

Speakers



Dr Johannes Blümel
Paul-Ehrlich-Institute (Federal
Agency for Vaccines and
Biomedicines)



Dr Albrecht Gröner
PathoGuard Consult



Dr Michael Ruffing
Boehringer Ingelheim Pharma



Michael Schiffer
CSL Behring

Virus Safety – Best Practices and Emerging Trends



Live Online Training on 18/19 February 2025



Highlights

- Overview about regulatory Background
- The Impact on the Manufacture of Biopharmaceuticals/Biologics
- Current Detection, Inactivation and removal Techniques
- Design and Documentation of Validation Studies
- Pathogen Safety Risk Assessment
- Interactive Workshops

With interactive Workshop Sessions

Objectives

The course aims to explain the complex nature of viruses that move between the concepts of life and death. It provides participants with a fundamental understanding of viral and pathogen safety in the pharmaceutical industry. Participants will acquire basic knowledge of virology, including the physiology of viruses, their replication cycles, transmission routes and resistance mechanisms. This knowledge is essential for risk assessment and the development of safety strategies.

In addition, the programme teaches advanced safety strategies for dealing with viruses and testing methods, including NGS (next generation sequencing) and other modern diagnostic methods. Participants will learn best practices for viral inactivation and validation to ensure products meet industry requirements and global regulatory frameworks such as ICH Q5A, the European Medicines Agency (EMA) and the European Pharmacopoeia.

The course also provides practical insights into the control of viral contamination, including risk mitigation strategies through facility segregation, risk analysis and contamination risk management. Finally, advanced virus detection methods, including NGS, and safety-related aspects of Advanced Therapy Medicinal Products (ATMP), such as gene and cell-based therapies, will be highlighted.

Background

The past has shown us that the development and production of vaccines can also attract enormous public attention. This makes it all the more important, especially when it comes to approval and production under time pressure, that the quality standards of good manufacturing practice are observed.

Virus safety is one of the major concerns in the development and production of biopharmaceuticals and biologics. Huge efforts are undertaken to prevent viral contamination. A series of guidelines was dedicated to that topic exclusively.

For many people who are involved in the development and production of biopharmaceuticals and biologics the world of viruses is a “black box”.

Target Audience

This Education Course is directed to responsible personnel involved in the development and production of biopharmaceuticals and biologics

- Research & Development
- Quality Assurance
- Regulatory Affairs
- Production
- Engineering
- Quality Control

It is also useful for service providers, such as contract research organisations and contract manufacturers.

Programme

Elemental (basic) Virology

- Physiology (if you can use such a word)
- Replication cycles
- Vectors
- Resistance properties

Virus Safety Strategy: Approaches and Test Procedures

- Viral safety approach: Regulations and principles
- Virus testing concept
- Methods for detection of exogenous & endogenous virus

Virus Management: Methods for Inactivation and Validation Studies in Adventitious Virus Management

- Virus contamination of starting material for biologicals
- Dedicated virus reduction steps vs. manufacturing steps for protein purification and concentration
- Down scaling of manufacturing steps for virus clearance studies
- Virus clearance studies
 - Virus spike preparation
 - Controls as cytotoxicity / interference / balance / inactivation kinetic
 - Virus detection methods – infectivity vs. NAT
 - Robustness of virus reduction methods / DoE studies

Virus Safety: Regulatory Background

- ICH Guidelines (ICH Q5A)
- European Guidelines (EMEA)
- European Pharmacopoeia
- Risk assessment
- Clinical trials in Europe

Virus Contamination Control in pharmaceutical Production

- Adventitious agents contamination control strategies
- Facility segregation & risk analysis
- Methods of risk assessment and minimization
- Case studies

Pathogen Safety Risk Management

- Strategies for ensuring product quality and safety
- What to consider and how to perform risk assessments regarding pathogen safety
- Deviations and change management
- Case studies

Next Generation Sequencing (NGS) - a powerful Technology for Virus Detection

- Technology & applications
- Regulations, e.g., in ICH Q5A & Ph. Eur.

Virus-based Advanced Therapy Medicinal Products (ATMPs)

- Applications
- Oncolytic viruses: Mode of action & adventitious virus safety approach
- AAV - efficient gene therapy vector
 - Production of AAV for gene therapy
 - Quality Control of AAV
 - Clinical applications of AAV

Virus Safety Aspects of Advanced Therapy Medicinal Products (ATMP)

- Regulatory background/certification
- Gene therapy medicinal products
- Cell based medicinal products

Transmissible Spongiform Encephalopathy (TSE) – Biology & Regulatory

- Nature and transmission of TSE agent
- TSE agent detection methods
- Prion reduction methods
- EU legislation / EMA note for guidance / reflection paper
- EDQM TSE Certification



Interactive Workshops with Case Studies and Examples

During these workshops, the participants develop approaches to manufacture pathogen safe products, e.g. choosing testing strategies and calculating safety margins.

Speakers



Dr Johannes Blümel
Paul-Ehrlich-Institute (Federal Agency for Vaccines and Biomedicines), Germany
Head of Viral Safety

Johannes started his career in the field of research on virus diagnostics at the University of Bonn. Since 1998 he has been working for the Paul-Ehrlich-Institute, the German Federal Agency Vaccines and Biomedicines. At present Johannes is heading the section of viral safety. His main areas of responsibility are risk evaluation of medicinal products (blood products, biopharmaceuticals) and applied research. Johannes is also an assessor for the evaluation of the reduction of TSE risk at EDQM.



Dr Albrecht Gröner
PathoGuard Consult, Germany
Owner & Founder

Albrecht spent many years in R&D of vaccines and plasma derivatives at the Behringwerke and successor companies in Marburg focusing on pathogen safety of biologicals. At present, after retirement from CSL Behring as Head of Pathogen Safety, he consults companies producing plasma- and cell culture derived biologicals and devices manufactured with material of human or animal origin in this field.



Dr Michael Ruffing
Boehringer Ingelheim Pharma, Germany
Global Development CMC Biologicals

Michael was trained as a post-doc in virology at the German Cancer Research Centre Heidelberg and at Hoffmann-La Roche prior to joining regulatory authorities in Switzerland and Germany. He then joined the GFB Biopharmaceuticals of Boehringer Ingelheim in Biberach. After acting as head of the group virology & contamination detection, Michael is now in the Analytical Development Biologicals Department of the Innovation Unit responsible for adventitious agents topics of Biologicals including virus therapeutics



Michael Schiffer
CSL Behring, Switzerland
Global Head Strategy & Support

Michael Schiffer worked at Novartis from 2013 to 2020 in various functions in the area of fill & finish of commercial and clinical biopharmaceuticals and their launch. After his start in microbiological quality assurance and then working as a process expert in manufacturing, he headed a quality control laboratory for chemical-physical release and stability testing. Since 2020 within Research and Development at CSL Behring in the Global Pathogen Safety department, he provides global support to general matters related to Pathogen Safety and leads the scientific support team for Switzerland.

Reservation Form (Please complete in full)



Virus and TSE Safety made simple – Best Practices and Emerging Trends Live Online Training on 18/19 February 2025

If the bill-to-address deviates from the specifications on the right, please fill out here:

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)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 4 weeks prior to the conference 10 %
 - Cancellation until 3 weeks prior to the conference 25 %
 - Cancellation until 2 weeks prior to the conference 50 %
 - Cancellation within 2 weeks 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 HEIDELBERG will 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.

cellation 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).

note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.



Date of the Live Online Training

Tuesday, 18 February 2025 08.00 - 17.30 h (CET)
Wednesday, 19 February 2025, 08.00 - 16.30 h (CET)

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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 conference 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 22099.**

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.

CONCEPT HEIDELBERG

P.O.Box 10 17 64

69007 Heidelberg, Germany

Phone +49(0)62 21/84 44-0

Fax +49(0)62 21/84 44 34

info@concept-heidelberg.de

www.concept-heidelberg.de

For questions regarding content please contact:

Mr Clemens Mundo (Operations Director) at
+49(0)62 21/84 44 42, or at
mundo@concept-heidelberg.de.

For questions regarding organisation etc. please contact:

Mr Maximilian Bauer (Organisation Manager) at
+49(0)62 21/84 44 25, or at
bauer@concept-heidelberg.de.