ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers


Dr Panagiotis Fakitsas
F. Hoffmann-La Roche


Dr Rainer Gnibl
GMP Inspector


Dr Alexander Pontius
Bayer


Dr Frank Seibel
Roche Diagnostics


Dr Georg Sindelar
Recipharm


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Vetter Pharma-Fertigung

Quality Oversight

Supervision of the Pharmaceutical Quality System: Challenges and Opportunities

17/18 June 2026 | Copenhagen, Denmark

Highlights

- FDA and EU Expectations
- Managing Quality Oversight
- Case Studies
  - Gap Analysis and Implementation
  - Performance Review and Monitoring
  - CMO Business
  - Quality Product Leader Model
  - Small Company
  - Digital Transformation

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 help you turn 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 management elements are fully integrated and interconnected.

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.

Social Event

In the evening of the first day, 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.

Programme

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 inspector's 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?

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 – Motor in a Multinational Company

- Implementation of a successful Quality Oversight strategy and programme
- 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

Testimonials

„Overall the whole course was a very interesting topic and provided a lot of valuable information on Q-Oversight and I would always recommend this course to others - to colleagues interested in Q-Oversight." | Stefan Trentmann, DAIICHI SANKYO Europe

Workshop: Performance Review and Monitoring

- Approaches to selecting and calculating KPIs
- Inputs / outputs
- Meetings und reports
- Aggregation for higher Management Oversight

Case Studies:

(1) Pharma Quality System: from Compliance Check to Quality Oversight (how to get there)

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

- Elements of an integrated QMS oversight concept
- How to implement effective and efficient review systems
- Quality and Management Systems to lead the way to Quality Oversight
- The use of Quality Metrics
- Lessons learned

(2) Case Study Vetter Pharma-Fertigung: Quality Oversight in a CMO Business/Sterile Manufacturing

- Establishing a Quality Oversight system at a 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) Oversight at a small Manufacturing Site

- Managing Quality Oversight by a small Company-internal Quality Unit in a Complex CMO Network

(5) Quality Oversight in Times of digital Transformation

- Dashboarding and Real Time Trending
- Prospective Quality Oversight
- Links to Knowledge Management and Artificial Intelligence (AI)

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 Bavaria, Germany
Dr Rainer Gnibl is GMP Inspector and Head of the Inspectorate of the District Government 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 VP and Head of Quality International, overseeing the country quality affiliates.

Dr Frank Seibel
Roche Diagnostics, Germany
Dr Frank Seibel is Quality Site Head at Roche Diagnostics in Penzberg. Before that he was, amongst others, Senior Vice President Corporate Quality & HSE at Aenova Holding and Director Global Manufacturing Quality Strategy at AbbVie.

Dr Georg Sindelar
Recipharm AB, Sweden/Germany
Dr Georg Sindelar is Head of Corporate QMS. Before that he was Head C&Q at Bayer and Consultant.

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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GERMANY

Reservation Form (Please complete in full)

Quality Oversight | 17/18 June 2026, Copenhagen, Denmark

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
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 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.

Date
Wednesday, 17 June 2026, 9.00h – 17.30h
(Registration and coffee 8.30h – 9.00h)
Thursday, 18 June 2026, 8.30h – 15.30h

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
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Phone +45 (0) 33 96 50 00

Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
By e-mail to info@concept-heidelberg.de, or search and register directly at www.gmp-compliance.org under the number 22249.

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.

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