Speakers

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

Dr Albrecht Gröner
PathoGuard Consult

Dr Michael Ruffing
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Michael Schiffer
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Virus and TSE Safety made simple

All you need to know

05/06 March 2024 | Barcelona, Spain

Photo: Courtesy Sartorius Stedim Biotech S.A

Highlights

- Overview about 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
- Pathogen Safety Risk Assessment
- Interactive Workshops

With interactive Workshop Sessions

Objectives

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.

Background

The current situation 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

Exogenous (Adventitious) and Endogenous Virus

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

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 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

Virus Safety Aspects of Advanced Therapy Medicinal Products (ATMPs)

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

Pathogen Safety Risk Assessments

- What to consider and how to perform risk assessments regarding pathogen safety, incl. deviations and changes
- Introduction into Segregation Risk Analysis
- Case studies

Virus Safety: Regulatory Background

- ICH Guidelines (ICH Q5A)
- European Guidelines (EMEA)
- 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)
- EMEA TSE note for guidance
- EDQM TSE Certification Procedure
- Regulations for blood and urine derived medicinal products

Interactive Workshops with Case Studies and Examples

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

Moderator

Clemens Mundo, Concept Heidelberg

Social Event

On 05th March you are invited to take part in an evening programme. 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-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. 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
Senior Manager Global R&D, CSL Behring, Switzerland

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.

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GERMANY

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

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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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 05 March 2024, 09.00 – 18.00 h
(Registration and Coffee 08.30 – 09.00 h)
Wednesday, 06 March 2024, 09.00 – 16.30 h

Venue
Barceló Sants Hotel
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Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes 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 message.
Or you register online at www.gmp-compliance.org.

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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