ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Petra Barth
QS-Training.de, Germany

Dr Panagiotis Fakitsas
F. Hoffmann-La Roche, Switzerland

Dr Rainer Gnibl
GMP Inspector for EMA, Germany

Dr Alexander Pontius
Bayer, Germany

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

05/06 May 2022 | Vienna, Austria

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
  - Complaint Handling in the Supply Chain

Programme

Objective

This 2-day Master Class 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.

Programme

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

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?

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

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

Workshop

Managing Quality Oversight in the Company

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

Case Studies

(1) 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

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

Part 3: Performance Review and Monitoring
- The use of Quality Metrics
- Feedback loops
- Lessons learned

(2) 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

(3) 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

(4) Case Study Procter & Gamble: Quality Risk Management in a complex global pharmaceutical Organisation 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

(5) Quality Oversight for a GDP Process: Offshoring of Complaint-Handling to Shared Service Centers
- Establishing a tailor-made, novel QMS incl. corresponding processes and procedures
- Qualification and training of personnel for the new units
- Implementing variants for multi-national and multi-language purposes
- Concept for process validation and hypercare phase
- Making the new units ready for Quality audits
- Several aspects of Quality oversight beyond GxP

Petra Barth
QS-Training.de, Germany

Petra Barth has more than 20 years experience in global pharmaceutical business as QC and QA Manager, amongst others as Head of QA Systems at AbbVie GmbH & Co. KG, Germany. Since 2016 she works as independent Trainer for QA & Compliance Topics.

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 Alexander Pontius
Bayer AG, Germany

Alexander Pontius is Head of Region Europe II and Quality System Manager within the enterprise-wide Corporate Quality function.

Audrey Schwebel
Procter & Gamble, France

Audrey Schwebel is Senior QA Manager Risk and Consumer Voice Management, Global Quality Processes & Systems. 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.

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Reservation Form (Please complete in full)

Quality Oversight | 05/06 May 2022, Vienna, Austria

Title, first name, surname

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Date
Thursday, 05 May 2022, 9.00h – 17.45h
(Registration and coffee 8.30h – 9.00h)
Friday, 06 May 2022, 8.00h – 15.30h

Venue
Austria Trend Parkhotel Schönbrunn
Hietzinger Hauptstr. 10-14
1130 Vienna
Austria
Phone.: +43 (1) 878 08 0
E-mail: parkhotel.schoenbrunn@austria-trend.at

On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

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 and includes conference documentation, 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 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your 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 reservation, hotel, organisation etc. please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0)62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de