20 YEARS | ECA Academy
Your GMP/GDP Information Source

Quality Oversight

Supervision of the Pharmaceutical Quality System: Challenges and Opportunities

Speakers:


Petra Barth
form. AbbVie, Germany


Dr Rainer Gnibl
GMP Inspector for EMA, Germany


Dr Panagiotis Fakitsas
F. Hoffmann-La Roche Ltd, Switzerland


Dr Rodrigo Pereira
Bial - Portela & Cª, Portugal


Audrey Schwebel
Procter & Gamble Personal Healthcare, France


Dr Georg Sindelar
Chemgineering Business Design, Germany


Hans Steier
Vetter Pharma-Fertigung, Germany

10 - 11 April 2019, Berlin, Germany

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

This conference is recognised for the ECA GMP Certification Programme „Certified QA Manager".
Please find details at www.gmp-certification.eu

Quality Oversight

10 -11 April 2019, Berlin, Germany

Objectives

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 the new **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 cGMP 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 conference 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

- 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
- What does Quality Oversight mean in EU?
- 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 different quality standards 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 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) Case Study Merck:
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 & Co KG, 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. GMP Systems within her responsibility/area of expertise are: supplier qualification and oversight, inspection management, training, documentation, risk management and internal/ external audits.

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. Before that, he was also working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

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. Before that, he was Quality Site Manager Steriles.

Dr Rodrigo Pereira
Bial - Portela & Cª, S. A., Portugal
Dr Rodrigo Pereira is a Black Belt in Lean/ Six Sigma and Head of Quality & Projects at Bial, an international pharmaceutical group with products available in more than 50 countries. Before that, he was working in Quality Control at Eli Lilly and at Reading Scientific Services Ltd.

Audrey Schwebel
Procter & Gamble Personal Healthcare, 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
Chemgineering Business Design GmbH, Germany
Dr Georg Sindelar is Managing Consultant GMP Compliance for the Chemgineering Group where he is currently managing the implementation of a Quality Oversight program for a multinational company. Before that, he was Process Engineer GMP Production at DSM Biologics.

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.

Social Event

In the evening of the first conference day you are cordially invited to a social event (city tour and dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

GMP/GDP Certification Programme

This seminar is recognised within the GMP/GDP Certification Programme (ECA Certified QA Manager). By attending selected seminars, the participant can acquire an additional certificate.

We offer the following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
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ECA Certified Pharmaceutical Development Manager
ECA Certified GMP Auditor
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ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Lufthansa Mobility Partner

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As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 10 April 2019, 9.00h – 17.45h
(Registration and coffee 8.30h – 9.00h)
Thursday, 11 April 2019, 8.30h – 15.30h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 30 21 27 0
Fax +49 30 21 27 117
berlin@steigenberger.de

Accomodation
CONCEPT HEIDELBERG has reserved a limited numger 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.

Conference fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-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.

Registration
Via attached reservation form, by e-mail or by fax message.
Or you register online at 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.

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
+49-62 21/84 44 39 or per e-mail at
w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Jessica Stürmer (Organisation Manager) at
+49-62 21/84 44 60, or per e-mail at
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Registration form (please complete in full)

Quality Oversight
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Department

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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).
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