20 YEARS ECA Academy Your GMP/GDP Information Source

Virus and TSE Safety made simple

All you need to know

With interactive workshop in small groups

Photo: Courtesy Sartorius Stedim Biotech S.A.

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

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
- Eleminate misunderstandings on TSE
- Interactive Workshop

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

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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 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 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 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 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.

Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. Next to London, Frankfurt Airport offers the most frequent air connections in Europe. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

TLS: http://www.tls-heidelberg.de
Lufthansa Bus: http://www.transcontinental-group.com/en/frankfurt-airport-shuttles
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

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O Number, if applicable**

Street/P.O. Box

City | Zip Code | Country

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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: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 week prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. 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

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.

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 event. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Axel Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Neureuther (Organisation Manager), at +49(0)6221 / 84 44 49 or per e-mail at neureuther@concept-heidelberg.de.