GMP FORUM 2025

24 & 25 June 2025 | Barcelona, Spain

A 1 ½ day GMP Conference designed by the ECA

HIGHLIGHTS

- EMA: Update on Inspections, MRAs and Work Plan
- GMP Update 2025 and Outlook 2026 – Current Trends and Developments in Europe and US
- EU GMP Annex 11 – The EU Draft Paper
- ICH Q9 Trainingspackage: An overview
- Global Functions in Pharma large organizations and EU GMP – A critical discussion
- Artificial Intelligence and Digitalization in Pharma
- Version 3.0 Equipment Qualification Good Practice Guide
- The new ECA Good Practice Guide Auditors Reference Book, Vers. 2.0

Welcome

Dear Colleagues,

I am pleased to invite you to the European GMP Forum, taking place from 24-25 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 to a three day GMP & GDP Forum

- The first 1½ days are dedicated to Good Manufacturing Practice (GMP), offering expert presentations, regulatory updates, and discussions on emerging trends and practical implementations.

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

ECA Foundation

The ECA Foundation was founded in 1999 as an independent not-for-profit organisation. It was set up to provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. To accomplish it, the Foundation also seeks involvement in European Authorities' activities - and was added to the EMA's list of eligible industry stakeholder organisations.

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.

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: 24 June

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

EMA: Update on Inspections, MRAs and Work Plan
Brendan Cuddy

- 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

Day 2: 25 June (morning)

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 EVENT

On 24 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.

Speakers

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. 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.

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.

Brendan Cuddy

European Medicines Agency (EMA)

Lead Scientific Officer at European Medicines Agency

Ralf Gengenbach

ECA Validation Group , 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 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). Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Dr Peer Schmidt

AbbVie, 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. The Director Global Quality Systems also acts as EU Authorized Representative for AbbVie´s Medical Devices. He is a member of the ICH Q9 Revision 1 Expert Working Group.

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. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Dr Wolfgang Schumacher

Chairmen ECA IT Compliance Group, Switzerland

Dr Schumacher 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

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 inclusive reporting, data management and modelling, IDMP/SPOR and quality questions.

GMP 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

Venue
Barcelo Sants Hotel

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

Tel +34 93 503 53 00
Fax +34 93 490 60 45
sants@barcelo.com

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 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.

Fees GMP Forum € 1.790,-

ECA 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 GDP Forum directly after the GMP Forum in the same hotel and save 600 Euro!

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

Fees GDP Forum € 1.790.-
plus VAT

MAKE YOUR RESERVATION ONLINE!

Scan QR-Code or go to
https://www.gmp-conference.org/gmp-forum.html
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