ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers

Michael Grosser
Lonza Biologics,
Switzerland

Dr Svenja Lacher
F. Hoffmann-La Roche,
Switzerland

Dr Bettina Rietz-Wolf
GMP Inspector, Local Authority of
Baden Württemberg, Germany

Hans Steier
Vetter Pharma-Fertigung, Germany

Dr Florian Witte
Boehringer Ingelheim Pharma,
Germany

Quality Oversight in Sterile Manufacturing

Live Online Training on 3 December 2025

Highlights

- FDA Expectations for Quality Oversight
- Quality Oversight; Only an FDA Requirement? Quality Oversight from a European Perspective
- Typical Challenges in Practice
- Case Studies on Quality Oversight from
  - Boehringer Ingelheim Pharma
  - F. Hoffmann-La Roche
  - Lonza
  - Vetter Pharma Manufacturing
- Operator Training and Certification as Part of Quality Oversight
- Opportunities and Risks

Objectives

- Learn about the US FDA's expectation of a Quality Oversight programme.
- Is Quality Oversight just an FDA expectation? What are the expectations of European Inspectors?
- Quality Oversight; only a regulatory expectation? What advantages can you gain from the implementation for your own company?
- How are Quality Oversight requirements implemented in sterile production? In 4 case studies, you will be presented with concepts and implementation options

Background

In the „Guidance for Industry - Sterile Drug Products Produced by Aseptic Processing" published in 2004, the FDA clearly formulated the expectations for Quality oversight. The aim should be to ensure regular and independent checks of the processes and personnel involved in aseptic manufacturing and thus reduce the risk of product contamination. In several warning letters in recent years, companies have been criticised for insufficient „quality oversight".

In addition, against the background of new or revised European regulations, e.g. Annex 1 or Annex 15,

EU GMP Guide Annex 15 „1.3 ...However, there should be appropriate quality oversight over the whole validation life cycle".

every European company faces the question of how the American demands for Quality Oversight will also be taken up in the regulatory environment here in the future.

Target Audience

The Live Online Training is aimed at responsible employees in sterile production who are involved in the planning, establishment and implementation of a Quality Oversight programme in their companies. The following areas are specifically addressed

- Production
- Quality Assurance
- Microbiology

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

Programme

Quality Oversight and GMP in the EU

- Overview of regulatory requirements in the EU
- The PQS (Pharmaceutical Quality System) as a basis
- Requirements acc. to Annex 1

Expectations of an Inspector
Dr Bettina Rietz-Wolf

FDA Guidance for Industry „Sterile Drug Products Produced by Aseptic Processing" (2004)

„Similarly, the quality control unit should provide regular oversight of adherence to established, written procedures and aseptic technique during manufacturing operations".

Quality Oversight in Aseptic Manufacturing: FDA Expectation and Requirements
Dr Florian Witte

- FDA regulatory requirements
- Expectations regarding Quality Oversight: Requirements and Principles
- Background for FDA Quality Oversight Requirements

Implementation of Quality Oversight: Case Study Boehringer Ingelheim. Opportunity for Continuous Improvement or Formal Compulsion? *Dr Florian Witte*

- Learn how to implement Quality Oversight efficiently by means of concrete examples

Case Study Vetter Pharma-Fertigung: Quality Oversight in Sterile Manufacturing
Hans Steier

- Establishing a Quality Oversight system at an CDMO in sterile manufacturing
- FDA expectations and audit experiences
- Interfaces to other Quality system
- PIP - Person in the Plant Concept
- Advantages and challenges
- Regulatory outlook, Annex1 - Quality Oversight elements

Case Study Roche:
Dr Svenja Lacher

- Quality Oversight – Definition
- Quality Oversight Strategy at Roche Kaiseraugst
- Implementation of Quality Oversight at Roche Kaiseraugst
- Prerequisites, opportunities and risk of Quality Oversight

Aseptic Operator Certification Programme in Sterile Production within the Scope of QA-Oversight
Michael Grosser

- Training programme
- Certification and Re-certification procedure

Case Study Novartis: QA-Oversight in Sterile Production *Michael Grosser*

- QA Oversight concept
- Training of QA-Oversight personnel (Train-the-Trainer)
- Procedure in case of QA-Oversight observations

Speakers

Michael Grosser
Lonza Biologics, Stein, Switzerland
Michael Grosser is a microbiologist and has been working in contract laboratories and the pharmaceutical industry in Germany and Switzerland for more than 25 years. As Senior QA Expert Manufacturing, he is responsible for aseptic working and behaviour in cleanrooms and isolators.

Dr Svenja Lacher
F. Hoffmann-La Roche AG, Kaiseraugst, Switzerland
Team Lead QA Rocephin at a parenteral production site in Kaiseraugst responsible for QA Operations and QA-Oversight Value Stream Rocephin.

Dr Bettina Rietz-Wolf
GMP Inspector, Local Authority of Baden Württemberg, Tübingen, Germany
Bettina is a GMP Inspector for the District Government of Baden-Württemberg and the EMA and performs GMP inspections worldwide. She was head of the German expert group EFG3 "Manufacturing of sterile products" at the ZLG.

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.

Dr Florian Witte
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany
Florian Witte has been working in the pharmaceutical industry at Boehringer Ingelheim for more than 20 years in different positions, including quality assurance for aseptic filling of inhalation solutions. Since 2021 he is heading the quality assurance unit for device development

This could be of interest for you

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Why not online? GMP/GDP Training Courses/ Conferences, Webinars and E-Learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

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Reservation Form (Please complete in full)

Quality Oversight in Sterile Manufacturing
Live Online Training on 3 December 2025

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 %,
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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 https://www.gmp-compliance.org/privacy-policy). 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 of the Live Online Training

Wednesday, 3 December 2025, 09.00 – 17.15 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

ECA Members € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 645
The conference fee is payable in advance after receipt of invoice.

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 22080.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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