ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Auditor

Speakers

Dr Anke von Harpe
QProgress, Germany

Arnoud Herremans
Lean Kaizen Consultant,
The Netherlands

Cecilie Hejlskov
Syntese, Denmark

Wolfgang Schmitt
Concept Heidelberg, Germany

Dr Frank Seibel
Roche Diagnostics, Germany

Lean GMP Systems

Compliance – Efficiency – Quality

27/28 June 2024 | Barcelona, Spain

Highlights

- How Lean Thinking supports our GMP Status
- Basic Lean SixSigma Tools
- Case studies:
  - Linking Lean and Quality
  - Lean Documentation Systems
  - Lean and Kaizen in the Quality System
  - Hub Release Process Optimisation
- Parallel Sessions:
  - A3 Lean Thinking Approach
  - Lean Management of Quality Processes
  - Risk Assessment and Criticality Analyses in API Manufacturing

With a Workshop on the Application of Lean and SixSigma Tools

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

Those of us in the competitive and highly regulated pharmaceutical industry understand the need to balance operational efficiency with regulatory compliance. We must find ways to reduce complexities, eliminate redundancies and streamline operations while staying compliant with an array of regulations and guidance documents. Making changes to our quality processes requires overcoming challenges arising from these often competing interests.

However, to face regulatory requirements and expectations, pharmaceutical quality systems have been becoming more and more complex over the past years. In many companies, this has led to a certain inflexibility and inefficiency. But quality related processes, procedures and their related documents should monitor and support, not constrain the true core competence of pharmaceutical companies: the manufacture of cost-effective medicines and APIs at highest quality and in compliance with the regulations.

Quality Managers need to know how to fulfil the regulatory requirements efficiently and how to implement the necessary processes in a lean and cost-effective manner that supports efficacy and safety.

Target Audience

Managers and Executives from pharmaceutical and API 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

How Lean Thinking supports our GMP Status (Basic Lean SixSigma Tools)

- Background and definitions:
  - Lean thinking
  - Customer value
  - Continuous improvement
  - Waste (in a process)
- Fundamental problem-solving tools used to support Lean Six Sigma and other process improvement efforts

Workshops

The A3 Management Process and how to apply it
Learn and discuss the A3 lean thinking approach as a learning practice, problem solving tool and knowledge sharing.

Lean Management of Quality Processes
Learn to manage your quality processes in a practical and lean way through an interactive workshop with theory and group exercises.

- Process competence Assessment
- PfC Analysis
- Stability, complexity and control
- Tailored process controls
- Practical Lean accounting

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.

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

Case Studies:

Linking Lean and Quality

Discussion of various case studies in two interactive sessions, for example:

- Use historic data
- Get out of a mess
- Make use of a network

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

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.

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.

Cecilie Hejlskov
Syntese A/S, Denmark

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

Wolfgang Schmitt
Concept Heidelberg, Germany

Wolfgang Schmitt is Vice President and organises and conducts courses and conferences on behalf of the ECA Academy in the areas QA and GMP. Before that Wolfgang was Associate Director, QP and GMP-Auditor at Abbott.

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.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Lean GMP Systems
27/28 June 2024 | 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, 27 June 2024, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Friday, 28 June 2024, 8.00h – 14.30h

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 1.690.-
APIC Members EUR 1.790.-
(does not include ECA Membership)
Non-ECA Members EUR 1.890.-
EU GMP Inspectorates EUR 945.-
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 message. Or you register online at www.gmp-compliance.org.

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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64 | D-69007 Heidelberg
Phone: +49(0) 62 21/84 44-0
Fax: +49(0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content please contact:
Mr Wolfgang Schmitt (Operations Director) at
+49(0) 62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Helm (Organisation Manager),
at +49(0)6221 / 84 44 49 or per e-mail at
helm@concept-heidelberg.de