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

24/25 November 2020 | Barcelona, Spain

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

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 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

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

cGMP Issues for Upstream Processing

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

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

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

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

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: Design, Construction and Qualification of a New Production Line

- 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, 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, 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.

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GERMANY

Reservation Form (Please complete in full)

GMP for Vaccine Manufacturers, 24/25 November 2020, Barcelona, Spain

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)

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If you cannot attend the conference you have two options:
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Date

Tuesday, 24 November 2020, 09.30 h – 18.00 h
(Registration and coffee 09.00 h – 9.30 h)
Wednesday, 25 November 2020, 08.30 h – 17.00 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

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 and includes conference documentation, 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/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Social Event

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.

Registration

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

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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