Early Bird until 28.02.2025

GMP 24/25 June

GDP 25/26 June

FORUM 2025

BARCELONA

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 am pleased to invite you to the European GMP & GDP Forum, taking place from 24-26 June 2025 in Barcelona, Spain.

As many of you know, our ECA members have enjoyed biannual conferences dedicated to GMP and GDP for several years. Since 2021, we have combined these two into a unique event, bringing together the European GMP Conference and the European GDP Forum.

This three-day event is designed to provide flexibility and focus:

- The first 1½ days are dedicated to Good Manufacturing Practice (GMP), offering expert presentations, regulatory updates, and discussions on emerging trends and practical implementations.
- The second 1½ days will center on Good Distribution Practice (GDP), covering the latest developments and best practices in this area.

This flexible format allows you to tailor your participation according to your specific interests and needs. You may choose to attend only the GMP Forum, only the GDP Forum, or all three days of the event.

For our third Forum in June 2025 we have invited speakers from Regulatory Authorities, leading Organisations and the Pharmaceutical Industry to share and discuss with you the latest GMP & GDP developments.

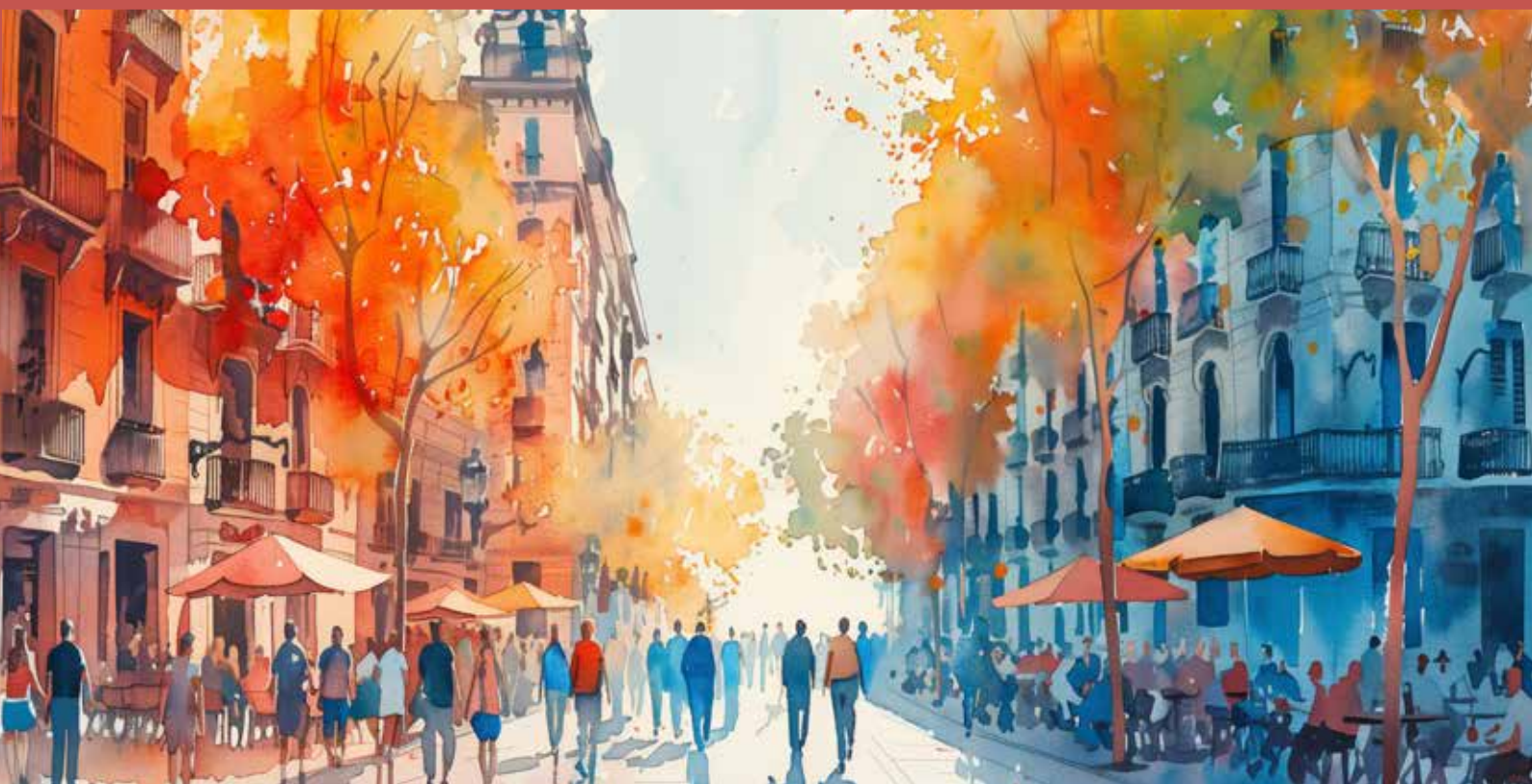
I look forward to welcoming you to this event – on-site in Barcelona!

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 & MODERATORS

GMP FORUM

David Abraham | *Head of ECA's European Auditor Association, UK*
David works as an independent quality consultant with Quality Resource Solutions Associates in UK and has extensive experience in both business and Quality Management system development.

Ib Alstrup | *Danish Medicines Agency, DMA, Denmark*
Ib Alstrup is a GxP IT Medicines Inspector with the Danish Medicines Agency.

David Cockburn | *European Qualified Person Association (EQPA)*
David Cockburn is a member of the EQPA Board of Directors and former Chair of the EMA GMP/GDP IWG.

Ralf Gengenbach | *ECA Validation Group , Germany*
Ralf Gengenbach is founder and managing director of gempex Co. Ltd., Germany. He is currently the Head of ECA´s Validation Group.

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

Dr Ulrich Kissel | *European QP Association, Germany*
Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA).

Dr Peer Schmidt | *AbbVie, Germany*
Peer Schmidt is Director Global Quality Systemy at AbbVie and acts as EU Authorized Representative for AbbVie´s Medical Devices.

Dr Franz Schönfeld | *GMP Inspector, 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.

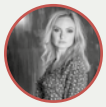
Dr Wolfgang Schumacher | *ECA IT Compliance Group, Switzerland*
Dr Schumacher was Head of the department of Quality Computer Systems at F. Hoffmann-La Roche and is currently Head of ECA´s Data Integrity & IT Compliance Group.

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 Jörg Stüben | *Boehringer Ingelheim International, Germany*
Head of Regulatory Information Management and Senior Expert. He is responsible for a RIM group.

GDP FORUM

Martin Egger | *Pharmserv, Germany*
CEO and experienced manager in the biotech and pharmaceutical industry.



Oleksandra Bakhurynska | *Quality Director at Farmasoft LLC*
15 years of experience in the pharmaceutical industry

Michael Fleischer | *Roche Pharma*
GDP Expert at Roche Pharma AG and certified Senior Lead Auditor in various industries.

Tina Geyer | *Pfizer Pharma*
Associate Director Quality & Responsible Person and Lean Six Sigma Black Belt at Pfizer Oncology

Saddam Huq | *GlaxoSmithKline, U.K*
Saddam Huq is Director, Cold Chain and Logistics at GSK

Alfred Hunt | *GMP/GDP Inspectorate, Local Government, Germany*
Consultant. He was an Inspector with the Health Products Regula-tory Authority (HPRA), formerly the Irish Medicines Board (IMB).

Robert Kayum | *DD, UK*
Head of Quality Assurance with over 15 years' experience as an RP and a wealth of knowledge and experience in various aspects of Good Distribution Practice.

Dr Zvonimir Majic | *IATA Senior Consultant for Healthcare, Croatia*
Dr Zvonimir Majic is former Global Director for supply chain quality assurance and GDP in Teva Pharmaceutical Industries Ltd.

Sue Mann | *Sue Mann Consultancy, UK*
Sue Mann has spent over 35 years in the industry in various roles including technical support, clinical trial supplies and quality assurance/management.

Dr Daniel Müller | *GMP/GDP Inspectorate, Local Government, Germany*
Daniel Müller is head of the GMP Inspectorate at the local competent authority in Tuebingen, Germany.

Dr Torsten Schmidt-Bader | *moveproTEC compliance advisory, Germany*
Managing Director at moveproTEC and a GMP/GDP lead auditor and compliance advisor.

Emil Schwan | *Swedish Medical Products Agency, Sweden*
Pharmaceutical Inspector at MPA and former Senior Consultant for RegSmart Life Science AB.

Mateusz Zawadzki | *IATA , Croatia*
IATA Product Manager with years of expierence in Special Cargo Supply Chain Management.

Welcome

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

EMA: Update on Inspections, MRAs and Work Plan
N.N. Brussels

- GMP/GDP Inspectors Working Group – Priorities for 2025 and 2026
- Harmonisation of Inspections in Europe

GMP Update 2025 and Outlook 2026 – Current Trends and Developments in Europe and US
Dr Ulrich Kissel

- New concepts and elements in new directive 2023/192/EC
- The EU GMP chapters under revision
- Supply chain reliability and security
- The matters of drug shortages
- Break Through and Prime in relation to ICH Q12

EU GMP Annex 11 – The EU Draft Paper
Ib Alstrup & Dr Wolfgang Schumacher

- Compliance requirements vs. challenges for the regulated industry
- Pros and Cons of the draft – practitioner's perspective

ICH Q9 Trainingspackage: An Overview
Dr Peer Schmidt

- Overview of the ICH Q9 revision
- Hazard identification instead of risk identification
- Formality according to ICH Q9(R1)
- Risks in drug availability
- Risk-based decision-making - a daily task
- Dealing with subjectivity
- The risk review

Global Functions in Pharma Large Organizations and EU GMP – A Critical Discussion
Dr Ulrich Kissel

- Why global functions? – characteristics of global function
- How far does EU GMP support global functions?
- Views and experience of the local function
- Gaps, tensions, and conflicts related to the concept of global functions
- A progressive concept to address current limitations

Summary Day 1: Impact of the Changes in GMP on the Pharmaceutical Industry
Dr Afshin Hosseiny

Agenda – Day 2 (morning): GMP Forum

25 June 2025

Artificial Intelligence and Digitalization in Pharma

Dr Joerg Stüben

- How will Artificial Intelligence (AI) influence GMP?
- Benefits and limits
- Possible consequences for the QP
- What else does the digital future bring?

Version 3.0 Equipment Qualification Good Practice Guide

Ralf Gengenbach & Dr Franz Schönfeld

- Overview about ECA´s Qualification and Validation Guide
- GEP vs GMP
- How to integrate suppliers in qualification activities
- Inspectors view on outsourcing of qualification activities

The new ECA Good Practice Guide Auditors Reference Book, Vers. 2.0

David Abraham

- Brief history
- The Journey to date
- Overview of current and future content
- Possibilities for information sharing

SOCIAL EVENTS

On 24 and 25 June 2025,
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.

Is your company interested in exhibiting at the GMP & GDP Forum 2025?

Take advantage of the unique opportunity to exhibit and get in touch with users and decision makers. Moreover, the Social Event will give you the chance to make new contacts with congress delegates and speakers in a more relaxed atmosphere.

You can find all details at:

www.gmp-conference.org/Exhibition.html

GDP Update & Outlook
Alfred Hunt

- Major GDP developments of the last few months
- Current trends in Europe and the US
- Outlook for 2025/2026

GDP Inspection Findings and Recent Trends
Emil Schwan

- Inspections of the competent authorities
- Typical GDP inspection findings

Managing a GDP Inspection to Maximise the Chance of Success
Sue Mann

- Importance of careful planning for a GDP inspection
- Specific roles throughout the inspection
- How to ensure the regulatory authority accepts your responses

Human and veterinary GDP regulations within the EU - are they really the same?
Dr Daniel Müller

- Regulatory framework for GDP
- Current relevant guidelines on GDP
- Similarities and differences, pitfalls
- Inspection focus

Resilience in the Pharma Supply Chain
Dr Martin Egger

- Current disruptions in the global supply chain and their effects
- Recommendations of the EMA to strengthen the supply chain of critical medicinal products
- Mitigation measures in the supply chain

GDP Challenges and Solutions in Ukraine's War-Torn Supply Chain
Oleksandra Bakhurynska

- BCP plan and reality
- Challenges in maintaining quality standards
- Solutions and changed approaches

Distribution Control – the magic of KPI, QPI and management dashboards for reliable GDP transports

Dr Torsten Schmidt-Bader

- Reliable pharma transports - what is wrong with global distribution?
- The world is not „GDP perfect" - how to prepare for the worst
- Transport performance - no data, no control
- KPI, QPI and dashboards - 5 critical process parameters
- Feedback & feedforward - how to implement risk principles into transportation
- Distribution control: The unknown management task in quality systems

Innovation in Pharmaceutical Quality Assurance – Enhancing Compliance and Efficiency

Robert Kayum

- IT based solutions
- Continuous improvement trends – Airlines & Logistics partners
- Temperature Control Packaging & Supply Chain Visibility
- Optimising your supply chain through reverse logistics and reusable temperature control packaging – passive and hybrid

Pharma and Healthcare Shipment Transported by Air: CEIV Pharma Certification

Mateusz Zawadzki

- IATA Temperature Control Regulations (TCR): Governance structure, regulatory context and upcoming key changes
- CEIV Pharma Program: certification scope and criteria, assessment process and upcoming enhancements

The Global Cold Chain Puzzle: Ensuring Compliance for Cold Chain Transportation

Tina Geyer

- Unraveling the GDP Maze: Understanding Global GDP Standards for cold chain transportation
- Transportation: Active and passive systems

Application of AI in Modelling Logistics Solution for Frozen Drug Substance Airfreight Transport

Dr Zvonimir Majic

- Introduction to airfreight deep frozen capabilities and solutions: Regulations beyond GDP
- Specific requirements for deep frozen APIs transported in airfreight
- The use of AI in risk-based route risk assessment for deep frozen APIs
- Airfreight route modeling and qualification under deep frozen conditions
- Ethical considerations in use of AI in pharma-airfreight

BUSINESS USE CASE:

Setting up a Logistics Network Hub – to enable Sea-Freight

Saddam Huq

- Optimize Logistics Network Design
- Selection and Assessment Criteria
- Proof of concept and Target model

Revolutionizing Quality Assurance through Automation – The Future of GDP

Michael Fleischer

- The early days of GDP – GDP Compliance in the early days
- Increased complexity in GDP – The dynamics of specialized products and therapies lead to a new mindset
- Evolution of GDP to digital – The rise of Robotic Process Automation
- Regulatory Considerations – Software qualification and validation of computerised systems

GMP & GDP FORUM 2025

Date GMP Forum
Tuesday, 24 June 2025, 09.00 – 17.15 h
(Registration and coffee, 08.30 – 09.00 h)
Wednesday, 25 June 2025, 09.00 – 12.00 h

Date GDP Forum
Wednesday, 25 June 2025, 14.00 – 18.00 h
(Registration for new participants and coffee 13.30– 14.00 h)
Thursday, 26 June 2025, 09.00 – 16.00 h

Venue
Barcelo Sants Hotel

Pl. Països Catalans, s/n
08014 Barcelona
Catalunya | Spain

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sants@barcelo.com

Early Bird until 28.02.2025

Fees (per delegate, plus VAT)

GMP FORUM	~~€ 1.790,-~~	€ 1.690,- until 28.02.2025
GDP FORUM	~~€ 1.790,-~~	€ 1.690,- until 28.02.2025
GMP & GDP FORUM	~~€ 2.980,-~~	€ 2.780,- until 28.02.2025

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.

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.

Conference language
The official conference language will be English.

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: (06221) 84 44-0 | Fax: (06221) 84 44-34
E-Mail: info@concept-heidelberg.de

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

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

MAKE YOUR RESERVATION ONLINE!

Scan QR-Code or go to www. www.gmp-conference.org to make you reservation **onlline.**

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
- ECA Good Practice Guide – GMP Auditors Reference Handbook