This education course is recognised for the ECA GMP Certification Programme “Certified Biotech Manager”. Please find details at www.gmp-certification.eu

HIGHLIGHTS:

- Four Case Studies:
  1. New building of a multipurpose vaccine production facility
  2. New filling facility in direct cooperation with an existing bulk production
  3. Different fogging and gassing systems for decontamination of isolators, lyophilizers and clean rooms
  4. GMP manufacturing of recombinant viral vaccines for clinical trials

- Peculiarities of viral and bacterial vaccines
- GMP issues for upstream and downstream processing
- Staff Safety

04-05 December 2018, Barcelona, Spain

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 Institute for Vaccines and Biomedicines

- Robert Schwarz
  FH Campus Vienna

- Dr Jörg Weyermann
  GlaxoSmithKline
Objectives

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 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 development 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

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 Bacterial Vaccines

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

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

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

Case Study: New Building of a 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

GMP for Vaccine Manufacturers

04-05 December 2018, Barcelona, Spain
Case Study: Different Fogging and Gassing Systems for decontamination of Isolators, Lyophilisers and Clean Rooms
- Different gassing systems
- System qualification
- Validation of a dry fog detergent

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

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

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

GMP 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

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

Case Study: Planning and Realization of a new Filling Facility in direct Cooperation with Existing Bulk Production
- Requirements of design
- Issues of construction
- Qualification challenges

Moderator
Axel H Schroeder, Concept Heidelberg

Speakers

Dr Robert Eskes, Novartis Technical Operations, Austria
Currently Robert Eskes is Head MS&T Unterach / Novartis Technical Operations – Aseptics at EBE-WE Pharma in Unterach, Austria. From 2014 to 2016 he was Quality Assurance head for Third Party Manufacturing at GSK, former Novartis Vaccines and Diagnostics GmbH. Before that, he held positions as Quality Assurance head for Rabies and FSME bulk production and in Manufacturing Science and Technologies leading the manufacturing support and tech transfer of Rabies and FSME bulk production also 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, Germany
Head of section “Microbiological Vaccines” (all bacterial, fungal and parasitic vaccines). Main responsibilities: 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.
**Reservation Form (Please complete in full)**

### GMP for Vaccine Manufacturers

04-05 December 2018, Barcelona, Spain

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**Fees (per delegate plus VAT)**

- EU GMP Inspectorates: €895
- Non-ECA Members: €1,790
- APIC Members: €1,690
- ECA Members: €1,590

**Accommodation**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please register for the event. Registration should be made directly with the hotel.

**Registration**

Via the attached reservation form, by email or by fax.

**Social Event**

In the evening of the first course day, you are cordially invited to a social event. The conference hotel is in a relaxed atmosphere.

**Venue**

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain

**Contact**

For questions regarding reservation, hotel, organisation, etc.: Ms. Nicole Bach (Organisation Manager) at +49 6221/84 44 22, or per e-mail at bach@concept-heidelberg.de.

For questions regarding content, organisation and contact: Mr. Axel H. Schroeder (Operations Manager) at +49 6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.

**Conference Language**

The official conference language will be English.

**Terms and conditions**

1. If you cannot attend the conference, you have two options:
   - We are happy to welcome a substitute colleague at any time.
   - If you have to cancel, we must charge the following processing fees: Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.
2. The event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. In case of cancellation, CONCEPT HEIDELBERG will not be responsible for any expenses, penalties or other costs incurred due to a cancellation.

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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 will be 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 personal data at any time via the contact form on this website.

**Contact for questions regarding hotel and organisation:**

08014 Barcelona, Spain

**Contact for questions regarding content:**

**Contact for questions regarding reservation, hotel, organisation etc.:**

**Terms of payment:**

Payable without deductions within 10 days after receipt of invoice.

**Important:** This is a binding registration and all fees are due in case of cancellation or no 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, we will inform you of the full registration fee, even if you have not paid 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.

**Venue:**

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain

**Date:**

Tuesday, 04 December 2018, 08.30 h – 18.00 h

Registration: 09.00 h – 18.00 h

**Fees (per delegate plus VAT):**

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- Non-ECA Members: €1,790
- APIC Members: €1,690
- ECA Members: €1,590

**Internet:**

www.gmp-compliance.org