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# Quality Metrics to foster Continual Quality Improvement

With an optional session on the  
FDA Quality Metrics Initiative

## SPEAKERS:



**Arnoud Herremans**  
*Lean Kaizen Consultant,  
The Netherlands*



**Henny Koch**  
*Qimp Management Systems,  
The Netherlands*



**Dorthe Christina Kroun**  
*Bavarian Nordic A/S,  
Denmark*



**Dr Daniel Marquardt**  
*Boehringer Ingelheim,  
Germany*



**Dr Ann McGee**  
*McGee Pharma International,  
Ireland*



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2-3 March 2017, Heidelberg, Germany

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## LEARNING OBJECTIVES:

- Quality Metrics
- Key Performance Indicators (KPIs)
- Continual Quality Improvement (CQI)
- Correlation with Process Controls and Business Continuity
- Tools and Techniques
- Psychological Aspects



# Quality Metrics to foster Continual Quality Improvement

2-3 March 2017, Heidelberg, Germany

## Learning Objectives

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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) and Business Continuity. This will support you turning your company's quality excellence goals into reality.

## Background

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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.**

Now, the U.S. **FDA has set up an initiative to use Quality Metrics for risk based inspections and published a draft Guidance for Industry in July 2015 and a Technical Performance Guide in June 2016.** In Europe agencies also use Quality Metrics. They are aiming to help regulators to separate manufacturing sites with poor standards from those continuously working on quality improvement.

In the end Quality Metrics will enable companies and regulators to benefit from a continuous investment in GMP to guarantee a **high quality performance** and the **continuity of quality product supply.**

## Target Audience

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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

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Wolfgang Schmitt

## Programme

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### Quality Metrics and beyond

- FDA's Quality Metrics Initiative
- Expectations in the EU
- 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)
- The role of Quality Impact Assessment & effectiveness checks
- The link to Opportunities for Improvement (OFIs), Continuous Quality Improvements (CQIs) and Business Continuity

### Techniques to evaluate Quality Performance

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

### 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

### Case Study: 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

## 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. The new FDA Guideline on Quality Metrics – what is it all about?

- Overview about the current status
- Key areas and data to be submitted
- How industry can prepare
- The link to ICH Q12: Quality Metrics as part of Product Lifecycle Management

### 3. Analysis Tools for assessing and optimising Process Flows

- How to choose and use the correct tools

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

## Psychological Aspects of Continuous Improvement

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

## Change Management as the Key

- How to 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

## Wrap-up: What the Future will bring

- True understanding of the quality risks specific to our businesses
- A shift to pro-active QRM from reactive risk assessment
- Integration of QRM and change management
- Moving away from the functional silo mentality
- Process and QMS improvement in the interest of patient care
- Meaningful performance evaluation criteria and metrics

## Heidelberg – Optimal Accessibility via Frankfurt Airport:

**Lufthansa Shuttle Bus** (operated by Busworld International): It leaves Frankfurt Airport approximately every 90 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/Airport-Shuttle-Heidelberg>

**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.

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



### Henry Koch

*Qimp Management Systems B.V., The Netherlands*

Henry 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. His last position was Global Compliance Manager at MSD.



### 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.



### Dr Daniel Marquardt

*Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*

Dr Daniel Marquardt is Vice President Global Quality Services. Before that, he was Plant Manager at the Boehringer Ingelheim site in Sao Paulo, Brazil and Director Business Process Excellence at the Headquarter in Ingelheim, Germany, where he was responsible for the Global Business Process Excellence Initiative.



### Ann McGee

*McGee Pharma International, form. Senior Inspector of the Irish Medicines Board, Ireland*

Ann McGee has extensive experience both in the pharmaceutical industry and as a regulator. She is a former Senior Inspector of the Irish Medicines Board, Chief Executive of the Pharmaceutical Society of Ireland and Deputy Chair of PIC/S. Ann McGee also has many years "hands-on" experience in industry.

## 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



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

### Quality Metrics to foster Continual Quality Improvement

2-3 March 2017, Heidelberg, Germany

Please choose TWO sessions:

- Managing Data: The Bridge from Quality Metrics to CQI
- The new FDA Guideline on Quality Metrics – what is it all about?
- Analysis Tools for assessing and optimising Process Flows

Mr.  Ms.

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Department

Important: Please indicate your company's VAT ID Number

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

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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 %

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.

**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)

**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

Thursday, 02 March 2017, 9.00h - 17.45h  
(Registration and coffee 8.30h - 9.00h)  
Friday, 03 March 2017, 8.00h - 15.30h

#### 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 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 message. Or you register online at [www.gmp-compliance.org](http://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.

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
info@concept-heidelberg.de  
www.concept-heidelberg.de

#### For questions regarding content:

Mr Wolfgang Schmitt (Operations Director) at  
+49(0) 62 21 / 84 44 39, or per e-mail at  
w.schmitt@concept-heidelberg.de.

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

Ms Nicole Bach (Organisation Manager) at  
+49(0) 62 21 / 84 44 22, or per e-mail at  
bach@concept-heidelberg.de.

#### 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.