- Inspection focus and prevalent findings

Disruption of the Global Supply Chain: How to still be able to be GDP-compliant

Peter Flury

- The "New Normal" – Unpredictable availability of mode of transport, equipment, carriers and capacity; Failure of global security architecture with high uncertainty and potential interruption of trade lanes and supplies "overnight"
- Strategies to manage and control the "New Normal"
- Usage of Open-source intelligence (OSINT) to understand geo-political risks, anticipate and integrate them into a supply chain strategy

Data Integrity in a Hybrid Working Environment

Alfred Hunt

- How to ensure good documentation practices and data integrity
- Use of document repositories
- Capturing approvals of remote workers
- Managing scanned documents

Validation of Computerized Systems under GDP Regulation

Dr Torsten Schmidt-Bader

- Validation requirements – regulatory overview
- GAMP oriented validation approach of GDP critical systems
- Validation of a new warehouse and material management system – case study 2023: Wholesaler Germany

Case Study on Thermostability

Saddam Huq

- Type of thermostability data
- Label claim versus thermostability data
- How thermostability data can be used for supply chain

Social Event

On 20 June 2023, 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.

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

Reservation Form (Please complete in full)

GMP & GDP Forum | 20 – 22 June 2023, Barcelona, Spain

- ☐ Day 1, or day 2 or day 3: € 1,190 per delegate plus VAT
- ☐ Day 1 and 2: € 945 per day and delegate (total € 1,890) plus VAT
- ☐ Day 2 and 3: € 945 per day and delegate (total € 1,890) plus VAT
- ☐ Day 1-3 € 730 per day and delegate (total € 2,190) plus VAT

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full 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 (receipt of payment will not be confirmed)! (As of July 2022).
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 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 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.

Date

Tuesday, 20 June 2023, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 21 June 2023, 09.00 – 17.00 h
(Registration for new participants and coffee 08.30 – 09.00 h)
Thursday, 22 June 2023, 09.00 – 16.00 h
(Registration for new participants and coffee 08.30 – 09.00 h)

Venue

Barcelo Sants Hotel | Pl. Països Catalans, s/n
08014 Barcelona | Catalunya | Spain
Phone +34 93 503 53 00 | Fax +34 93 4906045
E-Mail: sants@barcelo.com

Fees (per delegate, plus VAT)

Day 1 or day 2 or day 3: € 1,190
Day 1 and 2: € 945 per day (total € 1,890)
Day 2 and 3: € 945 per day (total € 1,890)
Day 1-3: € 730.- per day (total € 2,190)
ECA members and European GDP Association members receive a € 200 discount. APIC members receive a € 100 Euro discount. EU GMP Inspectorates receive a 50% discount.
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/POG when you have registered for the course. 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 https://www.gmp-conference.org.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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For questions regarding reservation, hotel, organisation etc.:
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or per e-mail at bach@concept-heidelberg.de