Speakers

Dr Robert Eskes
FAREVA Unterach

Mag. Petra Falb
AGES - Austrian Agency for Health and Food Safety

Faye Litherland
FPC Life Sciences

Dr Andreas Neubert
Klocke Holding

Robert G. Schwarz
GXP-TrainCon

Dr Frank Sielaff
GMP Inspector, Regional Authority, Darmstadt, Germany

Dr Jörg Weyermann
GlaxoSmithKline

GMP for Vaccine Manufacturers

Live Online Training on 28/29 October 2025

Classic and Modern Technologies -
Regulatory Requirements and Practical Implementation

Highlights

- Three Case Studies:
  1. Vaccine Facility Design
  2. Design, Construction and Qualification of a New Production Line
  3. GMP Development and Manufacturing of Recombinant Viral Vaccines for Clinical Trials
- Regulatory Requirements of Conventional and Modern Vaccines
- GMP Issues for Upstream and Downstream Processing
- Staff Safety

With Case Studies on New Manufacturing Buildings and Validation of Fogging/Gassing Systems

Objective

The development and production of vaccines makes high demands on the manufacturing pharmaceutical industry. The special requirements on handling and safety with live organisms necessitate measures which exceed the requirements of classic pharmaceutical manufacturing.

Topics like the enhanced risk of cross contaminations, questions about individual safety of staff and the issues of cleaning and disinfection of rooms and equipment concern a vaccine manufacturer in a considerable scale.

Specifically, the demands of the necessary bio safety classes with negative pressure of rooms versus that of aseptic processing with positive pressure requires a well thought-out design of vaccine facilities.

Also, the safety of environment and waste disposal should receive proper attention already in the design phase. But the dedicated requirements on staff safety are also a challenge in vaccine manufacturing.

This Live Online Training will give you the possibility to see the theoretical background as well as the practical implementation of GMP requirements in the vaccine production. A combination of theoretical requirements and practical case studies is the best way to learn this.

Speakers from regulatory bodies, consulting and practising experts will give you the chance to get to know the different views and you will have ample opportunity to discuss specific issues with speakers and other participants.

Background

“Vaccines are expected to be very safe” is one of the headlines in the presentation of the CBER “Vaccine safety team”. At the same time, new vaccines are needed for diseases for which currently no vaccine is available, and production technologies need improvement to deal with the shortage of certain types of vaccines. This has led to the emergence of new technologies. One of the important questions from the authorities however is “How safe are the new technologies”. There are several guidelines from the FDA and other authorities that deal with the safety of the different types of vaccines.

In the development of new technologies for the pharmaceutical and biopharmaceutical production of vaccines again the question of GMP compliance and safety is emphasised.

Furthermore, with the Quality Initiative for the 21st Century from the FDA new guidelines have been issued, which have an impact not just on conventional pharmaceutical industry, but also on vaccine manufacturers. Risk management and quality in design are essential in the implementation of new technologies and the introduction of new vaccines.

To assure the expected safety is one of the great challenges of all vaccine producers.

Target Audience

The Live Online Training is designed for personnel of pharmaceutical industries, their suppliers and regulatory bodies who

- are responsible for quality control and/or quality assurance in vaccine/biopharmaceutical production,
- manage the vaccine production,
- establish the operator protection,
- audit vaccine manufacturers,
- design or operate vaccine production sites.

Programme

GMP for Vaccines: What are the Issues?

- Differences between vaccines and conventional products
- Inactivated and live vaccines
- Control of vaccine strains and cell lines
- Risk of (cross-)contamination
- (Bio)safety issues

Regulatory Requirements of Conventional Vaccines

- Critical process steps
- In Process- and final product controls
- Specifications and stability
- Further relevant guidelines

Regulatory Requirements of Modern Vaccines

- Differences to conventional vaccines
- mRNA Vaccines: How to control the process and the final product
- Relevant guidelines and Ph Eur Monographs
- Vaccine platform technology master file

Modern Technology for Vaccine Manufacture

- Clean utilities design and installation - current trends
- Single use vs reusable technology
- Cell culture methods and equipment

Containment, Biological Safety and Product Protection

- Containment, product safety versus environmental safety
- Primary containment and additional measures
- Negative pressure areas in aseptic manufacturing
- Decontamination of facilities
- Personnel as critical component in containment

Virus Inactivation and Virus Removal Techniques

- Validation of decontamination procedures
- Virus inactivation: principles and methods
- Virus removal methods
- GMP issues on virus inactivation and virus removal techniques

Validation of a Decontamination System for Production Equipment, Process Devices and Cleanrooms

- Different gassing systems
- System qualification
- Validation of a dry fog detergent

Case Study: Vaccine Facility Design

- Identification of biological risk and management strategy
- Ergonomics for operation, cleaning and maintenance
- Designing for the future (expansion, change of manufacturing method, change of product)

Inspection of Vaccine Manufacturer – Topic of Focus & Common Issues

- Navigating the world of GMP guidelines
- Topics in GMP inspections
- How to deal with observations?

cGMP Issues for Upstream Processing

- General GMP concerns for upstream processing
- Raw materials and media preparation
- Cell culture
- Virus culture
- Inactivation of microorganisms

Issues of Staff Safety

- Requirements and guidelines
- Differences vaccines products and plasma products
- Use of S3 coveralls
- Environmental health and safety challenges
- Examples from daily business

Case Study: Isolator Filling Line for Vaccines

- Requirements of design
- Issues of construction
- Qualification challenges

cGMP Issues for Downstream Processing

- General GMP concerns for downstream processing
- (ultra)filtration techniques
- (ultra)centrifugation techniques
- Sterile filtration and aseptic processing

Case Study: GMP Development and Manufacturing of Recombinant Viral Vaccines for Clinical Trials

- Regulatory expectations for vaccine batches for phase 1/2/3 clinical trials
- Development vs. validation
- Regulatory expectations for implementation of analytical methods – qualification and validation
- Contract manufacturing of IMPDs

Dr Robert Eskes, FAREVA Unterach GmbH

After working for Aventis Behring, ZLB Bioplasma and CSL, Robert Esjes joined Novartis Vaccines, later GSK Vaccines, in 2007, most recently as Head QA/QC workstream integration Marburg - Quality. In 2016, he moved to Sandoz in Unterach, now Fareva Unterach in Austria. His current position is Director Manufacturing Science & Technology.

Petra Falb, AGES - Austrian Agency for Health and Food Safety

In 2003, Petra Falb joined the AGES with responsibilities in quality assessment of human and veterinary vaccines (national, decentralized and centralized procedures). Until 2016 her focus was on viral vaccines. In 2017 she took over new responsibilities for veterinary vaccines.

Faye Litherland, FPC Life Sciences

Faye Litherland has over 25 years' experience of contributing to the successful delivery of projects in the Pharmaceutical, Biotech, and Life Sciences industries. With broad experience within the pharmaceutical and life sciences sector, Faye's primary areas of interest are vaccine manufacturing, biological containment and clean utilities design. She is currently Director of Process Technology at FPC Life Sciences.

Dr Andreas Neubert, Klocke Holding GmbH

Andreas Neubert completed his study of veterinary medicine with graduation. He worked for several years in different positions at IDT, e.g. as head of production. Currently he is CSO at the Klocke Holding.

Robert G. Schwarz, GXP-TrainCon

From 2001, Robert Schwarz led the environmental monitoring team at Baxter, and from 2005 to 2018 he was a validation specialist for device qualification, sterilisation validation and cleaning validation. Since 2010, he has also been passing on his experience as a university lecturer. In 2019, he began working as a freelance trainer and founded his consulting company GXP-TrainCon in 2022.

Dr Frank Sielaff, Hessian State Office of Health and Care, Darmstadt, Germany

Frank is GMP Inspector at the competent authority of Hessen with the focus on inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP-inspectorate Dr Sielaff was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

Dr Joerg Weyermann, GlaxoSmithKline

Joerg Weyermann is Head Quality Assurance at GSK, former Novartis Vaccines and Diagnostics GmbH. Until 2009, he was the Head Quality Operations for Sandoz Industrial Products GmbH. Before that he was Head Quality Control at Sandoz.

Moderator:
Clemens Mundo

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Reservation Form (Please complete in full)

GMP for Vaccine Manufacturers, Live Online Training on 28/29 October 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

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Date of the Live Online Training

Tuesday, 28 October 2025, 08.30 h – 18.00 h
Wednesday, 29 October 2025, 08.30 h – 16.15 h
All times mentioned are 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 trainings 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The 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 22088.

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 Online 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 event.

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