

KPIs and QUALITY METRICS

SPEAKERS:



Alex Viehmann
CDER, FDA



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Dr Ann McGee
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With
FDA
Speaker discussing the
FDA Quality Metrics
Program



7-8 March 2019, Prague, Czech Republic

LEARNING OBJECTIVES:

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



KPIs and Quality Metrics: From Continual Quality Improvement to Business Continuity

7-8 March 2019, Prague, Czech Republic

Learning 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) 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.

A good quality metrics system supports both industry's profitability and GMP compliance. But a good system precludes overproduction of metrics; you only measure what adds value to quality in the most efficient way. This way the metric system is fit for purpose, enables you to maintain a high quality standard and allows you to lower your costs for quality. This can drive the price down and renders continuity to the business at the same time. To make this happen, industry must come together in courses like this to learn and discuss how to build a better quality system using smart quality metrics.

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

Programme

Quality Metrics and beyond

- FDA's Quality Metrics Initiative: what's the status quo 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

FDA's Quality Metrics Program

- Background
- What is the Status of the FDA Quality Metrics Program?
- The new Quality Metrics Feedback Program and Quality Metrics Site Visit Program
- Questions and Answers

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

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 FDA and other authorities
- What needs to be disclosed – what needs to be submitted?
- 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

Case Study: Boehringer Ingelheim's Quality Culture Initiative

- Cultural enablement as a foundation for CQI und Business Continuity
- Quality Culture at BI: From initiative introduction to operationalisation
- Dimensions of cultural excellence framework
- Is Quality Culture measurable?

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

Speakers



Alex Viehmann

CDER, FDA, USA

Alex Viehmann is Operations Research Analyst at the U.S. Food and Drug Administration FDA.



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. Since 2012, he is active as quality consultant within Life Science Industry.



Dr Daniel Marquardt

Boehringer Ingelheim Pharma GmbH & Co.
KG, Germany

Dr Daniel Marquardt is Head of Focused Factory Respimat. Before that, he was Vice President Global Quality Services and Plant Manager at the Boehringer Ingelheim site in Sao Paulo, Brazil.



Ann McGee

PharmaLex Ireland, form. Senior Inspector of the Irish Medicines Board

Ann McGee is Managing Director and 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.

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.



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

KPIs and Quality Metrics:

7-8 March 2019, Prague, Czech Republic

Please choose TWO sessions:

- Managing Data: The Bridge from Quality Metrics to CQI
- Quality Metrics Principles to foster Business Continuity
- Analysis Tools for assessing and optimising Process Flows

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Date

Thursday, 07 March 2019, 9.00 h – 17.45 h
 (Registration and coffee 8.30 h – 9.00 h)
 Friday, 08 March 2019, 8.00 h – 15.00 h

Venue

InterContinental Praha
 Parížská 30
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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 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.

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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