ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Petra Barth
form. AbbVie, Germany

Dr Panagiotis Fakitsas
F. Hoffmann-La Roche Ltd, Switzerland

Dr Rainer Gnibl
GMP Inspector for EMA, Germany

Dr Rodrigo Pereira
Bial - Portela & Cª, Portugal

Audrey Schwebel
Procter & Gamble, France

Dr Georg Sindelar
msg industry advisors, Germany

Hans Steier
Vetter Pharma-Fertigung, Germany

Quality Oversight

Supervision of the Pharmaceutical Quality System: Challenges and Opportunities

Live Online Training on 09 and 10 June 2020

Highlights

- FDA and EU Expectations
- Managing Quality Oversight
- Case Studies
  - Gap Analysis
  - Implementation
  - Performance Review and Monitoring
  - CMO Business
  - Quality Product Leader Model
  - The Link to QRM and Knowledge Management
- Quality Culture

Objective

This 2-day Online Training brings together well-experienced experts to discuss the latest expectations and best practices for effective and efficient Quality Oversight processes and how to get there. This will support you turning your company's quality excellence goals into reality.

Background

The US Food and Drug Administration FDA frequently criticises pharmaceutical companies for not having sufficient "Quality Oversight" on their operations and processes. The number of pharmaceutical companies that have received **FDA 483s and Warning Letters** indicates that management oversight of current good manufacturing practice (cGMP) compliance is a significant and continuing problem in the industry. On the other hand, FDA's Guidance for Industry on **Quality System Approach** to Pharmaceutical cGMP, **ICH Q9 and Q10** and **EU-GMP Guide Chapter 1** have been introducing a new way of quality thinking to the pharmaceutical industry. It is now expected that the various quality systems and quality management elements are integrated and linked.

Aside from being the thesis of major FDA enforcement actions, compliance to GMP regulations is, in fact, a part of normal pharmaceutical business that requires **diligent management oversight**. Just as it is with other business areas, management has the responsibility to ensure that systems are in place to effectively monitor the state of control in order to intervene with timely decisions to **manage risk, achieve goals, and add stakeholder value**. It is of utmost importance to **detect and heed possible problems early enough**.

This course explores the issues that can affect the ability of management to detect the warning signals of significant cGMP compliance problems and offers suggestions on how to gain control over this essential part of the business.

Target Audience

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

Participant's comment (April 2019)
„The event contains many different perspectives and sector examples. It will help me to improve my way of working." Ayşe Dilek Terzi, Sanofi Turkey

Programme 9 June 2020

09.00 – 09.10 h Introduction

09.10 – 10.15 h
Quality Oversight in the View of an EMA Inspector

- What does Quality Oversight mean in the EU?
- The Basis: Pharmaceutical Quality Systems (PQS)
- Which are the essential PQS-elements?
- QA Management of PQS and the benefit from an inspectors point of view
- Inspectors' expectations on EU Quality Oversight
- How to synchronize EU with US?
- EU answer to US-FDAs "Quality Metrics Guideline"
- Which approach makes sense from various experience in inspections?

10.15 – 10.30 h Time for additional Questions & Discussion

10.30 – 10.50 h Break

10.50 – 11.30 h
Current FDA Expectations and future Developments

- How the FDA defines Quality Oversight and what FDA expects from management and the Quality Control Units (QCU)
- Where to find expectations and requirements: 21 CFR 210 and 211, rules and guidance, Warning Letters etc.
- Typical problems FDA sees
- How the industry in the U.S. is dealing with this approach

11.30 – 12.30 h
Quality Oversight – Motor in a multinational Company

- Implementation of a successful Quality Oversight strategy and program
- The role of the Quality Assurance department
- Definition of critical processes and integration of a management control and reporting system
- Management of significant cGMP internal compliance problems and of a "warning system"
- One company with various sites: how to keep quality oversight
- The link to continuous improvement

12.30 – 12.45 h Time for additional Questions & Discussion

12.45 – 13.45 h Break

13.45 – 15.30 h
Managing Quality Oversight in the Company

- How to evaluate performance of different sites of the company and outsourced activities
- Maintenance, monitoring and feedback

15.30 – 16.00 h Break

16.00 – 16.45 h
Pharma Quality System: from Compliance Check to Quality Oversight (how to get you there) – a Case Study in three Steps

In this case study you will see how a multinational pharmaceutical company has gone through the transition from a fragmented Quality System to integrated Quality Oversight processes.

Part 1: Starting Point

- The Warning Letter
- GAP Analysis

16.45 – 17.30 h
Case Study Procter & Gamble: Quality Risk Management as enabler for Knowledge Management and Quality Oversight

- How to implement QRM oversight: harmonisation as one of the key elements
- Management of risks
- Example of implementation of an IT tool enabling a better overview
- Delimitation of responsibilities and interfaces over the product life cycle

17.30 – 17.45 h Time for additional Questions & Discussion

Programme 10 June 2020

08.30 – 09.20 h
Pharma Quality System: from Compliance Check to Quality Oversight (how to get you there) – a Case Study in three Steps

Part 2: Implementation Phase

- How to establish an appropriate meeting culture
- What we can learn from ISO
- The need to restructure quality departments
- How to implement effective and efficient review systems
- Quality and Management Systems to lead the way to Quality Oversight

09.20 – 10.00 h
Case Study Roche: The Quality Product Leader Model

- How a Quality Product Leader acts as a single point of contact for consistent end-to-end product quality oversight and continuous improvement
- Monthly Product Quality Report
- Annual Product Quality Plan

10.00 – 10.15 h Time for additional Questions & Discussion

10.15 – 10.45 h Break

10.45 – 11.45 h
Quality Oversight – the effective Arm in your Transfer and CMO Business

- Best practise - designing and integrating Quality Oversight in transfer and outsourcing
- Risk management and quality system oversight in the third party manufacturing network
- How to deal with the various quality and documentation systems at different CMOs
- How to evaluate CMO performance

11.45 – 12.30 h
Case Study Vetter Pharma-Fertigung: Quality Oversight in a CMO Business

- Establishing a Quality Oversight system at an contract manufacturer
- Interfaces to other systems
- How it was seen by FDA
- Person in the Plant Concept: advantages and challenges

12.30 – 12.45 h Time for additional Questions & Discussion

12.45 – 13.45 h Break

13.45 – 14.40 h
Pharma Quality System: from Compliance Check to Quality Oversight (how to get you there) – a Case Study in three Steps

Part 3: Performance Review and Monitoring

- The use of Quality Metrics
- Feedback loops
- Lessons learned

14.30 – 15.20 h
Managing Quality in different Quality Cultures

- Differences in culture and quality culture: what are the challenges?
- Quality Operations in different continents: considerations, examples and best practices

15.20 – 15.30 h Final Discussion

Speakers

Petra Barth
form. AbbVie GmbH & CoKG, Germany

Petra Barth has more than 20 years experience in global pharmaceutical business as QC and QA Manager. In her last role she was Head of QA Systems at AbbVie.

Dr Panagiotis Fakitsas
F. Hoffmann-La Roche Ltd, Switzerland

Dr Panagiotis Fakitsas is Commercial Quality Product Leader Small Molecules at Roche's Pharma Global Quality and Compliance Group.

Dr Rainer Gnibl
GMP Inspector, District Government of Upper Franconia, Germany

Dr Rainer Gnibl is GMP Inspector for the District Government and the EMA and performs GMP-inspections worldwide. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Rodrigo Pereira
Bial - Portela & Cª, S. A., Portugal

Dr Rodrigo Pereira is a Black Belt in Lean/ Six Sigma and Head of Quality & Projects. Before that, he was working in Quality Control at Eli Lilly and at Reading Scientific Services Ltd.

Audrey Schwebel
Procter & Gamble, France

Audrey Schwebel is Quality Manager Continual Improvement, Global Quality Operations Systems and Services. Amongst others, she is responsible for Quality Oversight and the implementation and maintenance of the global strategy for Quality Risk Management.

Dr Georg Sindelar
msg industry advisors, Germany

Dr Georg Sindelar is Head of Pharma QMS Consulting. Before that he was Managing Consultant GMP Compliance for the Chemgineering Group where he implemented a Quality Oversight program for a multinational company.

Hans Steier,
Vetter Pharma-Fertigung GmbH & Co. KG, Germany

Hans Steier is Director Quality Assurance at Vetter, where he is responsible for Quality Systems, Quality Operations and Quality Oversight. Before that he was Head of Production at Vetter. Hans Steier is a trained Six Sigma Black Belt.

Date of the Live Online Training

Tuesday, 09 June 2020, 09.00h – 17.45h
(Registration and coffee 08.30h – 9.00h)
Wednesday, 10 June 2020, 08.30h – 15.30h

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Important: Deadline for your registration is 12 noon on 08 June 2020

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Wolfgang Schmitt (Director Operations) at
+49 (0)62 21/84 44 39 or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding organisational details please contact:
Ms Jessica Frechen (Organisation Manager) at
+49 (0)62 21/84 44 60, or per e-mail at
frechen@concept-heidelberg.de

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

GMP and GDP In-house Training Programme

What are GMP/GDP In-house Training Courses?
GMP/GDP in-house Training Courses are an ideal solution and a cost-effective way to train a larger number of people (ten or more) than you would normally want to send to an external course. You determine date and time, and the training is provided in your premises – or, alternatively, online, as most of the trainings can also be conducted via Internet.

Why GMP/GDP In-house Training?
Our GMP/GDP in-house trainings help your employees to put the GMP/GDP requirements into practice, to understand why they have to observe GMP/GDP rules and to develop a positive attitude towards GMP/GDP. In discussing of questions, your staff becomes familiar with the GMP/GDP rules, and solutions to concrete problems are found.

The courses you can choose from
Training content depends on your individual needs and ideas. A course can take into account the specific situation in your company and considers the latest GMP publications. Then both the training course's content and structure are tailored to the target group - also considering group-dynamic effects.

Now online
Almost all of our in-house trainings can also be conducted online. This allows for maximum flexibility since your employees can take part in the same session no matter where they are located.

Professional GMP Trainers
Your GMP trainers have been working for us as speakers for many years. Only GMP trainers with a track record from our open GMP Education Courses or European Conferences can conduct in-house training courses as associated partners. Each special field is covered by a different trainer. This way you can be sure that you have a competent GMP trainer, no matter if the course is about current Part 11 trends or about cleanrooms for aseptic manufacture.

Documentation and Certification
Every participant receives a folder with detailed training documentation. As a recognised organisation for advanced training, we issue certificates that document the participation in the training measure and that are accepted by the supervisory authorities.

Please visit our website www.gmp-compliance.org for more information.

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Quality Oversight - Live Online Training on 09 and 10 June 2020

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

Phone / Fax

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
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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 HEIDELBERGwill 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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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.