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

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
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 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.
**Reservation Form (Please complete in full)**

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

<table>
<thead>
<tr>
<th>Title, first name, surname</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
</tr>
<tr>
<td>_________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Department</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
<td>_________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Important: Please indicate your company’s VAT ID Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>ZIP Code</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
<td>_________________________</td>
<td>_________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone / Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E-Mail (Please fill in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
</tr>
</tbody>
</table>

---

**General terms and conditions**

1. We are happy to welcome a substitute colleague at any time, or speakers without notice or to cancel an event.
2. 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 recommend you to inform us in writing. The cancellation fee for your registration fee will then be calculated according to the point of time at which we receive your message.
   - Cancellation until 2 weeks prior to the conference 10%.
   - Cancellation until 1 week prior to the conference 100%.
   - Cancellation within 1 week prior to the conference 50%.

**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). Instead, I can ask for the modification, correction, deletion of my data at any time via the contact form on this website.

---

**Conference**

The official conference language will be English. The conference language may be changed by the conference organizer at any time.

**Registration**

You can register online at www.gmp-compliance.org. The conference fee is payable in advance. After receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

**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 be no opportunity to print your certificate of participation on site. If you will automatically print your certificate of participation directly with the hotel. Early registration is recommended.

**Accommodation**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early registration is recommended.

**Fees (per delegate, plus VAT)**

<table>
<thead>
<tr>
<th>Fees (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIC Members 1,590</td>
</tr>
<tr>
<td>ECA Members 1,790</td>
</tr>
<tr>
<td>EU GMP Inspectorates 1,990</td>
</tr>
<tr>
<td>Non ECA Members 1,990</td>
</tr>
</tbody>
</table>

---

**Venue**

ECA has entrusted Concept Heidelberg with the organisation of this event.

**Organisation and Contact**

CONCEPT HEIDELBERG has entrusted Concept Heidelberg with the organisation of this event. The conference fee is payable in advance. After receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

---

**Accommodation**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early registration is recommended.

**Fees (per delegate, plus VAT)**

<table>
<thead>
<tr>
<th>Fees (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIC Members 1,590</td>
</tr>
<tr>
<td>ECA Members 1,790</td>
</tr>
<tr>
<td>EU GMP Inspectorates 1,990</td>
</tr>
<tr>
<td>Non ECA Members 1,990</td>
</tr>
</tbody>
</table>

---

**Venue**

ECA has entrusted Concept Heidelberg with the organisation of this event.