ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Auditor

Speakers

Anke von Harpe
QProgress

Arnoud Herremans
Lean Kaizen Consultant

Dr Andreas König
Quality König

Linda Reijinga
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Dr Frank Seibel
Roche Diagnostics

Francois Vandeweyer
VDWcGMP Consulting

Lean GMP Systems

Compliance – Efficiency – Quality

28/29 June 2023 | Vienna, Austria

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:
  - Lean and SixSigma Tools Application
  - Efficient Data Pooling
  - 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

Parallel sessions (2 out of 3):

1. **APIs: How to use Risk Assessment and Criticality Analyses to improve Quality Processes**
   - How to develop syntheses and process criticality analyses and use the benefit in:
     - Lean deviation handling
     - Lean batch record review
     - Lean release process

2. **Lean and SixSigma Tools and how to apply them**
   Learn and discuss how to implement and use the most important Lean SixSigma tools.

3. **Efficient Data Pooling: KPIs, PQR, APR, Management Review**
   - How to define meaningful KPIs?
   - What are useful KPIs?
   - What risks are involved using KPIs?
   - How to drive the development of an underperforming Quality System

You will be able to attend 2 of these sessions.

Please choose the ones you like to attend when you register for the course.

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

Optimisation of the Ferring Supply Process and EU Hub Release

- Process analysis
- Improvement actions
- Evaluating and Monitoring Effectiveness

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 Coach, 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.

Dr Andreas König
Quality König GmbH, Germany

Dr Andreas König is General Manager of Quality König GmbH. Before that he was amongst others Senior Vice President Corporate Quality & HSE at Aenova Holding GmbH and Vice President Global Quality Operations Animal Health at Schering Plough.

Linda Reijinga
Ferring GmbH, Germany

As QA-Manager, Linda Reijinga is responsible for GMP-Training and reporting of Quality KPIs. She is also the system architect for the tracking tool for planning, manufacturing and supply status. Linda is a certified Green Belt.

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.

Francois Vandeweyer
VDWcGMP consulting GCV, Belgium

Francois Vandeweyer was Director Pharmaceutical Regulatory Compliance EMA/APAC at Janssen Pharmaceutica. In 2019 he started his own Consultancy office.

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GERMANY

Reservation Form (Please complete in full)

Lean GMP Systems, Live Online Training on 28/29 June 2023

Please choose TWO sessions:

☐ *APIs: How to use Risk Assessment and Criticality Analyses to improve Quality Processes*
☐ *Lean and SixSigma Tools and how to apply them*
☐ *Efficient Data Pooling: KPIs, PQR, APR, Management Review*

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 %.

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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 January 2012).
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 https://www.gmp-compliance.org/privacy-policy). 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, 28 June 2023, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Thursday, 29 June 2023, 8.30h – 15.30h

Venue

Radisson Blu Park Royal Palace Hotel
Schlossallee 8 | 1140 Vienna | Austria
Tel.: +43 1/89110
E-Mail: info.parkroyalpalace.vienna@radissonblu.com
On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on-site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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.

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