ECA ACADEMY

Both Global Pharma and small Companies will be discussed

Managing Pharmaceutical Quality

The new Paradigm for the Pharmaceutical Quality System

Speakers:

Dr Oliver Grosche
Novartis, Switzerland

Henny Koch
Qimp Management Systems B.V., The Netherlands

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

Louise Walsh
Allergan Pharmaceuticals, Ireland

4 – 5 March 2015, Munich, Germany

Highlights

- The Implications of (new) EU GMP Chapter 1 and ICH Q10
- Initiatives and expectations of the FDA
- Relevant Aspects and their Integration:
  - Non-Conformance Management
  - Change Management
  - Continuous Improvement
  - Quality Risk Management
  - Assignment of Metrics
- Parallel Sessions:
  - Global and small Pharma
  - Modern QA Organisation
- Case Study:
  From GMP to Pharmaceutical Quality System - Three steps in the Transition Phase

This conference is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

Managing Pharmaceutical Quality

4 – 5 March 2015, Munich, Germany

Objectives

This 2-day Master Class brings together well-experienced experts to discuss **the latest expectations and requirements for Pharmaceutical Quality Systems** and how to get there. This will support you **turning your company's quality excellence goals into reality**.

Background

The pharmaceutical industry has a strictly regulated environment. The core of the regulations is represented by the GMP rules. However pharmaceutical industry has been facing a lot of new quality approaches, models and techniques over the last few years. **FDA's** Guidance for Industry on Quality System Approach to Pharmaceutical cGMP, **ICH Q10**, SixSigma and **Lean SixSigma, Risk Management** and last but not least **the new EU-GMP Chapter 1** have been introducing a new way of quality thinking to the pharmaceutical industry. It is now expected that various quality systems and quality management elements are integrated and linked.
To bring everything together, Managers and Executives must have a **brought knowledge of the requirements, the business processes and the respective Quality management tools** to be able to integrate the quality system into operative business.

Target Audience

Managers and Executives from pharmaceutical Quality Assurance and Quality Management but also Business Executives and Production Managers and those involved in improving the Pharmaceutical Quality System.

Moderator

Wolfgang Schmitt, Concept Heidelberg

Programme

Where it all comes from

- A brief history of pharmaceutical Quality
- Review of Changes and Expectations of GMP regulations
- The organisational structure, management responsibilities and the management review

EU GMP Chapter 1 and ICH Q10

- The Quality Management System throughout the Product Lifecycle
- Continuous and Continual Improvement
- Elements of the Quality Management Review and responsibilities of Senior Management
- Maintenance of cGMP: Regulatory Surveillance, Quality Manual
- Quality Systems Interdependency

Integration of Non-Conformance Management and Change Management in Continuous Improvement

- Understanding critical processes & where quality risks lie/ process mapping
- Managing non-conformances to minimise the potential for recurrence
- The importance of integration of Non-Conformance and Change Management
- The role of Quality Impact Assessment & effectiveness checks
- The link to Opportunities for Improvement (OFIs) and Continuous Quality Improvements (CQIs)
- Meaningful metrics (and the pitfalls)

Relevant aspects of Quality Risk Management for the Evaluation of pharmaceutical Processes in Product Life Cycle

- Elements for risk management are reviewed from perspective of the Product Life Cycle (from R&D to manufacturing, surveillance and discontinuation).
- The use of Quality Risk Management for evaluation of performance measurement (KPIs) following the end-to-end product supply chain processes.

Parallel Sessions (2 out of 3):

1. Pharmaceutical Quality System: what's important for Global Pharma

2. Pharmaceutical Quality System: what's important for Small Pharma

3. Elements of modern QA Organisations:
- Introduction of actors and factors of importance to quality and process dynamics
- Stages of identifying and mapping of key processes

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

Assignment of Metrics and Correlation with Process Controls
- FDA's Quality Metrics Initiative
- The importance of proper use and relevance of lagging and leading KPIs is explained in correlation with the process controls.
- The set up and implementation of a risk based data evaluation method is provided for continual improvement and input for Management Review.

Case Study: The Transition Phases
In this case study a step by step process will show how a pharmaceutical company has gone through the transition from GMP to Pharmaceutical Quality System.

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

Dr Oliver Grosche, Novartis Animal Health, Switzerland
Dr Oliver Grosche is Head Analytical Development, Global Technical Development. Before that he was Governance & Regulations Lead, Global Pharma QA Auditing and Compliance, implementing a Quality Governance Processes according ICHQ10 in a global environment over 24 manufacturing sites. He was also based in Japan for an international assignment and was leading the Pharmacopeia and GxP intelligence process at Novartis Pharma Global Technical Operations

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.

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

Louise Walsh, Allergan Pharmaceuticals Ireland
Louise Walsh, BSc, MSc (hons), is Senior QA Manager and Qualified Person (QP). She is responsible for the maintenance of the site quality systems. Prior to joining Allergan, Louise worked in a number of chemistry and microbiology laboratories including University College Hospital Galway, LIP Services and CAS Services Coventry.

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

Date
Wednesday, 4 March 2015, 9.00 h – 17.45 h
(Registration and coffee 8.30 h – 9.00 h)
Thursday, 5 March 2015, 8.30 h – 15.00 h

Venue
Holiday Inn Munich -City Centre
Hochstraße 3
81669 München, Germany
Tel.:+49 (0)89 - 4803 0
Fax: +49 (0)89 – 448 7170

The Holiday Inn Munich -City Centre –
Optimal Accessibility via Munich Airport:
Located in the heart of Munich, the hotel is only 35 minutes away from Munich Airport (direct S-Bahn connections with S1 or S8 every 10 minutes). The train station "Rosenheimerplatz" provides direct access to the hotel.

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 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.

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content:
Mr Wolfgang Schmitt (Director Operations) at +49-62 21/84 44 39, or per e-mail at schmitt@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at +49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

Social Event
On 4 March, 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..

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

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P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Registration form (please complete in full)

Managing Pharmaceutical Quality, 4 – 5 March 2015, Munich, Germany

Please choose TWO Parallel Sessions:
☐ Pharmaceutical Quality System: what's important for Global Pharma
☐ Pharmaceutical Quality System: what's important for Small Pharma
☐ Elements of modern QA Organisations

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

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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 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.
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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). 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.