The Parenteral Drug Association presents:

**Virus Forum**

Advanced Technologies for Virus Detection & Clearance in Biological Products

**CALL FOR ABSTRACTS**

8-9 May 2018

Hilton Florence Metropole

Florence | Italy

Register by 17 March 2018 and SAVE!
Dear Colleagues,

We would like to invite you to submit a paper or poster abstract for presentation at the 2018 PDA Europe Virus Forum to be held on 8-9 May 2018 in Florence / Italy.

This conference was established in 2001 and, held annually since then, alternates between Europe and the U.S. These truly global meetings are organized under the leadership of PDA in close cooperation with European regulatory agencies and the U.S. FDA. They provide an overview and updates on regulatory expectations and scientific investigations related to virus and TSE safety of biotechnology, plasma-derived and cell-derived medicinal products.

As in previous years, virus contamination of raw materials as well as emerging viral threats will be discussed. Appropriate risk mitigation strategies consisting of two elements: (1) Testing and processing of raw materials and (2) Virus removal/inactivation capacity of the processes used for production of medicinal products will be taken into consideration.

This PDA Europe Virus Forum reliably provides attendees a unique opportunity for interactive discussion and benchmarking. Exchange of information between industry and regulators will improve the understanding and acceptance of new techniques, highlight new and emerging risks and explain new regulatory approaches.

Panel Discussions, luncheons, dinners and a networking event will hopefully complete this impressive program and make it into a worthwhile and well-rounded learning experience for you!

We warmly invite you to join us in Florence in Spring 2018!

Johannes Blümel, PhD,
Paul Ehrlich Institute, Conference Chair

Call for Abstracts

Topics areas of interest will include but are not limited to the following:

1. EMERGING VIRUSES
   - Current threats (Hepatitis E Virus, Parvoviruses, others)
   - New concerns in Europe, U.S. or in other areas (Zika virus, others)
   - Reference Materials & Standards

2. VIRUS SAFETY OF STARTING AND RAW MATERIALS
   - Case studies for implementation of media treatment, including regulatory experience
   - New threats for human plasma
   - Cell substrates
   - Raw materials for cell culture
   - Cell-sorting antibodies
   - Serum and trypsin

3. VIRAL SAFETY OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP)
   - Viral safety of human platelet lysates & sera
   - Xenogeneic cells, used as feeder layer or therapeutic substance
   - Case studies, gene therapy products, cell based medicinal products

4. VIRAL CONTAMINATION AND RISK MITIGATION
   - Virus detection methods
   - Next generation sequencing (NGS)
   - Other nucleic acid based methods for virus detection and identification
   - Comparison between specific virus detection methods and potential replacement of animal tests
   - Cell Culture Media Treatment
   - Virus inactivation / removal by HTST, UV-C, filtration or other technologies
   - Model organisms, equipment and conditions (temperature, exposure time, dose etc.)
   - Case studies on implementation
5. CASE STUDIES ON SPECIFIC UNIT OPERATIONS
- Precipitation
- Filtration
- Inactivation (detergents, others)
- Chromatographies

6. TSE CONTAMINATION RISK
- Raw materials
- Blood products
- Cell based products
- Cell substrates

7. TSE RISK MITIGATION
- New concepts for testing
- Inactivation of equipment
- Infectability of cell substrates

8. VIRUS REDUCTION STUDY DESIGN
- Continuous Processing
- DoE studies
- Mechanism of action of virus removal/inactivation
- Robustness of specific unit operations
- Identification of critical process parameters
- Sanitization of chromatographic columns including virus-carry-over studies
- Impact of virus spike quality

9. VIRUS CLEARANCE EVALUATION
- Study design
- Spike preparations
- Cell-based Assays
- Prion Specific Filtration Methods

limited to the following
Paper abstracts and posters must be non-commercial in nature, describing new developments or work that significantly contributes to the body of knowledge relating to all aspects of virus safety of medicinal products (biotech products, plasma products, ATMPs, vaccines, etc.).

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. PDA Europe will provide one complimentary registration per podium presentation. Additional presenters and poster presenters are required to pay appropriate conference registration fees. Abstracts not selected for a 30 minute podium presentation may be invited to join as a scientific poster contribution.

Please click or scan the QR Code to submit your abstract.

**Deadlines**
Abstracts for Podium Presentation: **31 January 2018**
Poster Applications: **30 April 2018**

If you have any further questions, please do not hesitate to contact becker@pda.org

**TO EXHIBIT:**
Exhibition and sponsorship opportunities are available and limited. Contact expo-europe@pda.org