ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

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

Dr Albrecht Gröner
PathoGuard Consult

Dr Michael Ruffing
Boehringer Ingelheim Pharma

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
- Eleminate 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 microorganisms. 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 (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 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.

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GERMANY

Reservation Form (Please complete in full)

Virus and TSE Safety made simple | 03/04 March 2020 Barcelona, Spain

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)

General terms and conditions
If you cannot attend the conference you have two options:
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- Cancellation until 1 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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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
08014 Barcelona, Spain
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sants@barcelo.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.

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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