ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Auditor

Speakers


María J. Prol García
Novo Nordisk


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Ferring


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Lean GMP-Systems

Compliance – Efficiency – Quality

28/29 April 2020 | Barcelona, Spain

Highlights

- How Lean Thinking supports our GMP Status
- Basic Lean SixSigma Tools
- Case studies:
  - Linking Lean and Quality
  - Lean Documentation Systems
  - Lean CAPA process
  - 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

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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

Speakers

María J. Prol García
Novo Nordisk, Denmark

María J. Prol Garcia is QMS Specialist in the Corporate Quality function of Novo Nordisk. She is responsible for the CAPA System that complies with requirements from authorities, Novo Nordisk QMS and business needs across the company.

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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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Lean GMP-Systems, 28/29 April 2020, Barcelona, Spain

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week 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
Tuesday, 28 April 2020, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 29 April 2020, 8.30h – 15.30h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG 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.

Certificate of Attendance
Shortly after the event, you will receive your certificate of attendance byw email.

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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