

## Speakers



Dr Panagiotis Fakitsas  
F. Hoffmann-La Roche



Dr Rainer Gnibl  
GMP Inspector



Dr Alexander Pontius  
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Dr Frank Seibel  
Roche Diagnostics



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Vetter Pharma-Fertigung

# Quality Oversight

Supervision of the Pharmaceutical Quality System:  
Challenges and Opportunities

28/29 May 2024 | Copenhagen, Denmark



## Highlights

- FDA and EU Expectations
- Managing Quality Oversight
- Case Studies
  - Gap Analysis
  - Implementation
  - Performance Review and Monitoring
  - CMO Business
  - Quality Product Leader Model
  - Complaint Handling in the Supply Chain
  - 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 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.

## 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

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- 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-FDA's "Quality Metrics Guideline"
- Which approach makes sense from various experience in inspections?

### Current FDA Expectations and future Developments

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- 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

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- 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

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- 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



## 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 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) Quality Oversight for an Interface GMP/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

### (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 Gnihl**  
GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnihl is GMP Inspector and Head of the Inspectorate of the District Government and performs GMP-inspections worldwide. Rainer Gnihl also holds a lectureship at the University Erlangen-Nürnberg.



**Dr Alexander Pontius**  
Bayer AS, Norway

Alexander Pontius is the 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.



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Reservation Form (Please complete in full)

## Quality Oversight | 28/29 May 2024, Copenhagen, Denmark

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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P.O. Box 101764  
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GERMANY

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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:
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  - Cancellation until 2 weeks prior to the conference 50 %
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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.  
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sonal 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](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

Tuesday, 28 May 2024, 9.00h – 17.30h

(Registration and coffee 8.30h – 9.00h)

Wednesday, 29 May 2024, 8.30h – 15.30h

## Venue

Radisson Blu Scandinavia Hotel

Amager Boulevard 70

2300 Copenhagen S

Denmark

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## Fees (per delegate, plus VAT)

ECA Members € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

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

Via the attached reservation form, by e-mail or by fax message.

Or you register online at [www.gmp-compliance.org](http://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.

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