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 for EMA

Dr Alexander Pontius
Bayer

Dr Frank Seibel
Roche Diagnostics

Dr Georg Sindelar
Bayer

Hans Steier
Vetter Pharma-Fertigung

Quality Oversight

Supervision of the Pharmaceutical Quality System: Challenges and Opportunities

Live Online Training on 27/28 May 2025

Highlights

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

Objective

This 2-day Live 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 U.S. 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 challenge for the industry. On the other hand, FDA's Gui-dance 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**.

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.

Moderator

Ms Sarah Schmidt
Concept Heidelberg, on behalf of ECA

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 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?

Current FDA Expectations and future Developments

- Quality Reviews in USA (Overview)
- QA-Department´s Responsibilities in USA
- US-FDA Findings on Quality Oversight
- US-FDA Findings on Management Oversight
- US-FDA „Quality Metrics"-Guideline
- EU-Equivalent to US-FDA´s „Quality Metrics"

Quality Oversight – the Engine in a Multinational Company

- Definition of Quality Oversight
- Elements
- Levels
- Implementation

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

Case Study Roche: The Quality Product Leader (QPL) Model

- How a Quality Product Leader acts as a single point of contact for consistent end-to-end product quality oversight and continuous improvement
- Development of the Model

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

- Design of a Transfer
- Risk Management and Quality Oversight
- The Role of the QTA
- Performance Evaluation

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

Case Study: Quality Oversight at a small Manufacturing Site

Quality Oversight in Times of digital Transformation

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

Speakers

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 the EMA and performs GMP-inspections worldwide. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Alexander Pontius
Bayer AS, Norway

Alexander Pontius is Site Quality Head at Bayer AS in Oslo, bearing the Quality oversight of Bayer's radiopharmaceutical product portfolio (commercial and development).

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
Bayer AG, Germany

Dr Georg Sindelar is Head C&Q at the Bayer site in Leverkusen. Before that he was Consultant and Manager, amongst others in the areas of Pharma Compliance, Qualification and Auditing.

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.

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

_____

_____

_____

_____

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 27/28 May 2025

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 %.

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 HEIDELBERG will 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 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 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.

Date of the Live Online Training
Tuesday, 27 May 2025, 9.00h – 16.15h
Wednesday, 28 May 2025, 8.30h – 16.30h
All times mentioned are CEST.

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,890
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.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21678.

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:
Mr Maximillian Bauer (Organisation Manager) at
+49 (0)62 21/84 44 25 or per e-mail at
bauer@concept-heidelberg.de