

Speakers



Dr Johannes Blümel
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Vaccines and Biomedicines



Dr Albrecht Gröner
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Virus and TSE Safety made simple

All you need to know

03/04 March 2020 | Barcelona, Spain



Photo: Courtesy Sartorius Stedim Biotech S.A.

Highlights

- 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

With interactive workshop
in small groups

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 Audience

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

Exogenous (Adventitious) and Endogenous Virus

- Terminology
- Viral safety approach
- Effects of virus infection on host cell
- Detection of exogenous / endogenous virus

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

Design and Documentation of Virus Validation Studies

- Sources
- Virus spike preparation
- Cytotoxicity/Interference
- Infectivity assay or NAT assay
- Down scaling of manufacturing step

Methods 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

Virus Safety Aspects of Advanced Therapy Medicinal Products (ATMP)

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

Virus Safety: Regulatory Background

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

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

Transmissible Spongiform Encephalopathy (TSE) - Regulatory

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



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.

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.

Social Event

In the evening of the first 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.



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

Reservation Form (Please complete in full)

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Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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GERMANY

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

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:
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 - Cancellation until 1 week prior to the conference 50 %
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- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

or speakers without notice or to cancel an event.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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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). I 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

Tuesday, 03 March 2020, 09.30 h – 18.00 h
(Registration and coffee 09.00 – 09.30 h)

Wednesday, 04 March 2020, 08.30 h – 15.30 h

Venue

Barcelo Sants Hotel

Pl. Països Catalans, s/n

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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.

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 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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