



Continuous Quality Improvement

Process Analysis, KPIs and
GMP Performance Measures

16-17 February 2012, Prague, Czech Republic

SPEAKERS:

Ingo Ebeling
Abbott Products

Michael Hopper
GxPpro

Aidan Madden
FivePharma

Dr Daniel Marquardt
Boehringer Ingelheim

HIGHLIGHTS:

- Continuous Quality Improvement
 - Techniques and Implementation
- KPIs and GMP Performance Measures
 - How to use the Tools
- Change Management as the Key
 - People Empowerment
 - How to get to the desired status
- Case Studies
 - Cycle Time of Documents
 - Deviation Reporting and CAPA Systems
- Workshops
 - KPIs and GMP Performance Measures
 - Analysis Tools for assessing and optimising Process Flows



Continuous Quality Improvement

16-17 February 2012, Prague, Czech Republic

Objectives

This Education Course will show you which key performance indicators and GMP performance measures you should select and how they can be used to improve your quality performance. You will learn how to use these measures 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 continuously improved. Important tools in this context are accurate GMP performance measures and the right Key Performance Indicators (KPIs).

This education course will provide you with practical guidance on:

- How to select the right KPIs and performance measures for your quality system
- How to quickly interpret and report the data and information
- How to simplify your quality system
- How to improve your processes
- How to reduce costs

Target Audience

QA personnel who wants to improve and simplify 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

Aidan Maddan

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.



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

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

Implementation of Continuous Quality Improvement

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

B: KPIs and GMP Performance Measures

Implementation and efficient Use of a Balanced Scorecard

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

Workshops:

- KPIs and GMP Performance Measures
- Analysis tools for assessing and optimising process flows

C: Change Management

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)

Speakers

Ingo Ebeling

Abbott Products, Germany

Ingo Ebeling is responsible for production compliance, process optimisation and analytical improvements. In former positions he was Head of Quality Assurance and Business Excellence Manager.

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.

Aidan Madden

FivePharma, Ireland

Aidan Madden is Managing Directive 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.

Dr Daniel Marquardt

Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Daniel Marquardt is amongst others responsible for Operation's Global Business Process Excellence Initiative at Boehringer Ingelheim GmbH. After joining Boehringer Ingelheim in 2002 he has held different positions, i.e. Head of Process Quality Assurance Solids/ Qualified Person, Pharmaceutical Production Manager and Post Launch Manager, Director Supply Chain Management and Director Business Process Excellence.

Conference Folder

You cannot take part in this event? Just order the documentation at the price of € 180.- + VAT + postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, the conference folder will not be available until 2 weeks after the event.

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

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.



Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will **receive up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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)

Continuous Quality Improvement

16-17 February 2012, Prague, Czech Republic

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
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, instructors, 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!).

Date

Thursday, 16 February 2012, 9.30 h - 17.30 h
(Registration and coffee 9.00 h - 9.30 h)
Friday, 17 February 2012, 8.30 h - 15.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
140 69 Prague 4, Czech Republic
Phone +420 261 191 111
Fax +420 261 225 011

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 845.- per delegate plus VAT
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. Please use this form for your room reservation or be sure to mention "XCON150212" to receive the specially negotiated rate (single/double room € 95,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 18 January 2012. 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

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

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager)
at +49 (0)62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de.