GDP FORUM 2025

25 & 26 June 2025 | Barcelona, Spain

A 1 ½ day Conference designed by the ECA and the European GDP Association

HIGHLIGHTS

- Major GDP Trends and Developments
- Current GDP Challenges and Solutions
- Continuous Improvement Trends
- Managing GDP Inspections
- Distribution Control
- Automation and Application of AI
- Use Cases

Background & Objectives

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. In the last few years the world of GDP has changed in scope and complexity and continues to evolve to meet new challenges with the continued aim of safeguarding public health.

This 1½ day event will cover the latest developments and best practices in this area. We have invited speakers from Regulatory Authorities, leading Organisations and the Pharmaceutical Industry to share and discuss with you the latest GDP developments.

Target Audience

The GDP Forum is of particular interest for all personnel involved in GDP – pharmaceutical storage, transportation, cold chain and distribution activities and the control of these activities.

About the GDP Association

The European GDP Association aims to support Pharmaceutical Industry, Authorities and Logistic Providers with regard to the implementation of Good Distribution Practice. It represents all stakeholders e.g. from Pharmaceutical Industry, Authorities and Logistic Providers and supports all members and stakeholders by providing them information and support in the implementation of GDP.
The Association is a not for profit organisation under the umbrella of the ECA Foundation. Membership is free to all individuals involved in Good Distribution Practice.

Find more information at www.gdp.gmp-compliance.org.

ECA Good Distribution Practices Association
An ECA Foundation Interest Group

Conference Exhibition

Is your company interested in exhibiting at the GDP Forum 2025? Take advantage of the unique opportunity to exhibit and get in touch with users and decision makers. You can find all details at:

www.gmp-conference.org/Exhibition.html

Agenda

Day 1: 25 June (afternoon)

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

- Experiences and findings during inspections of MAHs
- The reflection paper on GMP for MAHs in practise

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

SOCIAL EVENT

On 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.

Sponsored by Qualifyze Spain S.L.U.

Day 2: 26 June

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

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

AI in Pharma Distribution: Navigating Opportunities and Challenges
Aleksandar Raić

- Demand Forecasting and Inventory Optimization
- Logistics and Cold Chain Management
- Risk Management and Compliance
- Challenges in AI Adoption

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

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

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

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

Speakers

Oleksandra Bakhurynska

Quality Director, Farmsoft LLC., Ukraine

Oleksandra Bakhurynska has 15 years of experience in the pharmaceutical industry, including implementing pharmaceutical quality systems, quality control, ISO 9001:2015, obtaining wholesale distribution licenses, and passing inspections to acquire GDP and ISO 9001:2015 certifications.

Dr Martin Egger

CEO Infrareal Holding GmbH & Co. KG and *Pharmserv, Germany*

Dr Martin Egger is an experienced manager in the biotech and pharmaceutical industry with many years of experience in business development, supply chain management and quality management.

Michael Fleischer

GDP Expert - Logistics Compliance, formerly with Roche Pharma, Germany

Michael Fleischer is a certified Senior Lead Auditor in various industries, from airlines to IT. Prior to that, he was Director and Global Head of Quality for the World Courier Transport Division, where he was responsible for compliance at World Courier locations worldwide.

Tina Geyer

Associate Director Quality & Responsible Person and Lean Six Sigma Black Belt, Pfizer Pharma, Germany

Tina Geyer is Associate Director Quality & Responsible Person and Lean Six Sigma Black Belt at Pfizer Oncology. She has over 13 years of experience in the healthcare sector and industry (biotech and pharma).

Saddam Huq

Director, Cold Chain and Logistics, GlaxoSmithKline, U.K

Saddam Huq is Director, Cold Chain and Logistics at GSK. He is subject matter expert for cold chain shipment, road freight, air freight, sea freight, thermostability, controlled temperature storage, temperature excursion management, logistics, supply chain and warehousing.

Alfred Hunt

Consultant, Hunt Pharma Solutions, Ireland and European GDP Association Chairman

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).

Robert Kayum

Astellas, UK

Robert Kayum has more than 15 years' experience as an RP, with a wealth of knowledge and experience in various aspects of Good Distribution Practice. Approaching 30 years of global experience, Robert has previously worked with Softbox Systems, Envirotainer, OBG Pharmaceuticals, Unipart/NHS Supply Chain, MSI Reproductive Choices, Kammac, Masters Speciality Pharma, DD, and has consulted to organisations such as McKinsey and Eurazeo.

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. She has worked with both commercial and investigational medicinal products and most major dosage forms. She is presently a pharmaceutical consultant working for Pharmaceutical and Biopharmaceutical companies.

Dr Daniel Müller

GMP/GDP-Inspectorate Tuebingen, Germany

Daniel Müller is head of the GMP Inspectorate at the local competent authority in Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA- and overseas inspections.

Aleksandar Raić

Pontis Technology, Croatia

Aleksandar Raić is a management board member at Pontis Technology and Global VP of AI at Bridgewest Group. He began his 20+ year career at Pliva and later served as CIO at Teva Europe, followed by leading global integration efforts at Teva's headquarters in Tel Aviv.

Dr Torsten Schmidt-Bader

Managing Director, GMP/GDP lead auditor and compliance advisor, moveproTEC, Germany

Since 2010 Dr Torsten Schmidt-Bader 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.

Emil Schwan

Swedish Medical Products Agency, Sweden

Emil Schwan comes from the Swedish Medical Products Agency (MPA), where he spent eight years as a pharmaceutical inspector. As an inspector he inspected sites in Sweden and in countries outside EU, e.g. China, India, USA. After working as a Senior Consultant for RegSmart Life Science AB, he returned as an inspector with the MPA in 2021.

GDP FORUM 2025

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

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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 content:
Dr Markus Funk (Operations Director) at +49 (0) 6221/84 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 (0) 6221/84 44 22
or per e-mail at nicole.bach@concept-heidelberg.de

Fees GDP Forum € 1.790,-

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.

Join also GMP Forum directly before the GDP Forum in the same hotel and save 600 Euro!

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

Fees GMP Forum € 1.790.-
plus VAT

MAKE YOUR RESERVATION ONLINE!

Scan QR-Code or go to
https://www.gmp-conference.org/gdp-forum.html
to make your reservation **online.**

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