ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Cecilie Hejlskov
Syntese, Denmark

Arnoud Herremans
Lean Kaizen Consultant,
The Netherlands

Henny Koch
Qimp B.V., The Netherlands

Dorthe Christina Kroun
MinervaX, Denmark

Christof Langer
OSConsulting, Austria

Jason McGuire
Fagron, USA

Prof Florian Priese
Anhalt University of Applied Sciences

KPIs and Quality Metrics

How to foster Continual Quality Improvement

09/10 April 2025 | Berlin, Germany

Highlights

- Key Performance Indicators (KPIs)
- Continual Quality Improvement (CQI)
- Correlation with Process Controls, Quality Costs and Business Continuity
- Psychological Aspects
- Case Studies:
  - FDA's Quality Metrics Program
  - Deviations Handling
  - Quality Metrics as a Key Driver for CQI

Objectives

This 2-day Master Class brings together well-experienced experts to discuss the latest expectations and requirements for Quality Metrics and KPIs and how they are linked to Continual Quality Improvement (CQI), the cost of non-conformance and Business Continuity. This will support you turning your company's quality excellence goals into reality.

Background

To remain 'regulatory compliant' and to ensure the continuity of product supply in a cost-effective way, systems and processes must be evaluated and the respective processes simplified and controlled. Important tools in this context are accurate Quality Metrics, the right Key Performance Indicators (KPIs) and Continual Quality Improvement.

Quality Metrics in itself are not new, though. They have already been used in pharmaceutical industry for years –mainly internally to measure operational performance. But quality can be measured on different levels and for many processes. Done in the right way, Quality Metrics can enable companies to reach a high-quality performance. They will benefit from a continuous improvement in both operational performance and GMP compliance. And both are important for the continuity of business and product supply.

Target Audience

Managers and Executives from pharmaceutical Quality Assurance and Quality Management but also Business Executives and Production Managers and those involved managing the continuity of product supply.

Moderator

Wolfgang Schmitt, on behalf of ECA

Social Event

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

Programme

Quality Metrics and Beyond

- Expectations of the agencies
- Quality Culture as the basis for quality improvements
- How to involve the management in Quality Metrics
- Set up of a practical review system
- Follow up actions on management reviews

Integration of Quality Metrics Systems and KPIs in Continuous Improvement and Business Continuity

- Understanding critical processes & where quality risks lie/ process mapping
- Defining the right KPIs
- Meaningful metrics (and the pitfalls)
- Quality Impact Assessment & effectiveness checks
- Opportunities for Improvement (OFIs), Continuous Quality Improvements (CQIs) and Business Continuity

Psychological Aspects of Continuous Improvement

- What do the numbers tell us?
- Business culture
- Empowerment of people

Assignment of Metrics and Correlation with Process Controls

- The importance of proper use and relevance of lagging and leading KPIs in correlation with process controls.
- The set up and implementation of a risk-based data evaluation methods for continual improvement and the Management Review

KPIs and the Cost of Non-Conformance

- Quality by the numbers: what are quality costs?
- How to determine the cost of poor quality
- Quantify – analyse - improve
- Calculating return on investment

Testimonial

"Just enjoyed all the presentations and as well the workshops" (A. Tigchelaar)

Case Studies:

Quality Metrics as a Key Driver for CQI

- Why did we implement Metrics?
- How did we do it?
- What was the outcome?
- Lessons learned
- How to apply Quality Metrics as a Key Driver for CQI

FDA's Quality Metrics Program

- What is the status of the FDA Quality Metrics Program?
- The new Quality Metrics Feedback Program and Quality Metrics Site Visit Program
- Experience made with the FDA Quality Metrics Pilot Phase

KPIs Applied: The Turnaround of Deviations Handling

- Why did we need an intervention?
- Prognosing the future while understanding the past
- The flashlight effect; choose wisely
- Visual triggers for continuous improvement
- Tribal knowledge versus "real" data

Parallel sessions (2 out of 3)

1. Managing Data: The Bridge from Quality Metrics to CQI

- Defining the right KPIs and meaningful metrics (work on examples)
- What to learn from the data

2. Quality Metrics Principles to Foster Business Continuity

- Expectations of authorities, what is essential for performance metrics?
- The link to ICH Q12: Quality Metrics as part of Product Lifecycle Management.
- Case Study: Continual risk mitigation to transform lagging performance data into Leading Metrics and Quality Objectives

3. Constructing KPIs that drive high Quality Behaviour

- How to choose and use the correct tools and KPIs

You will be able to attend 2 of these sessions. Please choose the ones you like to attend when you register for the course.

Cecilie Hejlskov
Syntese A/S, Denmark

Cecilie Hejlskov is Operational Excellence Manager at Syntese (a Ferring company). Before that she was Specialist in Global Operational Excellence at Xellia Pharmaceuticals. Some of her former positions include Manager of Chemical Production, Value Stream Manager and Lean Office Manager. Cecilie also has a Lean Six Sigma Green Belt Certification.

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 - 6Sigma and Kaizen methods to the life sciences industry.

Henny Koch
Qimp B.V., Netherlands

Henny Koch is Managing Director at Qimp Management Systems B.V. During 36 years in pharmaceutical industry he held several positions in R&D, Manufacturing and Quality. Since 2012, he is active as quality consultant within Life Science Industry.

Dorthe Christina Kroun
MinervaX, Denmark

Dorthe Kroun is Vice President QA. Before that she was (amongst others) an Inspector at the Danish Medicines Agency DKMA.

Christof Langer
OSConsulting, Austria

Christof Langer is a certified Risk Manager, Lean Six-Sigma Black Belt and independent consultant. Before that, he was Managing Director at Baxter BioScience (now Shire) in Switzerland and the Czech Republic.

Jason McGuire
Fagron, USA

Jason McGuire is Senior Vice President Operations, responsible for two sites in the US. He has been working many years in pharmaceutical and healthcare industry, from QA/QC to Business Development and Operational Excellence.

Prof Dr Florian Priese
Anhalt University of Applied Sciences, Germany

Florian Priese is Full Professor Pharmaceutical Quality Management and Analytics, Anhalt University of Applied Sciences, Köthen (Germany) and consultant for Operational Excellence, Quality and Project Management. Before that he worked 15 years in several roles in the pharmaceutical industry (e.g. Novartis, Boehringer, IDT Biologika).

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GERMANY

Reservation Form (Please complete in full)

KPIs and Quality Metrics | 09/10 April 2025, Berlin, Germany

Please choose TWO sessions:

☐ *Managing Data: The Bridge from Quality Metrics to CQI*
☐ *Quality Metrics Principles to foster Business Continuity*
☐ *Constructing KPIs that drive high Quality Behaviour*

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks 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 July 2022).
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 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
Wednesday, 09 April 2025, 9.00h – 17.30h
(Registration and coffee 8.30h – 9.00h)
Thursday, 10 April 2025, 8.30 – 15.30h

Venue
DoubleTree by Hilton Berlin Ku´Damm
Los-Angeles-Platz 1
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Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes lunch on both days, dinner on day one 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 – or search and register directly at www.gmp-compliance.org under the number 21588.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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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