ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Alexandra Bauloye
GSK, Belgium

Cheryl Chia
BeiGene, The Netherlands

Dr Rainer Gnibl
Government of Upper Bavaria, Germany

Savvas Koulouridas
Fagron BV, The Netherlands

Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland

Supply Chain Oversight

Supervision of the Pharmaceutical Supply Chain: Challenges and Opportunities

26/27 June 2025 | Barcelona, Spain

Highlights

- Regulatory and legal Background
- Control and Oversight
- Import/ Export
- Contracts
- Necessary GMP Systems

Objective

This 2-day Master Class brings together well-experienced experts to discuss the latest expectations and best practices for effective and efficient Supply Chain Oversight processes and how to get there.

Background

There is a steady increase in dependence on global supply chains. Pharmaceutical companies not only source starting materials from all over the world, but also outsource manufacturing activities. The finished products are then distributed globally. These complex supply chains with different transport routes and manufacturing locations lead to major challenges in terms of maintaining the quality of materials, intermediates and medicinal products.

This has increased the risk of potential compliance and delivery problems, having a negative impact on a company's business and on the patient. Managing these supply chains and complying with GMP and GDP regulations require a comprehensive supply chain oversight with appropriate risk management measures.

The manufacturer, the Qualified Person (QP) but also the Responsible Person (RP) are primarily responsible for compliance with EU/EEA requirements:

- EU-GMP Annex 16, General principles: "The ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy, lies with the marketing authorisation holder (MAH)."
- EU-GMP Annex 16, 1.7.2: "The entire supply chain of the active substance and medicinal product up to the stage of certification is documented and available for the QP. This should include the manufacturing sites of the starting materials and packaging materials for the medicinal product and any other materials deemed critical through a risk assessment of the manufacturing process. The document should preferably be in the format of a comprehensive diagram..."

In the meantime, the competent authorities and inspectorates are also focusing on supply chain oversight processes; manufacturers and especially the marketing authorisation holder must know and control every level of the supply chain.

Target Audience

QPs, RPs, Managers and Executives from pharmaceutical Quality and Supply Chain Units but also Senior Management, Business Executives and those involved in improving and controlling the pharmaceutical supply chain.

Moderator

Wolfgang Schmitt
(on behalf of ECA)

Programme

Supply Chain Security: Regulatory Background

- Globalization: Challenge & risk also besides GMP/GDP
- Legal „oversight" requirements
- Responsibilities
- GMP-/GDP interface
- What do inspectors expect?
- Which are the essential tools?

Other legal Aspects to consider

- The EU Supply Chain Act and its consequences for pharmaceutical companies (Corporate Sustainability Due Diligence Directive (CSDDD)
- EMA recommendations to strengthen supply chains of critical medicinal products and other necessary actions to avoid drug shortages (MSSG, CMA)
- Strategies to avoid drug shortages

Supplier Control

- How to keep oversight over the pool of suppliers and brokers
- Ongoing Supplier Qualification
- Active Supply Chain tracking
- Filing second source suppliers for APIs

Useful Supply Chain Diagrams

- Initiation and creation
- Management and change control
- Examples

Master Data in the Supply Chain

- The broader framework on Master Data
- How will this impact the pharmaceutical supply chain?
- What does this mean for supply chain organisations?
- What does this mean for the quality organisations supporting the supply chain?
- Become a master of your data!

Import and Export: Regulatory Perspective in EU

- Annex 16: Supply chain focus
- Annex 21: Consequences
- Inspector´s considerations on "best practices"

Contract Handling

- Different contracts in the Supply Chain (Forecasting, Supply, Quality/ Technical Agreement ...)
- Who needs to sign
- Contract handling: how to keep them up to date, how to avoid contradictions

Risk Management in the Supply Chain

- How to control quality, supply and business risks
- Drug shortages: requirements and mitigation
- Risk Register

Shipping Lane Risk Assessments

- Do we need them?
- What aspects of the shipping lane should be included?
- How much detail should be included?
- What actions might come out of the shipping lane assessment?

Social Event

On 26 June, 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.

Speakers

Alexandra Bauloye
GSK, Belgium
Senior Director

Alexandra Bauloye is Senior Director and Global Process Owner for Risk Management within GSC Quality.

Cheryl Chia
BeiGene, The Netherlands
Senior Director Distribution Quality

Cheryl Chia is Senior Director Distribution Quality. Before that she was cconsultant for GMP and GDP compliance in the pharmaceutical supply chain. Cheryl is also member of the Board of Directors of the European QP Association.

Dr Rainer Gnibl
Government of Upper Bavaria, Germany
Head of Inspectorate and GMP Inspector

Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA). He is also member of the Board of Directors of the European QP Association.

Savvas Koulouridas
Fagron BV, The Netherlands
Global Innovations Director

Savvas Koulouridas is a lawyer in profession and has also worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts).

Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland
Consultant

Prior to the funding of his consultancy business, Jens-Uwe Rengers acted as General Manager at Akorn AG. Before that he was Director Quality and QP and held different other roles at Byk Gulden, Cytos Biotechnology AG and Siegfried Ltd.

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GERMANY

Reservation Form (Please complete in full)

Supply Chain Oversight
26/27 June 2025, Barcelona, Spain

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:
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- 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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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Thursday, 26 June 2025, 9.00h – 17.00h
(Registration and coffee 8.30h – 9.00h)
Friday, 27 June 2025, 8.30h – 15.00h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
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Email sants@barcelo.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 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.

Accomodation
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 21608.

Presentation/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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