ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Energy Kristina Hansen
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Roche, Switzerland

CMO Oversight

Quality Oversight of Pharmaceutical Contract Manufacturing Organisations

10/11 December 2025 | Berlin, Germany

Highlights

- Requirements and Responsibilities
- Challenges and possible Solutions
- Quality System Aspects
- Supply Chain Maps
- Dealing with difficult CMOs
- GDP Interface
- CDMO Oversight: Case Study on IMPs

What MAHs and Virtual Companies need to know

Objectives

Hear and discuss the expectations and best practices for effective and efficient Contract Manufacturing Organisations (CMO) Quality and Supply Chain Oversight processes and how to get there. This will support you turning your company's quality excellence goals into reality.

Background

Marketing Authorisation Holders (MAHs) but also innovative Start-Ups and Research & Development organisations outsource parts, if not all, of manufacturing, testing and distribution activities for their product(s).

There are some good reasons for such an approach. It gives **smaller organisations** the opportunity to bring their own product(s) to the market and keep the focus on research and development and it also helps attracting investors. The actual employees can concentrate on core competencies. For **larger companies**, it offers more flexibility, focus on core competences and a good way to quickly add new products to the portfolio and develop markets faster.

Of course, such a business model also brings **some challenges.** The contract giver needs a high degree of trust with the business partners in the supply chain, must be able to deal with differences in corporate and quality culture and, above all, have the **necessary oversight of the quality and supply chain** of all activities and products.

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

QA Managers and Executives from MAHs/Virtual Companies including Senior Management and Business Executives and those involved in improving the Pharmaceutical Quality System.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

Programme

Regulatory Background and Requirements

- What does 'Oversight' mean?
- Applicable GMP requirements when working with CMOs
- Which are the essential Pharmaceutical Quality Systems (PQS) elements?

Marketing Authorisation Holder (MAH) Responsibilities

- The ultimate responsibility for the performance of a medicinal product
- Articulating MAH responsibilities in a complex organization
- Effective MAH governance

Quality and Supply Chain Oversight when working with CMOs – what is different and what are the Challenges?

- What does CMO oversight mean and what is expected?
- What aspects of the supply chain are relevant and how is sufficient oversight achieved?
- How to handle more than one quality system
- How to manage differences in culture and language

Supply Chain Maps – Examples of Complexities involved

- What is required of a Supply Chain Map (SCM)?
- Control and format of SCMs and setting the scope of responsibilities
- Achieving value from use of SCMs – and aligning company's approach for supply

Interactive Session: What is needed in your Organisation? (Specific Quality System Aspects)

- How the PQS should interact with other companies' systems
- Detailed review of possible points of interaction (e.g. change controls, deviations/non-conformances, complaints & recall, preparation of the Product Quality Review, audits.....)
- How to ensure effective and efficient interaction and communication.
- What are the challenges to overcome?

Batch Certification – Minimum Requirements & Best Practices

- Arrangements for QP Certification at the contract giver
- Manage deviation reporting and change control implementation
- Batch Certification – Considerations for outsourcing
- Case studies, examples of effective arrangements

Case Study IMPs: CDMO Oversight at Roche

- Responsibilities
- Contract Development and Manufacturing Organisations (CDMO) selection and control
- Overview management
- Point of contacts
- Reviews and quality reports (external/ internal)

Dealing with difficult CMO Stakeholder Behaviour

- Top 10 most difficult behaviours to handle
- Reasons
- How to increase engagement

CMOs needing high Level of Oversight

- Triggers, figures and stickers
- Handling below satisfactory CMOs

Use of Quality Risk Management (QRM)

- Objective of QRM and how best to use this tool
- When to use QRM proactively and how to ensure this is effective
- Examples of when QRM has to be used reactively and how to make informed, scientific decisions

Post Product Release Oversight Responsibilities

- MAH's responsibilities after certification and release of medicinal product
- Establishing arrangements for effectively managing defect reporting, potential market actions, supervisory authority engagement

The GDP Interface

- Reminder of GDP guidance available for APIs and products
- How this interface should work to ensure product reaches patient in suitable condition
- Challenges to overcome

Question and Answer Sessions

A set of Q&A Sessions will give you the possibility to discuss your issues and get answers to your questions.

Speakers

Energy Kristina Hansen
MilCor Consulting, Denmark
Senior QA Specialist

Energy Kristina Hansen is a Quality Expert with 24+ years of experience in quality assurance and compliance, spanning across food, health, manufacturing, pharmaceutical, and government sectors. Energy Kristina is also Guest Lecturer at the University of Copenhagen.

Canice Kearney
Takeda, Ireland
Head of Quality, Biologics External Supply

Canice Kearney is QP and Head of Quality, Biologics External Supply at Takeda with QA, QC, Microbio, Disposition and Operational Excellence responsibilities with global teams.

Sue Mann
Sue Mann Consultancy, U.K.
Consultant and Qualified Person

Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. She was Vice President of International Quality Assurance at Shire Pharmaceuticals before founding her company in 2009.

Jette Petersen
Roche, Switzerland
Quality Assurance Specialist IMP

Jette Petersen is Quality Assurance Specialist - External Quality Operations. Before that she was, amongst others, QP at Fisher Clinical Services.

Social Event

On the evening of the first course 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.

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Reservation Form (Please complete in full)

CMO Oversight, 10/11 December 2025, Berlin, Germany

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 %.

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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 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

Wednesday, 10 December 2025, 09.00h – 17.15h
(Registration and coffee 8.30h – 9.00h)
Thursday, 11 December 2025, 08.30h – 15.15h

Venue

HYPERION Hotel Berlin
Prager Straße 12
10779 Berlin, Germany
Phone +49 (0) 30 / 236250 0
Email hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The course fee is payable in advance after receipt of invoice and includes 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.

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 21898.

Conference language

The official conference language will be English.

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.

Organisation and Contact

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