



# 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 biennial 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](http://www.gmp-conference.org/Exhibition.html)





## 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

## 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
- The Challenges: Difficult Audits

## 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.*

## Summary Day 1: Impact of the Changes in GMP on the Pharmaceutical Industry

*Dr Afshin Hosseiny*

# 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 gem-pex 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 Schöfeld

*GMP Inspector, Germany*

Dr Franz Schöfeld 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.



### Dr Ingrid Walther

*Pharma Consulting Walther, Germany*

Consultant, former Head of the Business Unit iv Drugs, Fresenius

Dr Walther was employed in various positions at Fresenius and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. Since July 2009 she runs her own business as consultant.

# 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

Phone: +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: +49 (0)6221/84 44 0 | Fax: +49 (0)6221/84 44 34  
info@concept-heidelberg.de

#### For questions regarding content (GMP part):

Mr Sven Pommeranz (Operations Director) at +49 (0) 6221/84 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 (0) 6221/84 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  
plus VAT

€ 1.790,-

## MAKE YOUR RESERVATION ONLINE!



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