



Speakers



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Knowledge Management

Building a Knowledge Framework in GMP



Live Online Training on 17/18 September 2025



Highlights

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

Objectives

This 2-day Live Online 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



Examples:

Identifying critical Knowledge Areas

This session 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



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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

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Reservation Form (Please complete in full)

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Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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Date of the Live Online Training

Wednesday, 17 September 2025, 9.00h – 17.30h

Thursday, 18 September 2025, 8.30h – 15.30h

All times mentioned are CEST.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. 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.** To avoid incorrect information, please give us the exact address and full name of the participant.

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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