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

Live Online Training on 02/03 March 2021

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
- Case Studies

Objectives and 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".

It is the aim of this Live Online Training 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 Live Online Training will give you a scientifically sound introduction into the field of TSE and the impact on the pharmaceutical industry.

Target Audience

The Live Online Training 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
- Facility segregation to avoid cross-contamination of product intermediates

Virus Safety Aspects of Advanced Therapy Medicinal Products (ATMPs)

- 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

Case Studies and Examples for Assessing Approaches to Manufacture Pathogen Safe Products

In this section of the training all trainers will use case studies and examples to show you different approaches to dealing with problems in vaccine/niopharmaceutical production.

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 is a biologist and received his doctorate from the German Cancer Research Centre in Heidelberg. He was a postdoctoral fellow at Hoffmann-La Roche, Basel, before joining regulatory authorities in Switzerland and Germany. He joined Boehringer Ingelheim in 2003 and has held various positions in the field of microbiology/quality in recent years, e.g. Director of Virology & Contamination Control in the Biopharma Quality Department. He is currently working in the Analytical Development Biologicals department.

This Training Course is recognized for the GMP/GDP Certification Scheme “Certified Microbiological Laboratory Manager”

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.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)

Virus and TSE Safety made simple | Live Online Training on 02/03 March 2021

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:
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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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 of the Live Online Training

Tuesday, 02 March 2021, 09.00 – 18.00 h CET
Wednesday, 03 March 2021, 09.00 – 16.30 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...." This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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

For questions regarding content please contact:
Mr Axel H. Schroeder (Operations Director) at
+49(0)62 21/84 44 10, or at
schroeder@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Isabell Neureuther (Organisation Manager) at
+49(0)62 21/84 44 49, or at
neureuther@concept-heidelberg.de.