Virus and TSE Safety made simple
All you need to know

With interactive workshop in small groups

LEARNING GOALS:

- Overview of relevant aspects of virology
- The impact on the manufacture of biopharmaceuticals/biologics
- Current detection, inactivation and removal techniques
- Regulatory background
- Design and Documentation of Validation Studies
- Eliminate misunderstandings on TSE
- Interactive Workshop

SPEAKERS:

Dr Johannes Blümel
Paul-Ehrlich-Institut, Federal Agency Vaccines and Biomedicines

Dr Albrecht Gröner
PathoGuard Consult

Dr Michael Ruffing
Boehringer Ingelheim Pharma

7-8 March 2019, Heidelberg, Germany

This education course is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find details at www.gmp-certification.eu
**Background**

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”.

It is the aim of this course to enlighten this world between “dead and alive”.

The nature of viruses postulates significant differences to micro-organisms. This uniqueness poses particular challenges to the detection, inactivation and removal of viruses.

All these specifics will be discussed in detail at this education course – in an understandable manner.

Another threat poses TSE (Transmissible spongiform encephalopathy). Numerous studies have been conducted to understand the route of transmission and the causing agents better. Nevertheless, misunderstandings and rumours circulate and cumulate in the statement: “We need a TSE-certificate for our activated charcoal.”

This course will give you a scientifically sound introduction into the field of TSE and the impact on the pharmaceutical industry.

**Target Group**

The 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

*Johannes Blümel, Paul-Ehrlich-Institut, Federal Agency for Vaccines and Biomedicines*

**Exogenous (Adventitious) and Endogenous Virus**
- Terminology
- Viral safety approach
- Effects of virus infection on host cell
- Detection of exogenous / endogenous virus

*Michael Ruffing, Boehringer Ingelheim Pharma*

**Virus Safety of Raw Materials**
- Qualification of the material and its supplier
- Sourcing, testing and manufacture of raw materials
- Virus clearance studies
- Testing prior and at production of biotech product

*Michael Ruffing, Boehringer Ingelheim Pharma*

**Design and Documentation of Virus Validation Studies**
- Sources
- Virus spike preparation
- Cytotoxicity/Interference
- Infectivity assay or NAT assay
- Down scaling of manufacturing step

*Albrecht Gröner, PathoGuard Consult*

**Techniques for Virus Inactivation and Virus Removal**
- Virus reduction by manufacturing process steps for protein purification
- Virus reduction by dedicated virus reduction steps
- Robustness of virus reduction methods

*Albrecht Gröner, PathoGuard Consult*

**Virus Safety of advanced Therapy Medicinal Products**
- Regulatory background/certification
- Gene therapy medicinal products
- Cell-based medicinal products

*Johannes Blümel, Paul-Ehrlich-Institute, Federal Agency for Vaccines and Biomedicines*

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

*Johannes Blümel, Paul-Ehrlich-Institute, Federal Agency for Vaccines and Biomedicines*
Transmissible Spongiform Encephalopathy (TSE) - Biology

- The nature and transmission of TSE-agents (prions)
- Epidemiology
- Methods for detecting TSE agents
- Resistance/inactivation of prions, cleaning/disinfection
- Prion reduction techniques

Albrecht Gröner, PathoGuard Consult

Transmissible Spongiform Encephalopathy (TSE) - Regulatory

- EU-Legislation (food, medicinal products, medicinal devices)
- EMEA TSE note for guidance
- EDQM TSE Certification Procedure
- Regulations for blood and urine derived medicinal products

Johannes Blümel, Paul-Ehrlich-Institute, Federal Agency for Vaccines and Biomedicines

Interactive Workshop

During this workshop, the participants develop in small groups approaches to manufacture pathogen safe products, e.g., choosing testing strategies and calculating safety margins.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to get to know your colleagues from other companies in a relaxed atmosphere.

Speakers

Dr Johannes Blümel
Paul-Ehrlich-Institut, Federal Agency for Vaccines and Biomedicines, Germany
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-Institut, the German Federal Agency for 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
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
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. At present he is head of Virology at Boehringer Ingelheim, GFB Biopharmaceuticals.

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PMJ: http://www.pmj-fahrservice.de
Train: You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg.
http://www.bahn.de
**Reservation Form (Please complete in full)**

**Virus and TSE Safety made simple**  
7-8 March 2019, Heidelberg, Germany

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CONCEPT HEIDELBERG
P.O. Box 101764
D-69007 Heidelberg
GERMANY

**Date**

Thursday, 07 March 2019, 09.30 h – 18.00 h  
(Registration and coffee 09.00 – 09.30 h)

Friday, 08 March 2019, 08.30 h – 15.30 h

**Venue**

NH Heidelberg
Bergheimer Strasse 91
69115 Heidelberg
Phone +49 (0)6221 1327 0
nhheidelberg@nh-hotels.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, lunch and dinner on the first day, lunch on the second day, and all refreshments. VAT is reclaimable.

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If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time. If you have to cancel entirely we must charge the following processing fees:
   - Cancellation until 2 weeks prior to the conference: 10%
   - Cancellation within 1 week prior to the conference: 50%

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**Registration**

Via the attached reservation form, by e-mail or by fax message. On your registration please indicate your number of rooms in the conference hotel. You will receive a room reservation form when you have registered on the event. Please send this form to your hotel to reserve the room before the second day and all refreshments. VAT is reclaimable.

**Accommodation**

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