ECA ACADEMY

Both **Big Pharma** and **small Companies** will be discussed

From GMP to Pharmaceutical Quality System

The Implications of (new) EU GMP Chapter 1 and ICH Q10

25 – 26 March 2014, Heidelberg, Germany

Speakers:

Dr Oliver Grosche
Novartis Pharma AG, Basel, 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

Highlights

- GMP and regulatory Background
- Relevant Aspects and their Integration:
  - Non-Conformance Management
  - Change Management
  - Continuous Improvement
  - Quality Risk Management
  - Assignment of Metrics
- Parallel Sessions:
  - Big and small Pharma
  - Modern QA Organisation
- Case Study: 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

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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

The new 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 Big 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
- 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 be shown how a pharmaceutical company has gone through this transition.

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

Social Event

On 25 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..

Speakers

Dr Oliver Grosche, Novartis Pharma AG, Basel, Switzerland
Dr Oliver Grosche is Governance & Regulations Lead, Global Pharma QA Auditing and Compliance, implementing a Quality Governance Processes according ICHQ10 in a global environment over 24 manufacturing sites. Before that was 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
Tuesday, 25 March 2014, 9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 26 March 2014, 8.30 h – 15.00 h

Venue
Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone +49 (0)6221 917 0
Fax +49 (0)6221 210 07

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
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 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.

Conference language
The official conference language will be English.

Organisation and Contact
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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.

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Germany

Registration form (please complete in full)

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

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

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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.

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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)