Photo: Courtesy Sartorius Stedim Biotech S.A

Virus and TSE Safety made simple

All you need to know

18 - 19 March 2014, Heidelberg, Germany

SPEAKERS:

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

Dr Albrecht Gröner
CSL Behring

Dr Michael Ruffing
Boehringer Ingelheim Pharma

LEARNING GOALS:

- Get an overview about relevant aspects of virology
- Understand
  - the impact on the manufacture of biopharmaceuticals/biologics
  - current detection, inactivation and removal techniques
  - the regulatory background
- Eleminate misunderstandings on TSE

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Virus and TSE Safety made simple

18 - 19 March 2014, Heidelberg, Germany

Background

Viral 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 at 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.

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) virus

- Sources
- Methods of detection/Assay techniques
- Exclusion

Michael Ruffing
Boehringer Ingelheim Pharma

Endogenous virus – stably inherited characteristic of the cell line

- Retrovirus (murine leukaemia virus)
- Herpes virus
- Method of detection/Assay techniques

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
CSL Behring

Virus removal techniques

- Techniques for Virus Inactivation and Virus Removal
- Manufacturing process steps for protein purification
- Dedicated virus reduction steps
- Robustness of virus reduction methods

Albrecht Gröner
CSL Behring

Regulatory background

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

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

Virus safety of advanced therapy medicinal products

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

Johannes Blümel
Paul-Ehrlich-Institut, 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
CSL Behring

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-Institut, Federal Agency for Vaccines and Biomedicines

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
CSL Behring, Germany
Albrecht spent many years in R&D of vaccines and plasma derivatives at the Behringwerke in Marburg. At present he is the Head of Virology at CSL Behring, a global leader in the plasma protein biotherapeutics industry.

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

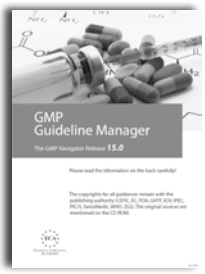
On 18 March you are cordially invited to a social event. This is an excellent opportunity to get to know your colleagues from other companies in a relaxed atmosphere.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.
The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a € 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.



How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **www.gmp-compliance.org.**

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

Virus and TSE Safety made simple, 18 - 19 March 2014, Heidelberg, Germany

☐ 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

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: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks 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)

Date

Tuesday, 18 March 2014, 09.30 h – 17.30 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 19 March 2014, 08.30 h – 15.30 h

Venue

NH Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
Phone +49 (0) 6221 1327 0
Fax +49 (0) 6221 1327 100

Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690,- per delegate (does not include ECA Membership)
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- per delegate plus VAT
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 when you have registered for the event. Please use this form for your room reservation o to receive the specially negotiated rate for the duration of your stay. 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

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:
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.:
Ms Nicole Bach (Organisation Manager) at
+49-62 21/84 44 22 or per e-mail at
bach@concept-heidelberg.de.