ECA Academy
Your GMP/GDP Information Source

Lean GMP Systems

Compliance – Efficiency – Quality

SPEAKERS:

Arnoud Herremans
Lean Kaizen Consultant

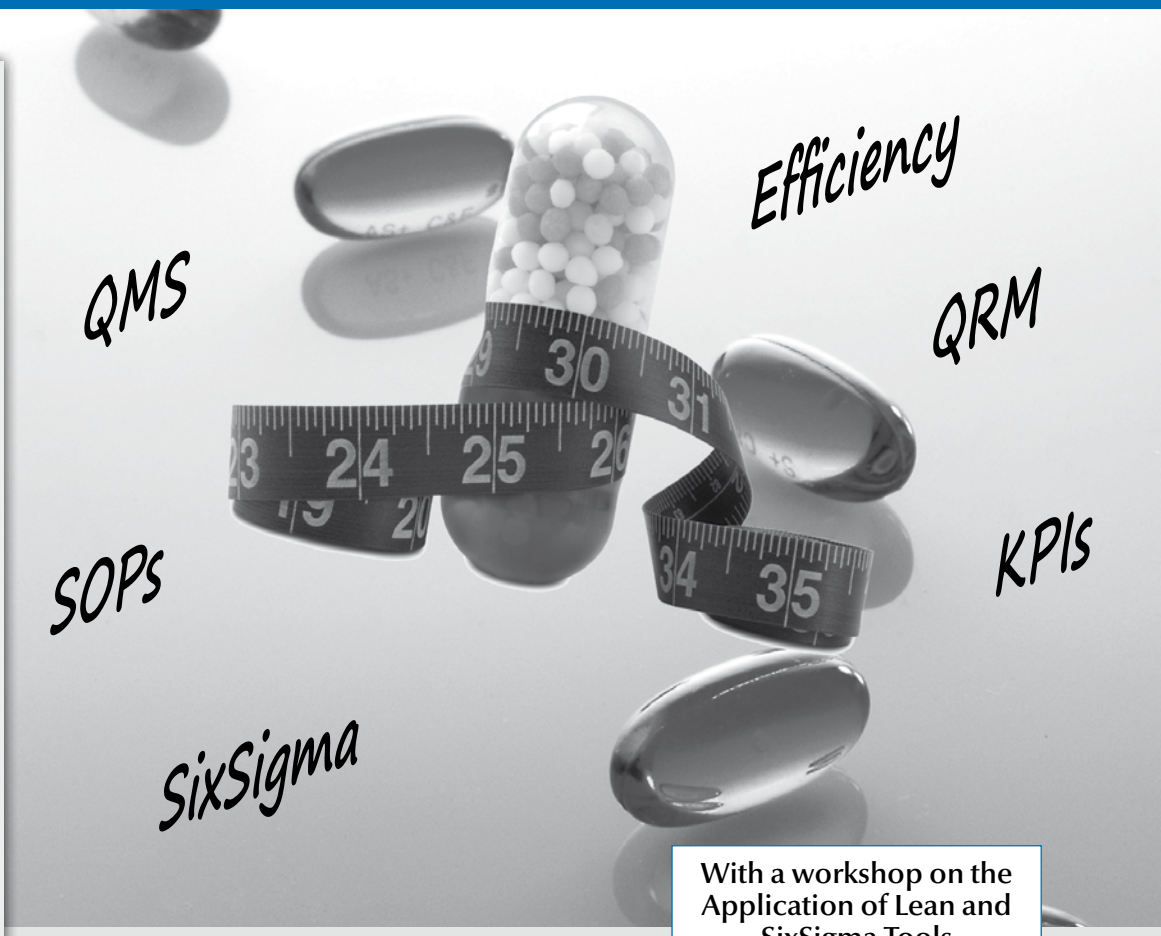
Dr Afshin Hosseiny
Tabriz Consulting

Dr Andreas König
Quality König

Linda Reijinga
Ferring

Dr Bernd Renger
ECA

Francois Vandeweyer
Janssen Pharmaceutica



With a workshop on the Application of Lean and SixSigma Tools

18-19 June 2019, Copenhagen, Denmark

LEARNING OBJECTIVES:

- The Role of the Quality Organisation
- Modern Quality Management Systems (QMS)
- Basic Lean SixSigma Tools
- Case studies:
  - Linking Lean and Quality
  - Lean SixSigma Tools in Practice
  - Reducing the Number of SOPs
  - Process Criticality Analysis
- Parallel Sessions:
  - Lean and SixSigma Tools Application
  - Efficient Data Pooling
  - How to implement new Regulations

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager".
Please find details at www.gmp-certification.eu

Lean GMP Systems

18-19 June 2019, Copenhagen, Denmark

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, guidance documents and regulations. Making changes to our quality processes requires overcoming challenges arising from these often competing interests.

However, to face regulatory requirements and e xpectations, 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 control 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 Quality Management and Assurance, Business Executives and Production Managers and those involved in continuous improvement projects. But also Quality and Business executives from smaller organisations with highly constrained resources.

Moderator

Wolfgang Schmitt

Programme

The Role of the Quality Organisation

- How do you measure quality?
- How to facilitate quality based decisions using risk management techniques
- Developing a QA organisation to support seamless operations: How can QA manage
  – process validation
  – change management
  – batch disposition
  – inspection readiness
  without reducing efficiency and increasing costs

Basic Lean SixSigma Tools

- Fundamental problem-solving tools used to support Lean Six Sigma and other process improvement efforts

Parallel sessions (2 out of 3):

1. How to implement new Regulations

- Is there a need to immediately implement any new regulation?
- How to implement them without disrupting day to day activities
- How to avoid failure to comply with the new requirements
- Are alternative approaches possible (can we always rely on a risk based approach)?

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

How to reduce the Number of SOPs while remaining in Compliance

- Rationalise the existing SOPs
- Reduce the total number
- Introduce an efficient SOP review process
- Remain compliant with the cGMP requirements

How to use Lean SixSigma Tools in Practice

- Example: Optimisation of the Ferring EU hub release processes
- Process analysis
- Improvement actions
- Evaluating and Monitoring Effectiveness

Process Criticality Analysis

- How to develop syntheses and process criticality analyses and use the benefit in:
  - Lean deviation handling
  - Lean batch record review
  - Lean release process

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.

Speakers

Arnoud Herremans

Lean Kaizen Coach, The 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 Afshin Hosseiny

Tabriz Consulting, form. GSK, U.K.

Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. and formerly Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. Afshin is a QP and Chairman of the ECA Executive Board.

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, Project Management and the reporting of Quality KPIs. She has led the project of the Ferring EU hub release processes optimisation.

Dr Bernd Renger

Bernd Renger Consulting, Germany

Dr Bernd Renger is a member of the ECA Advisory Board and was Chairman of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung.

Francois Vandeweyer

Janssen Pharmaceutica, Belgium

Francois Vandeweyer is Director Pharmaceutical Regulatory Compliance EMA/APAC. He has also started his own Consultancy office (VDWcGMP consulting GCV).

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Lean GMP Systems
18-19 June 2019, Copenhagen, Denmark

Please choose TWO sessions:
☐ How to implement new Regulations
☐ Lean and SixSigma Tools and how to apply them
☐ Efficient Data Pooling: KPIs, PQR, APR, Management Review

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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 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 http://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

Tuesday, 18 June 2019, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 19 June 2019, 8.30h – 15.30h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 3396 50 00
Fax +45 3396 55 00
Scandinavia.meetings.events@radissonblu.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 event. Reservation should be made directly with the hotel. Early reservation is recommended.

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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