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
Fidelio Healthcare

Linda Reijinga
Ferring

Michael Schousboe
Novo Nordisk

Francois Vandeweyer
VDWcGMP Consulting

Lean GMP Systems

Compliance – Efficiency – Quality

Live Online Training on 06/07 May 2021

Highlights

- How Lean Thinking supports our GMP Status
- Lean and SixSigma Tools Application
- Efficient Data Pooling
- Risk Assessment and Criticality Analyses in API Manufacturing
- Case studies:
  - Linking Lean and Quality
  - Lean Documentation Systems
  - Kaizen in the Quality System
  - Hub Release Process Optimisation

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)

Your Benefits: Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

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

Lean and SixSigma Tools and how to apply them

Learn and discuss how to implement and use the most important Lean SixSigma tools.

Case Studies:

Linking Lean and Quality

Discussion of various case studies in two dedicated 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

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

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

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

Case Study:

Optimisation of the Ferring Supply Process and EU Hub Release

- Process analysis
- Improvement actions
- Evaluating and Monitoring Effectiveness

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

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

Speakers

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
Fidelio Healthcare Limburg GmbH, Germany

Dr Andreas König is General Manager of Fidelio Healthcare Limburg GmbH, a new CDMO. 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.

Michael Schousboe
Novo Nordisk, Denmark

Michael Schousboe is Senior QMS Specialist, Quality Risk Management in the Corporate Quality function of Novo Nordisk. He has the overall responsibility for maintaining the Quality Risk Management processes across the quality management system.

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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Reservation Form (Please complete in full)

Lean GMP Systems | Live Online Training on 06/07 May 2021

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:
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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 of the Live Online Training

Thursday, 06 May 2021, 9.00h – 17.30h
Friday, 07 May 2021, 8.30h – 16.00h
All times mentioned are CEST.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice.

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 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.

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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