Safeguard your production facilities against adventitious agents by optimising your viral detection, inactivation and removal methods in line with international requirements

**Tuesday 18 - Wednesday 19 June 2013, NH Danube City, Vienna, Austria**

**Key Reasons to Attend:**

1. **Stop adventitious agents entering your facilities** by investing in the same winning strategies as market leaders Genentech, GSK, Bayer, Baxter and Crucell.
2. **Discover how serum providers, biotech manufacturers and regulators** are working together to improve the quality of raw materials – where do your responsibilities lie?
3. **Avoid regulatory delay by quizzing European and US authorities** on the latest viral safety standards expected for biotech, vaccine and plasma products.
4. **Evaluate the role of new screening technologies** to improve virus detection with independent analysis from Rebecca Sheets of the NIH - is industry ready to adopt these technologies?
5. **Optimise your virus filtration procedures** and evaluate the role of scale-down nanofiltration models to improve virus clearance with case studies from Baxter, Sartorius and Asahi.

**Pre-Conference Workshop W**

Monday 17 June 2013
Fundamentals of Comprehensive Viral Safety + Baxter Site Visit

**Evening Seminar S**

Tuesday 18 June 2013
Strategies for Improving the Testing and Monitoring of TSE

**Post-Conference Workshop X**

Thursday 20 June 2013
Adventitious Agent Control and Regulations of Raw Materials

**Speaker Highlights:**

- **Dr Mark Plavsic**, Head, Global Product Biosafety, Genzyme, A Sanofi company, USA
- **Dr Ivar J. Kljavin**, Director, QC Virus, Mycoplasma and Adventitious Agent Management, Genentech, USA
- **Dr Rosemary Versteegen**, CEO, International Serum Industry Association, USA
- **Dr Albert Stühler**, Deputy Head of Viral Safety, Paul- Ehrlich Institut, Germany
- **Dr Shengjiang Liu**, Head and Principal Scientist, Pathogen Safety, Global Biologics Development, Bayer Healthcare Pharmaceuticals, USA
- **Dr Arifa Khan**, Senior Investigator, CBER, FDA, USA
- **Dr Rebecca Sheets**, Consultant, Former Vaccine Scientific and Regulatory Specialist, NIH, USA

**Register online:** www.informa-ls.com/viral
**Pre-Conference Workshop W**
**Monday 17 June 2013**

Registration 08.30 • Start 09.00 • End 14.30
followed by Baxter Vienna Site Visit

**Fundamentals of Comprehensive Viral Safety – Control and Analysis**

**Introduction**
This workshop will enable attendees to successfully risk assess their manufacturing processes as well as easily interpret viral clearance data and information generated from novel next-generation sequencing techniques such as Massive Parallel Sequencing.

**Topics to be addressed include:**
- **Virus Control Strategies**
  - Proactive risk management
  - Adventitious virus control strategies
  - Verification of disinfection efficacy
  - Data from PCV inactivation studies
- **Understanding Viral Clearance Data**
  - Assays to detect viruses
  - How the log reduction values (LRV) are calculated
  - Pre-study data (cytotoxicity and viral interference) and their relationship to LRVs
  - Optimisations to maximize LRV

**Workshop leader:**
Dr Kathryn Martin Remington, Principal Scientist, Development Services, Clearance, BioReliance, USA

Followed by Exclusive Site Visit to Baxter

**EVENING SEMINAR – Tuesday 18 June 2013**

Registration is at 18.45 for a 19.00 start. The seminar will finish no later than 21.00.

**Strategies for Improving the Testing and Monitoring of TSE**

This evening seminar will take a detailed look at the current issues facing the field of TSE with a focus on the new detection methods, strategies and technologies being adopted by industry, academia and institutes.

**Topics to be addressed include:**
- Update on latest regulations
- New screening methods governing TSE available to detect TSE
- Coordinated efforts to discover new detection technologies - Latest from Professor John Collinge’s group at the MRC Prion Unit in the UK
- Update on new assays in development and discussion on recent publications
- Overcoming the challenges of developing cell-based assays for TSE testing

**Workshop Facilitators:**
Dr Graham Jackson, MRC Prion Unit, UCL Department of Neurodegenerative Disease, Institute of Neurology, UK
Dr Jillian Cooper, Head, CJD Resource Centre, NIBSC, UK

**Keep on top of the latest developments in TSE**

FREE WITH 4 DAY PASS

**Adventitious Agent Control and Regulations of Raw Materials**

**NEW for 2013**

**Introduction**
This workshop will examine the control of adventitious agents (viruses, mycoplasma, bacteria and prions) in raw materials used in biopharmaceutical manufacturing.

Case studies will demonstrate where these adventitious agents replicate in their host (cattle, swine, sheep, goats and insects that transmit viruses to these mammals) and how resistant they are to common inactivation and removal procedures.

**Topics to be addressed include:**
- Viruses that contaminate raw materials
- Control of adventitious agents in biopharmaceutical raw materials
- How to monitor raw materials in the supply chain
- Case studies of virus contamination of cell banks and unprocessed bulk
- Control of virus contaminations
- Questions companies should be asking their suppliers and QC departments
- Q&A with audience followed by practical exercises

**Workshop leader:**
Dr Barbara J. Potts, Senior Consultant, Potts and Nelson Consulting, USA

See website for more information

“Knowledge of your raw materials is your first viral barrier”

Kljavin, Genentech
**DAY ONE: TUESDAY 18 JUNE 2013**

08.00 Registration and Morning Coffee

08.30 Chairperson’s Opening Remarks and Market Outlook

**Dr Martin Wisher, Senior Director, Quality Assurance and Regulatory Affairs, BioReliance, UK**

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**GLOBAL STANDARDS FOR ENSURING VIRAL SAFETY**

09.00 **KEYNOTE PRESENTATION**

**Developing an effective viral safety strategy for biotherapeutics – an industry perspective**

Using case studies and experience taken from the sanofi/Genzyme group, this presentation will evaluate the current state of the adventitious agents industry; current challenges, where we are at with viral safety; what existing challenges still remain and what new detection and removal strategies companies should be investing in.

**Dr Mark Plavsic, Head, Global Product Biosafety, Genzyme, A Sanofi company, USA**

09.35 Latest feedback from European regulators on the management of adventitious agents

This presentation will discuss: European perspectives on viral safety of recombinant products; Feedback from the regulators on recent concerns and common enquiries; Risk assessment according to ICH Guideline Q5A – retroviral “safety margin” of recombinant products and regulatory perspectives on “excess capacity”.

**Dr Albert Stübler, Deputy Head of Viral Safety, Paul- Ehrlich Institut, Germany**

10.10 Discussion Panel on Latest Challenges in Viral Safety

10.30 Morning Coffee and Opening of Exhibition

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**EMERGING DETECTION TECHNOLOGIES TO IMPROVE VIRAL SAFETY**

11.00 **Pathways to incorporating new methods into adventitious agent testing strategies**

Adventitious agent test methods are rooted in the fairly distant past and next gen methods are on the horizon. Simply adding to the list of tests as each new method arises is an unsustainable approach, which is not science-based. Using case studies this presentation will look at: How to gain regulatory acceptance to remove old methods from the list or to modify and update them by making hybrid tests with next gen read-outs is unclear; Consideration needs to be given to applying 3Rs to in vivo methods; pathways forward to assure, without compromising, viral safety by modifying the old and embracing the new.

**Dr Rebecca Sheets, Consultant, Former Vaccine Scientific and Regulatory Specialist, NIH, USA**

11.35 **The role of Massive Parallel Sequencing (MPS) in detecting viral and microbial contaminants**

Massively Parallel Sequencing (MP-SeqTM) is a new method to identify all adventitious viruses, mycoplasma, bacteria and fungi. At present MP-Seq is used as an adjunct and not a replacement to traditional tests for these contaminants. This presentation will give examples of the use of this technique to characterise new cell substrates, to investigate possible cell line contamination events and to identify previously unknown viral contaminants.

**Dr Martin Wisher, Senior Director, Quality Assurance and Regulatory Affairs, BioReliance, UK**

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12.10 **Spotlight Presentation:**

These presentations are reserved by leading companies in the field of viral safety and viral clearance and offer to opportunity to hear about the latest developments and technological advances in the industry. If you would like to host a spotlight presentation please contact james.miguel@informa.com or +44 (0) 20 7017 5011

12.40 Lunch and poster/exhibition viewing time

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14.00 **Best practices in viral safety for vaccines – Feedback from the US regulators**

Topics to be discussed include: What advice do the US Agencies have for improving viral safety; Consideration of appropriateness between cell lines derived from human tumor for vaccines manufacture; Issue over tumorigenicity; Currently recommended assays and the role of new detection technologies in adventitious agent detection.

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

14.35 **Is industry ready for emerging detection technologies?**

- Does industry really want to be introducing new, more sensitive technologies? What are the dangers?
- How does the technology manage defective particles?
- Do you have to do everything?
- What do the regulators think about these new methods?
- What should they be used for: characterisation, in-process control or release testing?
- Is industry ready for this technology?

**Panelists:**

**Dr Rebecca Sheets, Consultant, Former Vaccine Scientific and Regulatory Specialist, NIH, USA**

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

**Dr Albrecht Gröner, Head, Pathogen Safety, CSL Behring, Germany**

**Dr Martin Wisher, Senior Director, Quality Assurance and Regulatory Affairs, BioReliance, UK**

15.00 Afternoon Tea and Partnering Time

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**PROTECT AGAINST NEWLY IDENTIFIED AGENTS**

15.30 **Protecting against the risk of new adventitious agents**

Viral safety is based on at least three elements: 1) the safety of raw materials and additives or excipients; 2) the steps able to eliminate/inactivate these agents during the manufacturing process, and 3) the control of intermediate or final products. National or international recommendations mention these but do not explain “How to manage a new microbiological risk”? In this talk, concrete examples will aim to provide an answer to this question: “Is it possible to guarantee sufficient security against a newly identified agent based on scientific data already existing?”

**Dr Pascal Clayette, Head of Immune Pharmacology & Biosafety Department, CEA, France**

16.05 **Cleaning and sanitation of equipment and material in the production of biological**

This presentation will detail potential batch-to-batch contamination by pathogens; methods used for cleaning and sanitisation and risk assessment regarding potential pathogen contamination

**Dr Albrecht Gröner, Head, Pathogen Safety, CSL Behring, Germany**

16.40 **FEATURED PRESENTATION**

Effective prevention of viral contamination in bioreactors

In the past two decades, significant advances have been made in the effective prevention of adventitious virus contamination of commercial bioreactors in the biotechnology area. Implementation of medium treatment by the high temperature short (HTST) process in the late 1990s resulted in eliminating contamination of CHO cell cultures by murine minute virus (MMV). Lately normal flow viral filtration for removal of viruses has been exploited in our facility. The performance of virus filters with high capacity removal of porcine parvovirus (PPV) and longevity have been demonstrated. To gain more insight into preventing contamination, host-cell-virus interaction has also been investigated and this has laid out an important path for the development of virus resistant host cell lines, thus ultimately the elimination of potential fermenter contamination by rodent parvoviruses.

**Dr Shengjiang Liu, Head and Principal Scientist, Pathogen Safety, Global Biologics Development, Bayer Healthcare Pharmaceuticals, USA**

17.20 **End of Day One Followed by Networking Drinks and Evening Seminar on TSE**

18.15 **Evening Seminar: Strategies for Improving the Safety and Testing of TSE**

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**FREE WITH 4 DAY PASS!**

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This presentation will look at: Viral risk mitigation challenges in biopharmaceutical manufacturing, raw materials sourcing and what it really means; viral risk mitigation strategies for raw materials.

Dr Ivar J. Kljavin, Director, QC Virus, Mycoplasma and Adventitious Agent Management, Genentech, A Member of the Roche Group, USA

This presentation will discuss: Origin and control of viral contamination; Information on raw material expected by European regulators from both suppliers and end-users; Use of virus inactivated material (e.g. foetal calf serum) and update on quality expectations for porcine trypsin

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

This presentation will look at: Viral safety of cell substrates according to types and features, different pre - filtration methods as well as product conditioning. This presentation focuses on different ways to optimise virus filtration to end up with the most efficient steps.

Dr Anika Meyer, Product Manager, Viral Clearance, Sartorius Stedim Biotech GmbH, Germany

Based on experiences at Baxter this presentation will look at basic to advanced down-scale designs; Benefits of advanced versus traditional down-scale models and new perspectives in the design of nanofiltration studies

Dr Andreas Bertiog, Baxter Biosciences, Austria

Until recently, disposable technologies have not been available for all relevant process steps in protein drug substance manufacturing at large scale – especially for downstream processing. With new equipment becoming available, this picture has changed. A comparative study between a disposable and a stainless steel system was carried out. The case study will focus on process economics (cost of goods including capital, labour, material, consumables) of the virus filtration step in a downstream process of a generic monoclonal antibody purification process.

Dr Stefan R Schmidt, VD, Downstream Processing, Reentschler Biotechnologie, Germany

Using case studies this presentation will look at: Development of a PCV-1 infectivity assay; Removal of PCV-1 by nanofiltration and ultracentrifugation and Inactivation of PCV-1 by UV irradiation and formaldehyde treatment

Dr Jens Modrof, Baxter Biosciences, Austria

Dr Nicole Schmitz, CEO International Serum Industry Association, USA

BioPharmaceutical Raw Materials

Co-located with Biopharmaceutical Raw Materials Informa Life Sciences'  2nd Annual Biopharmaceutical Raw Materials 18-19 June 2013, Vienna, Austria

Practical examples for raw material testing, supplier qualification, new analytical techniques and global sourcing strategies in line with the evolving regulations

Key Topics:
- Raw materials – compendia guidelines update and meeting industry standards
- Optimising QA and QC for identifying critical raw materials
- New analytic strategies to treat and monitor raw materials
- Risk assessing new and existing raw material suppliers
- How to approach inspection of disposables/consumables
- Overcoming the challenges of sourcing raw material from emerging countries
- Successfully applying QDB in your raw materials process

www.informa-ls.com/rawmaterials

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- Evening Seminar S Tuesday 18 June 2013:
  Strategies for Improving the Testing and Monitoring of TSE
- Post Conference Workshop X Thursday 20th June 2013:
  Adventitious Agent Control and Regulations of Raw Materials

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