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GMP Certification Programme
Certified Quality Assurance Manager

Speakers



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Knowledge Management

Building a Knowledge Framework in GMP

17/18 September 2025 | Hamburg, Germany



Highlights

- Knowledge Management in GMP
- Framework
- Critical Areas
- The Link to Operational Excellence and Quality Culture
- Case Study

Objectives

This 2-day Training brings together well-experienced experts to explain and discuss the basics, developments and expectations on Knowledge Management and why it is so important throughout the business. This will support you turning your company's operational excellence goals into reality.

- Get a comprehensive understanding of knowledge management (KM)
- Discuss tools and strategies to develop and implement effective KM frameworks in their organizations
- Hear about practical applications of KM to enhance compliance, quality, and operational efficiency

Whether you are just starting your KM journey or looking to enhance existing practices, this event offers valuable insights for professionals at all levels.

Background

"Knowledge management will never work until corporations realise it's not about how you capture knowledge but how you create and leverage it." – Étienne Wenger

Knowledge management has become an important cornerstone in industry practices, also in pharma, particularly with the increasing complexity of processes and stricter regulatory requirements. Efficient knowledge creation, transfer, and application are essential for maintaining compliance, minimizing mistakes and risks, eliminating waste of time and driving innovation. This course delves into the "what," "why," and "how" of KM in GMP, providing attendees with actionable insights to strengthen their systems and ensure long-term success in a competitive industry.

Target Audience

Managers and Executives from pharmaceutical Quality Management but also Business Executives and Operational Managers and those involved in KM initiatives.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg

Programme

Knowledge Management in GMP

- Examples of Knowledge Management requirements
- Examples from other industries and within pharma
- ISO 30401 and what pharma can learn from this standard
- ICH Q8, Q9 and Q10 Questions & Answers Document
- Impact on compliance, efficiency, and quality
- Tying KM to CAPA, change management, and quality systems
- KM and QRM, opposing forces or essential partners?
- The Ontology Pipeline

Building a Knowledge Management Framework in GMP

- Part 1
 - Core components: people, processes and technology. How they interact and reinforce each other.
 - Tools for knowledge management (A3, fishbone, process mapping)
- Part 2
 - Steps to develop and implement a Knowledge Management system
 - Ensuring your KM arrangements are compliant with Inspectors expectations (EU GMP Volume 4 Annex 11, CFR Part 11, GAMP 5)
 - Exploring the Risk-Knowledge Infinity Cycle (RKI Cycle) across the Product Lifecycle



Workshops:

Identifying critical Knowledge Areas

The workshop is based around a manufacturing process of a complex biotech product, problems have arisen in the manufacturing process and the task of the participants is to assess the problems and to identify where the application of KM would have prevented the problems arising.

What goes in? Stimulation of the Creation of new Knowledge (Creating a Knowledge Sharing Culture)

- Continuous improvement - radical innovation
- Breakthrough innovation, removing barriers in our thinking

Smart GMP: How Knowledge Management drives Operational Excellence

- Role of standards, SOP's and work instructions as knowledge carriers
- Making knowledge available at point of use



Case Study UCB: Strategies for Knowledge Transfer

- Where do we come from?
- Where are we now?
- Where do we want go?
- Lessons learned, the use of databases, IT-platforms and other tools

Social Event

In the evening of the first day, you are cordially invited to a social Event (city tour and dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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Speakers



Bertrand Dodelet
UCB Biopharma SPRL, Belgium

CMC Knowledge Management Community Head
Bertrand Dodelet is industrial pharmacist and CMC Knowledge Management Community Head.



Arnoud Herremans
Y47 Consultancy, The Netherlands

Lean Kaizen Coach
Arnoud Herremans was Senior Scientist at Solvay Pharmaceuticals and Research Unit Manager at Abbott Healthcare. He has a psychological background (Behavioral Neuroscience at Utrecht University) and has been applying Lean - 6Sigma and Kaizen methods to the life sciences industry.



Aidan Madden
FivePharma, Ireland

CEO
Aidan Madden is CEO of FivePharma, a Quality Services Company founded in 2003. Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories.

Your benefits:

This Training Course is recognized for the GMP/GDP Certification Scheme "Quality Assurance Manager"



Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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

Reservation Form (Please complete in full)

Knowledge Management | 17/18 September 2025, Hamburg, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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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:
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 - Cancellation until 3 weeks prior to the conference 25 %,
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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 http://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

Wednesday, 17 September 2025, 9.30h – 17.30h
(Registration and coffee 9.00 – 9.30 h)
Thursday, 18 September 2025, 8.30h – 15.30h

Venue

Barceló Hotel Hamburg
Ferdinandstraße 15
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Germany
Phone: +49 (0) 40/22 63 62 0
E-Mail: hamburg.res@barcelo.com

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes lunch on both days, dinner on the first day and all refreshments.

Accommodation

CONCEPT 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.

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.

Registration

Via the attached reservation form, by e-mail or by fax – **or search and register directly at www.gmp-compliance.org under the number 22075.**

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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