

## 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 & C<sup>a</sup>,  
Portugal



Audrey Schwebel  
Procter & Gamble,  
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Dr Georg Sindelar  
msg industry advisors,  
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Hans Steier  
Vetter Pharma-  
Fertigung, Germany

# Quality Oversight

Supervision of the Pharmaceutical Quality System:  
Challenges and Opportunities

09/10 June 2020 | 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
  - The Link to QRM and Knowledge Management
- Quality Culture

## 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-FDA's "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

### 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



#### 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

## 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 & C<sup>a</sup>, 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 Chemengineering 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.



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

## Reservation Form (Please complete in full)

### Quality Oversight, 09/10 June 2020, Copenhagen, Denmark

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

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Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

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GERMANY

#### 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 week prior to the conference 50 %
  - Cancellation within 1 week prior to the conference 100 %

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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](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, 09 June 2020, 9.00h – 17.45 h  
(Registration and coffee 8.30h – 9.00 h)

Wednesday, 10 June 2020, 8.30h – 15.30 h

## Venue

Radisson Blu Scandinavia Hotel

Amager Boulevard 70

2300 Copenhagen S, Denmark

Phone +45 3396 50 00

Email: [Scandinavia.meetings.events@radissonblu.com](mailto:Scandinavia.meetings.events@radissonblu.com)

## 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, 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/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Social Event

In the evening of the first conference 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.

## 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).

## 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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