ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Robert Eskes
Novartis Technical Operations

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

Dr Andreas Neubert
IDT Biologika

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

Robert Schwarz
FH Campus Vienna

Dr Jörg Weyermann
GlaxoSmithKline

GMP for Vaccine Manufacturers

Live Online Training on 24/25 November 2020

Current 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

Programme

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 with speakers and other participants about specific issues.

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". The FDA has issued a draft guideline on new cell substrates for vaccine manufacturing to detail requirements in this area.

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 Day 1

Provisional timetable, the actual schedule may vary depending on the situation

09.00 – 09.15 h Welcome and Organisational

09.15 – 10.00 h
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

10.00 – 11.00 h
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

11.00 – 11.15 h Break

11.15 – 12.30 h
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

12.30 – 13.00 h
Questions and Answers

13.00 -14.00 h Break

14.00 – 15.00 h
cGMP Issues for Upstream Processing

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

15.00 -15.45 h
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

15.45 -16.00 h Break

16.00 - 17.00 h
Decontamination, Virus Inactivation and Virus Removal Techniques

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

17.00 – 17.30 h
Questions and Answers

Programme Day 2

08.30 - 09.30 h
Validation of a Decontamination System for Production Equipment, Process Devices and Cleanrooms

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

09.30 – 10.30 h
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

10.30 – 10.45 h Break

10.45 – 11.45 h
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

11.45 – 12.15 h
Questions and Answers

12.15 – 13.15 h Break

13.15 – 14.15 h
Case Study: Design, Construction and Qualification of a New Production Line

- Requirements of design
- Issues of construction
- Qualification Challenges

14.15 – 15.15 h
cGMP Issues for Downstream Processing

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

15.15 -15.30 h Break

15.30 – 16.30 h
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 IMPD´s

16.30 – 17.00 h
Questions and Answers

Speakers

Dr Robert Eskes,
Novartis Technical Operations, Austria

Currently Robert Eskes is Head MS&T Unterach /Novartis Technical Operations – Aseptics at EBEWE Pharma in Unterach, Austria. From 2014 to 2016 he was Quality Assurance head for Third Party Manufacturing at GSK Vaccines,. Before that, he held positions as Quality Assurance head at Novartis Vaccines and as Validation manager at CSL-Behring GmbH.

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.

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

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, preclinic and clinic), batch release, assessment of clinical trial applications, provision of regulatory and scientific advise, managing of regulatory affairs issues.

Dr Andreas Neubert,
IDT Biologika, Germany

Andreas Neubert completed his study of veterinary medicine with graduation. He works since several years in different positions at IDT and is currently head of production there.

Robert Schwarz,
FH Campus Vienna, Austria

Robert Schwarz studied biotechnology and quality management. He joined Baxter in 2001 as coordinator of environmental monitoring. From 2005 he was validation specialist responsible for equipment qualification, sterilisation validation and cleaning validation. Since 2010 he is university lecturer in the field of biotech at the University of Applied Sciences in Vienna.

Dr Joerg Weyermann,
GlaxoSmithKline, Germany

Joerg Weyermann is head 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.

Date of the Live Online Training

Tuesday, 24 November 2020, 09.00 h – 17.30 h CET
Wednesday, 25 November 2020., 08.30 h – 17.00 h CET

Technical Requirements

For our Live Online Trainings and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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Your Benefit
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

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritisation
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

ECA Academy

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. **This training course is the first element for your additional certification.** Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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GERMANY

Reservation Form (Please complete in full)

GMP for Vaccine Manufacturers, Live Online Training on 24/25 November 2020

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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 January 2012).
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 http://www.gmp-compliance.org/eca_privacy.html). 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.