ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Auditor

Speakers

Dr Anke von Harpe
QProgress, Germany

Cecilie Hejlskov
Syntese, Denmark

Arnoud Herremans
Lean Kaizen Consultant,
The Netherlands

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Dr Frank Seibel
Roche Diagnostics, Germany

Right-sizing GMP and Compliance

How to implement Lean GMP-Systems

13/14 March 2025 | Barcelona, Spain

Highlights

- Basics of Lean Thinking
- Case studies:
  - Linking Lean and Quality
  - Lean Documentation Systems
  - Lean and Kaizen in the Quality System
- Interactive Sessions:
  - A3 Lean Thinking Approach
  - Lean Process Management
  - Right-sizing GMP and Compliance

Compliance – Efficiency – Quality

Objectives

Learn how to design lean, efficient and compliant Quality and GMP-Systems that will support you in turning your quality goals into reality.

Background

Good Manufacturing Practices (GMP) in the pharmaceutical industry are designed to ensure that products are consistently produced and controlled according to defined quality standards. However, some companies tend to overinterpret regulations, leading to unnecessary processes that can inflate costs and reduce efficiency. To right-size GMP and compliance, and move towards lean GMP-systems while still adhering to regulations and being compliant, companies can consider several strategies and use various tools. By focusing on these, companies can develop lean GMP-systems that are not only compliant but also optimised for efficiency and effectiveness. It's about finding the right balance between ensuring product quality and safety while eliminating unnecessary costs and processes.

Target Audience

Managers and Executives from pharmaceutical Quality Management and Assurance, Business Executives and Production Managers and those involved in continuous improvement projects.

Moderator

Wolfgang Schmitt, CONCEPT Heidelberg (on behalf of ECA)

Programme

Less is more: Insights from continuous Improvement to bring GMP to the Size you need

- What does lean thinking mean (and what does non-lean thinking mean)?
- Role of Quality functions
- Customer value
- Examples for problem solving tools
- Continuous improvement

Lean Process Management: Case Studies & Template Tools

- PfC Analysis
- Process Competent Assessment
- Effectiveness Check
- Templates

Linking Lean and Quality

- Using Lean Thinking for Improvements in the Quality Management System (QMS)
- Potential Target Areas of Lean
  - QC backlog
  - Timely deviation closure
  - Batch Record Review
  - “Non Make/Assess/Release”- areas
  - Lean leadership

Interactive Sessions

Coaching and Mentoring your People towards better GMP Improvements
Learn and discuss the A3 lean thinking approach as a learning practice, problem solving tool and knowledge sharing.

Lean Process Management: Workshop with Theory and Group Excersises
Learn to manage your quality processes in a practical and lean way through an interactive workshop with theory and group exercises.

Right-sizing GMP and Compliance
- The ‘What’ vs the ‘How’ - what is the right ratio?
- How to apply ‘Ensuring’ and ‘Controlling’ in a balanced manner
- The ‘7 deadly sins’ of right-sized compliance
- Ways to implement

Lean (Documentation) Systems

- Background
- Tools and structural elements for efficient GMP documents
- Training – how to ensure the right level for each role
- Case study: Batch Record Review to the point

Kaizen as a Powerful Tool for Optimisation of Complex Processes

- Does the system fit to the company?
- Methods for determining needs and finding solutions
- Customer-oriented project planning as a central success factor

Using LEAN Thinking for Improvements in the Quality Management System (QMS)

- Experiences in using LEAN/Six sigma methodology for QMS improvements
- Examples of process simplifications
- Deep dive in creating a LEAN CAPA process

Your Benefits:

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:
„... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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This Training Course is recognized for the Quality Assurance Manager Certification Scheme

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

Dr Anke von Harpe
QProgress GmbH, Germany

Dr Anke von Harpe started her consultancy business in 2018. Prior to that, she held various senior QA positions in the pharmaceutical industry, including QP and Director Quality Systems.

Cecilie Hejlskov
Syntese A/S, Denmark

Cecilie Hejlskov is Operational Excellence Manager at Syntese (a Ferring company). Some of her former positions include Specialist in Global Operational Excellence, Value Stream Manager and Lean Office Manager. Cecilie also has a Lean Six Sigma Green Belt Certification.

Arnoud Herremans
Lean Kaizen Consultant, Netherlands

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

Christof Langer
OSConsulting, Austria

Christof Langer is a certified Risk Manager, Lean Six-Sigma Black Belt and independent consultant. Before that, he was Managing Director at Baxter BioScience (now Shire) in Switzerland and the Czech Republic.

Dr Frank Seibel
Roche Diagnostics GmbH, Germany

Dr Frank Seibel is Quality Site Head at Roche Diagnostics in Mannheim. Before that he was, amongst others, Senior Vice President Corporate Quality & HSE at Aenova Holding and Director Global Manufacturing Quality Strategy at AbbVie.

Social Event

On 13 March 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.

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

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GERMANY

Reservation Form (Please complete in full)

Right-sizing GMP and Compliance
13/14 March 2025 | Barcelona, Spain

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **Terms of payment**: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of 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 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
Thursday, 13 March 2025, 9.00h – 17.30h
(Registration and coffee 8.30h – 9.00h)
Friday, 14 March 2025, 8.30h – 14.45h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n | 08014 Barcelona, Spain
Phone: +34 (93) 503 53 00
E-mail: sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members EUR 1,890.-
APIC Members EUR 1,990.-
(does not include ECA Membership)
Non-ECA Members EUR 2,090.-
EU GMP Inspectorates EUR 1,045.-
The conference fee is payable in advance after receipt of invoice and includes lunch on both days and all refreshments. VAT is reclaimable.

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.

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 21671.

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.

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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