ECA Academy
Your GMP/GDP Information Source

Speakers

Kerstin Hurst
F. Hoffmann-La Roche, Switzerland

Heide Nagel
Novartis Pharma, 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 17 November 2022

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
  - Novartis Pharma
  - F. Hoffmann-La Roche
  - 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 (Draft)

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:
Kerstin Hurst

- 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
Heide Nagel

- Training programme
- Certification and Re-certification procedure
- Training videos

Case Study Novartis: QA-Oversight in Sterile Production *Heide Nagel*

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

Speakers

Kerstin Hurst
F. Hoffmann-La Roche AG, Kaiseraugst, Switzerland
QA-Manager „Value Stream Vials Volume/Speed" at the parenteral production site in Kaiseraugst responsible for QA-Oversight.

Heide Nagel
Novartis Pharma Stein AG, Switzerland
Since 2012 at Novartis Pharma AG, as Senior QA Expert with main focus on QA-Oversight. Currently within Manufacturing Science & Technology (MS&T) as Senior Process Expert Microbiology, Sterility Assurance responsible to establish microbiological concepts for sterile manufacturing (Microbial Control Strategy).

Dr Bettina Rietz-Wolf
GMP Inspector, Local Authority of Baden Württemberg, Tübingen, Germany
Bettina is a pharmacist and 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 is Chemist by education. He has been working in the pharmaceutical industry at Boehringer Ingelheim since 22 years in different positions: Analytical, formulation and device development of inhalative medicines; process development and quality assurance for aseptic filling of inhalation solutions. Since 2021 he is heading the quality assurance unit for device development.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Quality Oversight in Sterile Manufacturing
Live Online Training on 17 November 2022

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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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training
Thursday, 17 November 2022, 09.00 – 17.15 h CET

Technical Requirements
We use Webex Events 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 € 990
APIC Members € 1,090
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org

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.

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:
Dr. Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or at
mangel@concept-heidelberg.de.

For questions regarding organisation etc. please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49(0)62 21/84 44 51, or at
strohwald@concept-heidelberg.de.