



Speakers



Dr Robert Eskes
FAREVA Unterach, Austria



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



Dr Andreas Neubert
Klocke Holding, Germany



Dr Volker Öppling
PEI, German Federal Institute for
Vaccines and Biomedicines



Robert G. Schwarz
GXP-TrainCon, Austria



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



Dr Jörg Weyermann
GlaxoSmithKline, Germany

GMP for Vaccine Manufacturers

19/20 November 2024, Hamburg, Germany



*Classic and Modern Technologies -
Regulatory Requirements and Practical Implementation*

Highlights

- Three Case Studies:
 1. Concept of Multipurpose Vaccine Production Facility
 2. Design, Construction and Qualification of a New Production Line
 3. GMP Development and Manufacturing of Recombinant Viral Vaccines for Clinical Trials
- Peculiarities of Viral and Bacterial 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 course 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 the 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. Ensuring the expected safety is one of the greatest challenges of all vaccine producers.

Target Audience

The course 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

The Peculiarities of Viral Vaccines

- From viral seeds to finished products
- Requirements for raw and starting materials
- Efficient process and product control
- Setting specifications adequately
- Appropriate tests and assays for product release
- Stability testing
- Viral safety aspects
- TSE compliance
- How to deal with OOS results?
- Requirements for early and late clinical trial phases

Modern Vaccines Part I

- Vector vaccines
- Plasmid-DNA vaccines
- Related regulations

The Peculiarities of Bacterial Vaccines

- Types of vaccines available
- Manufacturing of classical/modern bacterial vaccines
- Challenges in manufacturing (quality/regulatory issues)
- New technologies and products

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 virus inactivation step
- 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: Concept of Multipurpose Vaccine Production Facility

- Practical issues with flow of material, personnel and waste material
- Clean room qualification
- Segregation of cell preparation, virus production and downstream processing
- Change over procedures for manufacturing campaigns

Modern Vaccines Part II – GMP Inspectors' View

- Regulatory expectations
- Classic vaccines
- Aspects for modern vaccines, e.g. mRNA and protein-based
- Experiences from inspections

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

Speakers



Dr Robert Eskes FAREVA Unterach GmbH, Austria

Robert Eskes studied at the Universities of Utrecht and Vienna. After working for Aventis Behring, ZLB Bioplasma and CSL, he 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

Petra Falb studied at Veterinary University Vienna (Austria). From 1998 to 2001 she worked as scientist at the Institute for Virology and later at the Institute for pathology. 2001-2003 she was self employed as veterinary surgeon. In 2003 she joined the AGES with responsibilities in quality assessment of human and veterinary vaccines (national, decentralised and centralized procedures). Until 2016 her focus was on viral vaccines. In 2017, she took over new responsibilities for veterinary vaccines.

Speakers



Dr Andreas Neubert
Klocke Holding GmbH, Germany

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.



Dr Volker Öppling
Paul Ehrlich Institut (German Federal Agency for Vaccines and Biomedicines)

After study of Veterinary Medicine and his PhD he got appointment for specialist of Veterinary Microbiology. 1990-2007 he was responsible for human bacterial (especially polysaccharide based) and fungal vaccines in the Department "Human Bacterial Vaccines" at the Paul-Ehrlich-Institut. Currently, he is head of section "Microbiological Vaccines" (all bacterial, fungal and parasitic vaccines). Main responsibilities are: assessment of marketing authorisation applications (quality, preclinical and clinical), batch release, assessment of clinical trial applications, provision of regulatory and scientific advice, managing of regulatory affairs issues.



Robert G. Schwarz
GXP-TrainCon, Austria

Robert Schwarz has a degree in bioprocess engineering and biotechnological quality management. From 2001, he 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
GMP Inspector, Hessian State Office Of Health and Care, Darmstadt, Germany

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, Germany

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

Date

Tuesday, 19 November 2024, 09.00 h – 18.00 h

(Registration and coffee 08.30 – 09.00 h)

Wednesday, 20 November 2024, 08.30 h – 16.00 h

Venue

HYPERION Hotel Hamburg

Amsinckstr. 39

20097 Hamburg, Germany

Phone +49(0) 40 414 2000

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Fees (per delegate, plus VAT)

ECA Members € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

The conference 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 when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

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 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.

CONCEPT HEIDELBERG

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In the evening of the first course day, you are cordially invited to a social event. 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)

GMP for Vaccine Manufacturers, 19/20 November 2024, Hamburg, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

Country

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