Speakers

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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
Programme

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 Six Sigma 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 Six Sigma Tools and how to apply them
   Learn and discuss how to implement and use the most important Lean Six Sigma 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

Dr. María J. Prol García
Novo Nordisk, Denmark

Dr. María J. Prol García 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, Six Sigma 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 Pharmaceuticals. In 2019 he started his own Consultancy office.
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