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
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Virus Safety – Best Practices and Emerging Trends

03/04 March 2026 | Heidelberg, Germany

Photo: Courtesy Sartorius Stedim Biotech S.A

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 / inctivation 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 in small groups approaches to manufacture pathogen safe products, e.g. choosing testing strategies and calculating safety margins.

Social Event

On 03rd March you are invited to take part in an evening program. This is an excellent opportunity to share your experiences with the speakers and colleagues from other companies in a relaxed atmosphere.

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 works in CSL Behring's R&D Global Pathogen Safety department, which focuses on ensuring the safety of biopharmaceutical products. Before joining CSL Behring, he spent several years at Novartis, gaining experience in microbiological quality assurance, manufacturing, and quality control. Throughout his career, he has held leadership roles in biopharmaceutical manufacturing and development support, as well as associated laboratories, bridging scientific expertise with strategic decision-making.

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GERMANY

Reservation Form (Please complete in full)

Virus Safety – Best Practices and Emerging Trends
03/04 March 2026, Heidelberg, Germany

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

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Date
Tuesday, 03 March 2026, 08.30 - 17.30 h
(Registration and Coffee 08.00 - 08.30 h)
Wednesday, 04 March 2026, 08.30 - 16.30 h

Venue
Qube Hotel Bahnstadt
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Phone: +49 (0) 62 21/18 79 90
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Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
Academic Scientists/Students € 1,045
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/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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 22295.

Conference language
The official conference language will be English.

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.

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

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