



A pre-conference session to the
6th European GMP Conference

Speakers



Dick Bonner
Qualified Person and
ECA Chairman



Karthik Iyer
FDA



Henny Koch
Qimp Management
Systems



Dr Andreas König
Vice President Manufacturing
& Quality Aenova-Group



Dr Bernd Renger
Qualified Person and
Immediate Past Chairman
EQPA

Highlights

- FDA's Quality Metrics Program
- Developing, Establishing and Monitoring of Meaningful Quality Metrics in Quality Control
- How to use Quality Metrics to control the Supply Chain and the Supplier
- Inspection based on Compliance Information
- Quality Metrics and Management Review
- Case Study: Quality Metrics at Aenova-Group

How to establish Quality Metrics

8 June 2015, Heidelberg, Germany



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Objectives

This pre-conference session is designed to discuss the implementation of Quality Metrics in the manufacture of medicinal products and APIs. In the centre will be challenges and possible solutions to identify, measure and report meaningful Quality Metrics. For that purpose the ECA Foundation and its interest group, the European Qualified Person Association, have invited stakeholders from industry and authorities.

Background

Quality can be measured on different levels. This can take place on the level of products or processes. It can also be used as a measure of the site's ability to manufacture products fit for the intended use.

While so far only compliance and non-compliance were measured, Quality Metrics are a new step in the GMP development. Quality Metrics in itself are not new, though. They have already been used in pharmaceutical industry for years – even though mainly internally to measure and optimize the performance. However, currently there is no harmonised approach in place. This means that data can not be compared because of different standards.

The US FDA has set up an initiative to use Quality Metrics for risk based inspections. This development was triggered by the Food and Drug Administration Safety and Innovation Act. However, in Europe agencies also use Quality Metrics. Therefore, a harmonised approach possibly helps regulators worldwide to separate manufacturing sites with very poor standards from those continuously working on quality improvement.

In the end Quality Metrics enable companies with a high quality performance to benefit from a continuous investment in GMP.

Target Audience

This Pre-Conference Session addresses Quality and Manufacturing Managers who are involved in the planning and improvement of quality processes.

Moderator

Dick Bonner, Qualified Person and ECA Chairman

Programme

FDA's Quality Metrics Program

- Overview about the current status
- Quality Metrics to support drug quality and surveillance for CDER
- Impact for pharmaceutical industry

Karthik Iyer, FDA

Developing, Establishing and Monitoring of Meaningful Quality Metrics in Quality Control

- Quality Metrics - Challenges and risks
- Benchmarking based on different data sets
- Good Quality Control Practices
- Lean, Efficient and high Quality - does this fit?
- Some meaning Quality Metrics for Lab activities

Dr Bernd Renger, Qualified Person and Immediate Past Chairman EQPA

How to use Quality Metrics to control the Supply Chain and the Supplier

- How to oversight the Supply Chain?
- Is a complex supply chain always a risk?
- How to control and measure the supplier in the supply chain
- Supply Chain and Supplier Metrics

Dick Bonner, Qualified Person and ECA Chairman

Inspection based on Compliance Information

- How to anticipate supply chain and compliance risks
- How to improve compliance-related communication with industry
- Implementation a risk-based escalation process regarding inspection results within MHRA

Speaker to be named (EU Inspectorate)

Quality Metrics and Management Review

- 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

Henny Koch, Qimp Management Systems

Case Study: Quality Metrics at Aenova-Group

- Industry Quality Metrics – typical data sets and reports
- How to measure Quality Metrics in daily practice
- Lessons learned from implementation
- Comparison of quality metrics – potential risks and challenges

Dr Andreas König, Senior Vice President corporate Quality & HSE at Aenova-Group

Speakers



Richard M. Bonner, Chairman of ECA Foundation and the European QP Association, formerly with Eli Lilly

Richard Bonner was a Senior Quality Adviser for Eli Lilly and Company. Mr Bonner is a Qualified Person in Europe, Chairman of the ECA and of the Qualified Person Association Advisory Board.



Karthik Iyer, Food and Drug Administration (FDA), USA

Karthik Iyer is Acting Branch Chief for the Quality Intelligence Branch in FDA/CDER/Office of Pharmaceutical Quality/Office of Surveillance/Division of Quality Intelligence, Risk Analysis and Modeling.



Henny Koch, Qimp Management Systems B.V., The 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. His last position was Global Compliance Manager at MSD.



Dr Andreas König, Aenova Group, Germany

Dr Andreas König is Senior Vice President corporate Quality & HSE at Aenova-Group. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was head of QC and QA at Fresenius Kabi and later Global Quality Director at Intervet.



Dr Bernd Renger, Immediate Past Chairman of the European QP Association

Dr Bernd Renger is a member of the ECA Advisory Board and was Chairman of the European QP Association. Since 2011 he is an independent Qualified Person. 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, Altana Pharma and Baxter BioScience.

Easy Registration



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Germany



Reservation Form:
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info@concept-heidelberg.de



Internet:
www.www.gmp-conference.org

Date

Monday, 8 June 2015, 9:00h – 17:00h
(Registration and coffee 08:30h – 09:00h)

Venue

Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49 (0)6221 908-00
Fax +49 (0)6221 908-660

Fee (per delegate plus VAT)

EUR 890.-

A special fee of 690,- Euro is granted to participants who also register for the 6th European GMP Conference on 9-10 June 2015.

The conference fee is payable in advance after receipt of invoice and includes lunch 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 link when you have registered for the event. Please use this link for your room reservation to receive the specially negotiated rate for the duration of your stay. 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-conference.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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Reservation Form (Please complete in full)

Pre-Conference Workshop “How to establish Quality Metrics” on 8 June 2015

6th European GMP Conference, 9-10 June 2015, Heidelberg, Germany AND Pre-Conference Workshop “How to establish Quality Metrics” on 8 June 2015

I want to take part in the following **Working Group Session** (please tick only one)

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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 %

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