New for 2011 - Critical feedback on recent GSK, Merck and Genzyme contaminations, plus expanded regulatory session featuring FDA, PEI and AFSSAPS

Viral Safety for Biologicals 2011

Meet evolving regulatory requirements, equip yourself with latest detection methods and react effectively when faced with risk of viral contamination

Tuesday 10 – Wednesday 11 May 2011 • Angelo Hotel, Prague, Czech Republic

5 Key Reasons to Attend:

1. Gain critical, first-hand advice from the FDA, PEI and AFSSAPS to ensure regulatory compliance – expanded session for 2011
2. Create effective safeguards to detect, prevent and remediate viral contaminations – benchmark your strategies against leading companies: Amgen, Genentech, MedImmune, Merck Serono and Baxter – unpublished data presented
3. Discover the critical lessons learnt and preventative actions taken by GSK and Genzyme following recent contaminations – what can the industry do as a whole do to avoid it happening again?
4. Discuss the role of platform technology and in-house data to reduce viral validation studies
5. Know how to effectively respond to a potential contamination – advice on cleaning validation from both an industry and vendor perspective

Don’t miss

Pre-conference workshop Monday 9 May 2011
Ensuring Viral Safety of Biopharmaceuticals: Risk Assessment and Regulatory Considerations as applied to Marketed Products and IMPs

Evening Seminar Tuesday 10 May 2011
Interpreting Viral Safety Data – both in-house and from a CRO

Who you will meet:

3 Expert Regulators from Europe and US
• Dr Arifa Khan, Senior Investigator, CBER, FDA, USA
• Dr Albert Stähler, Deputy Head of Virus Safety Section, Paul-Ehrlich-Institut, Germany
• Dr Wahiba Oualikene-Gonin, AFSSAPS, France

10+ industry experts
• Professor David Onions, CSO, Bioreliance, UK
• Dr Sridhar Pennathur, Senior Director, Corporate Quality Control, MedImmune, USA
• Dr Ivar J. Kljavin, Product Quality Management, QC Virus and Mycoplasma, Genentech, USA
• Dr Hazel Aranha, Consultant, GAEA Resources, USA
• Dr Stephane de Walque, Technical Regulatory Affairs, ClaxoSmithKline Biologicals, Belgium
• Representative from Genzyme, USA
• Dr Andreas Berting, Global Pathogen Safety, Baxter, Austria
• Dr Houman Dehghani, Principal Scientist, Biosafety Development Group, Amgen, USA
• Dr Jens Peter-Gregersen, Technology Development, Virus Safety and New Projects, Novartis Vaccines and Diagnostics, Germany

RUNNING BACK-TO-BACK WITH...

Transmissible Spongiform Encephalopathies Conference
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Don’t miss
Ensuring Viral Safety of Biopharmaceuticals: Risk Assessment and Regulatory Considerations as applied to Marketed Products and Investigational Medicinal Products (IMPs)

Significant strides have been made in ensuring the viral safety of biologicals. However, recent contamination incidents have highlighted the fact that constant vigilance is mandatory if we are to continue to uphold the excellent safety record of biopharmaceuticals. While the regulatory approach to viral safety is well established, specific application is determined by a risk assessment that includes considerations such as product type, indication and the stage of product development.

Zero risk is a myth; safety can only be defined in terms of the extent of viral clearance (log10) achieved. This workshop will highlight regulatory requirements, facilitate understanding and appreciation for the philosophies that underlie these regulations, and provide a toolkit to the attendee in order to evaluate viral clearance methods and design virus clearance evaluation (validation) studies.

Topics to be covered include:

- Importance of a holistic approach to virus safety that includes appropriate sourcing of raw materials, product operations validated for virus clearance and in-process testing
- Necessity for characterization of cell lines (mammalian/avian/insect) and risk evaluation of raw materials and risk mitigation approaches to reduce virus contamination risks
- Application of risk assessment and management strategies in designing an overall virus contamination control strategy
- Current regulatory guidance as applied to marketed products and investigational medicinal products used in clinical trials
- Virus control (clearance) methods: ‘tried-and-true’ as well as emerging technologies
- Requirements and practical considerations in designing virus clearance evaluation (validation) studies. Case studies will be presented to illustrate several of these concepts including validation pitfalls and strategies to circumvent them.
- Incorporating Quality-by-Design principles throughout the product design and development continuum: leveraging data from platform technologies and design-of-experiment studies

Benefits of attending:

- Gain confidence from an in-depth understanding of the ‘state-of-the-art’ as related to virus and prion safety issues for biopharmaceuticals
- Develop an insight into how to evaluate available viral clearance strategies, how to conduct a risk assessment and design risk management strategies, and how much clearance to incorporate into your process by applying the acquired information
- Design an adequate virus validation program to demonstrate efficiency and comply with regulatory requirements

Who should attend?

Production managers, study directors, regulatory affairs managers and purification specialists responsible for designing robust processes and performing viral clearance studies

Biography

Dr Hazel Aranha is President of GAEA Resources Inc, a company focused on global regulatory consulting and medical communications. She is on several advisory boards of government/semi-government bodies and on the editorial board of BioProcess International Journal. In addition to courses on virus and prion safety of biologics, she teaches courses on ‘Good Clinical Practices’ (GCP), ‘Good Manufacturing Practices (GMP), ‘Downstream Processing’, ‘Navigating the Drug Development Cycle’, and ‘Effective Biomedical Writing’. Dr Aranha was honored as one of the ‘Women in Biotech in the Twenty-First Century’. Prior to her current assignment she was at Wyeth Vaccines and Pall Corporation

Just some of the reasons why 2010’s event attracted 100+ delegates

Excellent choice of subjects and presenters, good size/ number of participants for networking (Delegates 2010, Roche)

Great overview of current regulatory requirements as well as current practices in biopharma industry concerning viral safety (Delegate 2010, Sanofi Pasteur)

Excellent organisation and mixture of topics (Speaker 2010, PEI)
08.00 Registration
08.55 Chairperson’s Opening Remarks

GLOBAL REGULATORY REQUIREMENTS FOR VIRAL SAFETY - PLATFORM TECHNOLOGY, CELL SUBSTRATES AND VACCINES

09.00 Regulatory perspective on the use of ‘in-house experience’ in viral clearance and control of adventitious viruses for investigational medicinal products

In the guideline on Virus Safety Evaluation for Biotechnological Investigational Medicinal Products (IMP) a reduced programme of studies on assuring viral safety is envisaged compared with the data requirements for marketing authorisation. The current regulatory view on ‘platform technology and in-house data’ will be outlined. In addition, the regulatory perspective on the control of adventitious viruses to avoid potential contamination will be discussed.

Dr Albert Stühler, Deputy Head of Virus Safety Section, Paul-Ehrlich-Institut, Germany

09.35 Adventitious-agent testing of cell substrates and viral vaccines: Standard and new methods – Regulatory update from AFSSAPS

(Please check www.informa-ls.com/viral) for latest updates

Dr Wahiba Oualikene-Gonin, AFSSAPS, France

10.10 FDA’s regulatory perspective on viral safety for vaccine products

This talk will include discussion of potential sources of virus contamination and mitigation strategies, current testing methods and challenges for detection of adventitious viruses, and consideration of new technologies for virus detection.

Dr Arifa Khan, Senior Investigator, CBER, FDA, USA

10.45 Morning Coffee and Poster/Exhibition Viewing time

RECENT OUTBREAKS AND CONTAMINATIONS – LESSONS LEARNED

11.20 Déjà vu: What’s old is new again, half a century later- experience in ensuring virological safety of biologicals

Recent contamination incidents have once again focused the spotlight on virus contamination of and during the manufacture of biologicals. Issues relate to detection of virus sequences in marketed products that have the potential to compromise patient safety; also, contamination of production systems with viruses theoretically non-infective for humans adversely impacts product yield and market availability. This presentation will discuss pragmatic approaches to ensuring virological safety of biologicals

Dr Hazel Aranha, Consultant, GAEA Resources Inc, USA

11.55 Rotarix: GSK’s PCV-1 investigations, learnings and preventive actions

GlaxoSmithKline has been made aware of research data suggesting the presence of porcine circovirus type 1 DNA (PCV-1) in Rotarix™. Subsequent testing of Rotarix™ has confirmed that material of PCV-1 has been present in Rotarix™ since the initial stages of the vaccine’s development. Some starting materials are common to Rotarix and inactivated poliovirus antigens production. Material of PCV-1 was detected in the first steps of inactivated poliovirus antigens production. This presentation will focus on GSK investigations with respect to PCV-1 DNA detection, on the learnings and impact in terms of regulatory actions and quality control testing, and on the preventive actions that have been taken by the company in order to guarantee continuous quality and safety of GSK vaccines.

Dr Stephane de Walque, Technical Regulatory Affairs, GlaxoSmithKline Biologicals, Belgium

12.30 Spotlight Presentation

These presentations are hosted by leading companies who operate in the field of viral safety and offer the opportunity to learn about the latest developments and technological advancements in the industry. If you would like to host a spotlight presentation, please contact james.miguei@informa.com • +44 (0)20 7017 5011

13.00 Lunch and Poster/Exhibition time

14.30 Lessons learnt from the vesivirus contamination

(Please check www.informa-ls.com/viral) for latest updates

Representative from Genzyme, USA

WHY VIRAL DETECTION IS ONLY PART OF THE STRATEGY

15.05 Broadening the scope of the viral safety program for biotech: A perspective on viral detection as only part of the strategy

A viral safety program should include the execution of viral detection methods and an assessment of the viral removal capacity of the manufacturing process. However, one should also consider broadening the scope of viral safety by considering the limitations of viral testing, understanding the raw materials used in the manufacturing process and learning from past viral contamination experiences throughout the industry.

Dr Ivar J. Kljavin, Product Quality Management, Quality Control Virus and Mycoplasma, Genentech, a member of the Roche Group, USA

15.40 Afternoon Coffee and Poster/Exhibition Viewing time

RESPONDING TO A VIRAL CONTAMINATION IN THE MANUFACTURING PLANT

16.10 How should companies react to a contamination? – An industry point of view

• Amgen’s approach to cleaning validation for responding to potential viral contamination events
• Data on various cleaning agents for product contact and non-product contact surfaces
• Data on agents used for large-scale facility decontamination

Dr Houman Dehghani, Principal Scientist, Biosafety Development Group, Amgen, USA

16.45 Responding to viral contamination in the manufacturing plant: A perspective from a contract testing organisation

(Please check www.informa-ls.com/viral) for latest updates

Speaker TBC

17.20 End of Day One

18.00 Registration for Evening Seminar: “Interpreting Viral Clearance Data”

Evening Workshop S – Tuesday 10 May 2011

Interpreting viral clearance data

Registration 18.00 • Start 18.15 • End 20.30 • Dinner and Refreshments will be Provided

The goal of this workshop is to enable the attendee to easily interpret viral clearance data, whether it is from an in-house virology laboratory or a contract laboratory. Specifically, the following topics will be addressed:

• Virus assays and how they are performed
• How the virus titer results are calculated
• How to work with virus titers
• How log reduction values (LRV) are determined from the virus titer results
• How the cytotoxicity and viral interference results relate to the LRV
• How can studies be optimized to maximize the LRV

This workshop is intended for anyone who uses or reviews viral clearance data. Hands-on activities will provide practice in working with virus titer and calculating log reduction factors. Attendees are asked to bring a scientific calculator with them to the workshop.

Workshop leader:
Dr Kathryn Martin Remington, Principal Scientist, Development Services, Clearance BioReliance, USA plus to be confirmed end user
Meet evolving regulatory requirements, safeguard your facilities and react effectively when faced with risk of contamination

DAY TWO: WEDNESDAY 11 MAY 2011

08.15 Chairperson’s Opening Remarks

LATEST TOOLS FOR DETECTING ADVENTITIOUS AGENTS

08.20 Massively Parallel Sequencing (MP-Seq): A new tool for adventitious agent detection, genetic stability evaluation and clone selection

Recent contaminations of manufacturing processes by porcine circovirus and vesivirus have highlighted the need for broadly based and rapid methods to detect adventitious agents in cell banks, virus seeds and bulk product (drug substance). Massively parallel sequencing is a powerful new method for the identification of viruses and other adventitious agents, without prior knowledge of the nature of the event. BioReliance have developed MP-Seq methods to detect free viruses in raw materials and fermenter samples. Our application of this technology has resulted in the discovery of a new parvovirus in bovine serum capable of infecting human cells and we have used this technology in the investigation of fermenter contaminations. Perhaps the most exciting application of MP-Seq is in the developing field of clone selection. Recently nucleotide arrays have been used to identify genes differentially expressed in high and low producing CHO cells and the data have been used to modify the composition of the cell bank.

Professor David Onions, Chief Scientific Officer, Bioreliance and Honorary Professor, Faculty of Veterinary Medicine, University of Glasgow, UK

09.00 Molecular biology methods for viral safety: Danger tool or perfect solution?

The perception of molecular biology and PCR-based testing methods for viral safety is quite appealing and novel: the same PCR application could be considered misleading, if it provides false positive results, or the fastest viral safety is quite appealing and novel: the same PCR application could be considered misleading, if it provides false positive results, or the fastest regulatory characteristics (i.e. proliferation in bioreactors at high cell densities of the cells. EB66® cells maintain most of the desirable features of ES cells substrates that fulfill current industrial and regulatory requirements. ES cells have been isolated from ducks and were used to progressively derive EB66® cells using documented proprietary procedures and assuring the viral safety of the cells. EB66® cells maintain most of the desirable features of ES cells (i.e. High expression of telomerase and stem cells surface markers, long-term genetic stability, indefinite cell proliferation…). but display industrial and regulatory characteristics (i.e. proliferation in bioreactors at high cell densities as suspension cells, growth in serum-free media, freedom from adventitious agents, genetic stability, high susceptibility to various viruses, efficient genetic engineering and heterogeneous protein production…).

Dr Emiliano Toso, Head, Molecular Biology Lab, Merck Serono, Italy

09.35 Microbial detection array applied to product safety and public health

The Lawrence Livermore Microbial Detection Array (LLMDA) contains 380,000 DNA probes to detect any sequenced viruses or bacteria within 24 hours and was recently used to identify Porcine circovirus from a rotavirus vaccine. The array is able to achieve sensitive low-copy pan-microbial detection, and is a comprehensive and cost-effective technology to screen adventitious agents to assure vaccine safety.

Dr Crystal Jiang, Group Leader, Applied Genomics, Physical Life Sciences Directorate, Lawrence Livermore National Laboratory, USA

10.10 Morning coffee and exhibition viewing time

CO-INFECTION VIRUSES, ALTERNATIVE CELL LINES

10.40 What happens to co-infecting viruses in influenza virus isolates on their way to a vaccine candidate strain for an MDCK derived vaccine? (Please check www.informa-ls.com/viral for latest updates)

Dr Jens Peter-Gregersen, Technology Development, Virus Safety and New Projects, Novartis Vaccines and Diagnostics, Germany

11.15 Embryonic stem cells for the industrial manufacture of biologicals: Defined risk approach to manage viral safety

Embryonic stem cells hold exceptional biological properties that could theoretically be exploited for the derivation of new generations of cell substrates that fulfill current industrial and regulatory requirements. ES cells have been isolated from ducks and were used to progressively derive EB66® cells using documented proprietary procedures and assuring the viral safety of the cells. EB66® cells maintain most of the desirable features of ES cells (i.e. High expression of telomerase and stem cells surface markers, long-term genetic stability, indefinite cell proliferation…). but display industrial and regulatory characteristics (i.e. proliferation in bioreactors at high cell densities as suspension cells, growth in serum-free media, freedom from adventitious agents, genetic stability, high susceptibility to various viruses, efficient genetic engineering and heterogeneous protein production…).

Dr Celine Breda, Head of Quality Affairs, Vivalis, France

QUALITY BY DESIGN

11.50 The challenges faced in testing live virus vaccines for contamination by adventitious viral agents (Please check www.informa-ls.com/viral for latest updates)

Dr Sridhar Pennathur, Senior Director, Corporate Quality Control, MedImmune, USA

12.25 Characterising Model Viruses

Phenotypic characterisation of model viruses typically used in virus clearance studies

Viruses used in virus clearance studies should be characterised. We have analysed the phenotypic characteristics of a broad range of typical model virus. This includes the stability in different matrices during pH, temperature and chemical treatment, the matrix dependency of pre-filtration steps especially before nanofiltration, the susceptibility to different cell lines, etc. We could define significant differences among model viruses even of the same biophysical characteristics like different parvoviruses, different enveloped DNA viruses, etc. These data describe the “model” character of a specific virus strains more precisely and are very helpful in the selection of model viruses for specific process steps. The phenotypic characteristics of the different model viruses will be presented in the background of their relevance for the design and the interpretation of virus clearance studies.

Dr Horst Ruppach, Head of Viral/TSE Safety Studies, Charles River Biopharmaceutical Services, Germany

Spotlight Presentation

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13.00 Lunch and exhibition viewing time

Inactivating Hepatitis A, Parvovirus B19

14.00 Different inactivation characteristics of Hepatitis A Virus

For studies investigating the pasteurisation step of Human Serum Albumin (HSA) differences of several log steps in HAV inactivation were reported. However, the reason for this has never been investigated. To this end, the pasteurisation of four widely used cytopathic variants of the original HAV HM175 strain were investigated. As a result the respective HAV variant used, as well as the protein concentration of the HSA solution were found to affect the overall HAV inactivation that is achieved during pasteurisation.

Dr Andreas Berting, Global Pathogen Safety, Baxter, Austria

14.35 Virus inactivation in albumin by pasteurisation under conditions of high pH

The standard virus inactivation step included in the albumin process is terminal heating at 60°C for 10hr. However this step is not fully effective for non-enveloped viruses. By increasing the pH at this stage, the inactivation of viruses such as HAV and CPV was increased. The degree of aggregation, stability and dye binding properties of the albumin was not affected by this treatment.

Dr Peter Roberts, Senior Scientist, Bio Products Laboratory, UK

15.10 Afternoon tea and exhibition viewing time

B19 Virus: Inactivation characteristics and epidemiological aspects

For a long time the inactivation of B19V , a virus that at several occasions had been transmitted by plasma products, could not be investigated directly. Since practical infectivity assays, based on a molecular biology read-out, have now been developed, the inactivation characteristics of the earlier used animal paroviruses, i.e. model viruses, to the B19V itself can be compared. The surprisingly different results obtained for B19V versus animal parovirus inactivation when investigating several different inactivation procedures as well as recent epidemiological aspects of B19V will be reviewed.

Dr Jens Modrud, Global Pathogen Head, Baxter, Austria

REMOVAL OF NON-ENVELOPED VIRUSES BY NOVEL MEMBRANE ABSORBER

16.15 Removal of non-enveloped viruses by a novel membrane absorber- a pilot study (Please check www.informa-ls.com/viral for latest updates)

Dr Eckhard Flechsig, Head of Virus Validation, Biotest, Germany
CONFERENCE DAY 1: THURSDAY 12 MAY 2011

08.15 Registration
08.50 Opening remarks from the Chairperson

09.00 KEYNOTE PRESENTATION: EU Commission Feedback
TSE prevention and controls: opportunities and challenges
Koen Van Dyck, Head of Unit, SANCO DGD2.E2 - Food Hygiene, Alert System and Training, Health & Consumers Directorate General, European Commission, Belgium

09.35 KEYNOTE PRESENTATION: FDA Feedback
An update on FDA risk assessments for potential vCJD risks for blood and plasma-derived products
Steven Anderson, Deputy Director, Office of Biostatistics and Epidemiology, Centre for Biologies Evaluation and Research, U.S. Food and Drug Administration, USA

10.10 Regulatory update – revision 4 of the EMA Note for Guidance on TSE safety
Dr Albert Stühler, Deputy Head of Virus Safety Section, Paul-Ehrlich-Institut, Germany

10.45 Morning coffee break

11.00 Evolving Trends in the Regulation of TSE

11.15 Blood related variant Creutzfeldt-Jakob disease
Dr Robert Will, Professor of Clinical Neurology, National CJD Surveillance Unit, University of Edinburgh, UK

11.50 Assessment and management of the risk of variant CJD transmission by blood and tissues in the UK
Professor Marc Turner, Medical Director, Scottish National Blood Transfusion Service, UK

12.25 SPOTLIGHT PRESENTATION
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12.55 Lunch

13.00 Advances in Sensitive and Specific Prion (TSE) Detection Methods

14.00 Development of a blood test for vCJD

14.35 In vitro studies for evaluating prion transmission between species
Dr Joaquin Castilla, IKERBasque Research Professor, CIC bioGUNE, Spain

15.10 Afternoon coffee break

15.40 Animal-derived materials in the manufacture of pharmaceutical drugs and medical devices – assessing the TSE risk
Dr Gerhard Pölsler, Senior Manager, Global Pathogen Safety, Baxter, Austria

16.15 Globalisation and the challenges of securing the supply chain – an industry perspective
Dr Stephane de Walque, Technical Regulatory Affairs, GlaxoSmithKline Biologicals, Belgium

16.50 Final remarks from the Chairperson

17.00 End of conference

For more information please visit www.informa-ls.com/tse

CONFERENCE DAY 2: FRIDAY 13 MAY 2011

08.50 Opening remarks from the Chairperson

09.00 Successful TSE Risk Assessment Strategies in Practice

09.35 Living with uncertainty: the prion dilemma
Dr James Hope, TSE Programme Manager, Veterinary Laboratories Agency Lasswade, UK

10.10 The presence of prion proteins in human derived gonadotropins: a safety issue?
Diego Ezcurra, Global Scientific Director, Merck Serono, Switzerland

10.45 Controlling the TSE risk for plasma derived products
Dr Peter Roberts, Senior Scientist, Bio Products Laboratory, UK

11.15 PANEL SESSION: Probabilistic risk assessment – assessing and choosing the right parameters
Led by: Philip Comer, Principal Consultant, Del Norske Veritas, UK

11.50 Assessing the BSE risk of different countries – experiences from the EU and the OIE process
Dr Dagmar Heim, Animal Health Specialist, Swiss Federal Veterinary Office, Switzerland

12.25 SPOTLIGHT PRESENTATION
james.miguell@informa.com or Tel: +44 (0) 207 017 5011

12.55 Lunch

14.00 Recent Development in TSE Inactivation Techniques and Decontamination

14.35 Transmissible Spongiform Encephalopathies- routes of transmission, strain modification and mechanisms neurodegeneration
Professor Jean Manson, Group Leader and Head of Division, Neuropathogenesis Division, Roslin Institute, UK

15.10 Afternoon coffee break

15.40 The importance of the scale-down model for TSE reduction studies
Dr Kang Cai, Pathogen Safety, R&D, Talecris Biotherapeutics, USA

16.15 Prions - A challenge and paradigm for disinfection
Dr Michael Beekes, Scientific Director, Transmissible Spongiform Encephalopathies, Robert Koch-Institut, Germany

16.50 Final remarks from the Chairperson

17.00 End of conference

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