Continuous Quality Improvement

Process Analysis, KPIs and GMP Performance Measures

24-25 March 2015, Heidelberg, Germany

SPEAKERS:

Dr Siegfried Hackl
Boehringer Ingelheim

Arnoud Herremans
Lean Kaizen Consultant

Michael Hopper
GxPpro

Dorthe Christina Kroun
Bavarian Nordic A/S

Aidan Madden
FivePharma

HIGHLIGHTS:

- Continuous Quality Improvement
  - Techniques and Implementation
- Transform Strategy into Action
  - Balanced Scorecard
  - Change Management as the Key
- Case Studies
  - Cycle Time of Documents
  - Deviation Reporting and CAPA
  - Quality Metrics as a Key Driver
- Workshops
  - KPIs and GMP Performance
  - Analysis Tools for Assessing and Optimising Process Flows

ECA ACADEMY

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

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Objectives

This Course will show you examples and possibilities which will help you improving your quality performance. You will learn how to use the various tools to drive Continuous Quality Improvement.

Background

The quality of pharmaceutical products is determined by the effectiveness of the Quality System and the people operating it. Unfortunately, many Quality Systems have become complex, slow and bureaucratic.

To remain 'regulatory compliant' and to reduce costs, systems and processes must be evaluated and the respective processes simplified and controlled. Important tools in this context are accurate GMP performance measures and analysis, the right Key Performance Indicators (KPIs) and tools like the Balanced Scorecard.

Although **ICH Q10** is still reproduced in Part III of the **EU-GMP Guide**, several principles of ICH Q10 have been incorporated into the new Chapter 1of Part I, including continuous and continual improvement.

This course will provide you with practical guidance on:

- How to select the right KPIs and Quality Metrics for your Quality System
- How to make your Quality System more efficient
- How to improve your processes
- How to reduce costs

Target Audience

QA personnel who wants to improve their quality systems and increase performance and regulatory compliance but also managers and supervisors who are responsible for cost effective and 'low risk' quality operations.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg

Programme

A: Continuous Quality Improvement

The basics of Continuous Quality Improvement

- History
- Applicability
- Outlook

Techniques to evaluate Quality Performance

- Process Analysis
- Root Cause Analysis
- Cause-and-Effect Diagrams
- Risk Assessment
- Quality Cockpit
- KPIs, Tracking & Trending

Implementation of Continuous Quality Improvement

- Pre-requisites inside a company
- Accountability and ownership
- Planning of resources
- Business culture
- Empowerment of people

B: Transform Strategy into Action

Implementation and efficient Use of a Balanced Scorecard

- Balanced Scorecard as a strategic performance management tool
- Design
- Implementation

Change Management as the Key

- How shift individuals, teams, and organisations from a current state to a desired future state
- How to organise processes to empower employees to accept and embrace changes in their current business environment
- 8 Steps of Change (Kotter)

Case Studies:
How to translate Data and Knowledge into Action

- Case study 1: Cycle Time of Documents
- Case study 2: Deviation Reporting and CAPA Systems
- Case Study 3: Quality Metrics as a Key Driver for CQI

C: Workshops

- KPIs and GMP Performance Measures
- Analysis tools for Assessing and Optimising Process Flows

Speakers

Dr Siegfried Hackl
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Siegfried Hackl is Head of Life Cycle Management for the product Respimat. In his 20 years of experience in the pharmaceutical and biotech industry, he was heading various functions such as Aseptic Manufacturing, Quality Assurance, BPE/ Lean and Site Head of the BI Mexico plant.

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 (Behavioral Neuroscience at Utrecht University) and has been applying Lean - 6Sigma and Kaizen methods to the life sciences industry.

Michael Hopper
GxPpro, U.K.
Michael (Mick) Hopper set-up GxPpro after leaving Pfizer and has been working as a consultant. Mick has over 30 years experience of working in the pharmaceutical Industry, where he held several Technical, Management and QA roles. He also gained a green belt accreditation and led the implementation of several improvement initiatives including Human Error management, Quality Risk Management and yellow belt development.

Dorthe Christina Kroun
Bavarian Nordic A/S, Denmark
Dorthe Kroun holds an MSc in Quality Management in Scientific Research and Development from Cranfield University, UK and is currently heading a QA Support department at Bavarian Nordic, Denmark. Before that she was QA Director at Contura International A/S and QA Officer at Novo Nordisk A/S.

Aidan Madden
FivePharma, Ireland
Aidan Madden is Managing Director and Senior Consultant with FivePharma. Before that he was Quality Manager at Wyeth, Senior Microbiologist at Baxter and QC Manager at Fort Dodge Laboratories. He was also working at Teagasc, a government research laboratory and at the National University of Ireland in Galway.

Social Event

At the end of the first day of the course you are invited to take part in an evening programme. This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.

Heidelberg – Optimal Accessibility via Frankfurt Airport

Lufthansa Shuttle Bus: It leaves Frankfurt Airport approximately every 60 minutes to the Heidelberg Crowne Plaza Hotel, which is less than 1 km away from the nH-Hotel.
Info: http://www.lufthansa.com/de/en/Lufthansa-Airport-Bus
Airport Shuttle Service: Airport shuttle services bring you promptly and reliably from the airport to your hotel.
Info: https://www.tls-heidelberg.de/en/home/
Train: You can get on the train at the Airport Station.
A train leaves up to three times per hour and it usually takes less than one hour to get to Heidelberg.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme "Certified Quality Assurance Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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

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Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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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 %,
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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)

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Date

Tuesday, 24 March 2015, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 25 March 2015, 8.30 h – 15.00 h

Venue

nH-Hotel Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
Phone +49 (0)6221 1327 0
Fax +49 (0)6221 1327 100

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.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

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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