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# Lean GMP Systems

## Compliance – Efficiency – Quality

### SPEAKERS:



**Arnoud Herremans**  
*Lean Kaizen Consultant*



**Dr Afshin Hosseiny**  
*Tabriz Consulting*



**Dr Andreas König**  
*Quality König*



**Linda Reijnga**  
*Ferring*



**Dr Bernd Renger**  
*ECA*



With a workshop on the  
Application of Lean and  
SixSigma Tools

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17-18 April 2018, Vienna, Austria

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### LEARNING OBJECTIVES:

- Efficiency without compromising Quality
- Modern Quality Management Systems (QMS)
- In Time Management of Quality
- Case studies:
  - Linking Lean and Quality
  - Lean SixSigma Tools in Practice
  - Reducing the Number of SOPs
- Parallel Sessions:
  - Lean and SixSigma Tools Application
  - Efficient Data Pooling
  - Managing Quality and Compliance



# Lean GMP Systems

17-18 April 2018, Vienna, Austria

## Objectives

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Learn how to design lean, efficient and compliant Quality and GMP Systems that will support you in turning your quality goals into reality.

## Background

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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 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 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

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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

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Wolfgang Schmitt

## Programme

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### How to gain Efficiency in the Quality Unit without compromising Quality

- Systems to reduce deviations
- How do you measure quality?
- How to develop a control strategy
- How to facilitate quality based decisions using risk management techniques

### Basic Lean SixSigma Tools

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

### The modern QA Organisation

- Developing a QMS to support business objectives while remaining compliant
- Developing QA organisation to support seamless operations: How can QA manage
  - process validation
  - change management
  - batch disposition
  - inspection readinesswithout reducing efficiency and increasing costs

### Parallel sessions (2 out of 3):

#### 1. The Hare and the Hedgehog - new Regulations and how to implement them in a lean and efficient Way

- How can companies cope with the requirement to have something like a "regulatory and GMP intelligence"
- Is there a need to immediately implement any new regulation?
- How do we deal with guidelines that allow alternative approaches?
- Efficient Change Management

#### 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 KPI
- 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

## 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, SixSigma 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 with over 25 years experience and member of the ECA advisory board.



### Dr Andreas König

*Quality König GmbH, Germany*

Dr Andreas König is General Manager of Quality König GmbH. Until 2016 he was Senior Vice President Corporate Quality & HSE at Aenova Holding GmbH. Before that he was Vice President Global Quality Operations Animal Health at Schering Plough, Global Quality Director at Intervet and Head of QC and QA at Fresenius Kabi.



### Linda Reijnga

*Ferring GmbH, Germany*

As QA-Manager, Linda Reijnga is responsible for GMP-Training, Project Management and the reporting of Quality KPIs. She has lead 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. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma.

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

**Lean GMP Systems**

17-18 April 2018, Vienna, Austria

- Please choose TWO sessions:
- The Hare and the Hedgehog - new Regulations and how to implement them in a lean and efficient Way?
  - Lean and SixSigma Tools and how to apply them
  - Efficient Data Pooling: KPIs, PQR, APR, Management Review

Mr  Ms

Title, first name, surname

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Important: Please indicate your company's VAT ID Number

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E-Mail (please fill in)

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 Fax +49 (0) 62 21/84 44 34  
  
 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 week prior to the conference 50 %

- within 1 week prior to the conference 100 %

CONCEPT HEIDELBERG reserves the right to change the materials, in-

structors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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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](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, 17 April 2018, 9.00 h - 18.00 h  
 (Registration and coffee 8.30 h - 9.00 h)  
 Wednesday, 18 April 2018, 8.30 h - 15.30 h

**Venue**

Radisson Blu Park Royal Palace Hotel Vienna  
 (former Austria Trend Hotel)  
 Schlossallee 8  
 1140 Vienna, Austria  
 Phone +43 (1) 891 10 - 0  
 Fax +43 (1) 891 10-9090  
 Email [park.royal.palace@austria-trend.at](mailto:park.royal.palace@austria-trend.at)

**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 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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**For questions regarding content:**

Wolfgang Schmitt (Operations Director) at +49-62 21 / 84 44 39, or per e-mail at [w.schmitt@concept-heidelberg.de](mailto:w.schmitt@concept-heidelberg.de).

**For questions regarding reservation, hotel, organisation etc.:**

Mr Niklaus Thiel (Organisation Manager) at +49-62 21 / 84 44 43, or per e-mail at [thiel@concept-heidelberg.de](mailto:thiel@concept-heidelberg.de).