PDA
Parenteral Drug Association

PDA Europe Exchange Series 09 / 17

2017 PDA Europe Conference, Exhibition

Particles in Injectables

CALL FOR PAPERS & POSTERS

Register by 30 July 2017 and SAVE!

26–27 September 2017

Sofitel Berlin Kurfürstendamm

Berlin | Germany

Dear Colleagues,

This year marks the 2nd edition of the conference on **Particles in Injectables in Berlin, 26-27 September**, and the 10th Anniversary of PDA Europe's Monoclonal Antibodies Workshop. Both events and its respective Education Program will join forces as part of the PDA Europe Exchange Series 09/17. This new conference format gives you the chance to "Meet, Exchange and Connect" with colleagues, peers and professionals from different backgrounds around the globe and participate in both conferences with just one meeting ticket.

The Particles in Injectables conference provides you with a summary of information on the risks to human health associated with particulate matter. Particles can arise from many sources: foreign, intrinsic, or inherent to the product. Particulate matter, visible or subvisible, in sterile parenteral products is regarded a critical quality attribute, impacting patient safety. A session will focus on the nature and sources of these particles in parenterals and in infusion sets used in clinical studies and hospitals. The difference between particles in drugs and clinical infusions will be highlighted. Furthermore, packaging materials, such as glass vials, syringes and rubber stoppers are known to be major sources of particulate contamination. A session will discuss defects in packaging materials and strategies employed to detect and control them. Last but not least, manual inspection continues to provide the critical reference method for all compendial inspection activity. Therefore, the concluding session will look at the use of particle standards to qualify manual and automated inspection systems, control of critical inspection parameters, as well as the development of an inspection method.

So register for one, get access to two & attend those topics of interest to you in either meeting!

We look forward to welcoming you to in Berlin!

Call for Papers and Posters

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

1. REGULATORY UPDATES

- Regulatory Requirements Affecting the Visual Inspection Process
- Regulatory Requirements for Particles in Medical Devices
- Requirements regarding Particles in the European Pharmacopeia
- Requirements regarding Particles in the Japanese Pharmacopeia
- Requirements regarding Particles in the US Pharmacopeia

2. PRACTICAL CHALLENGES

- Small Batches in Clinical Trials and Hospital Pharmacies
- Aseptic Preparation
- Reconstitution for Administration
- Selecting In-Line Filters/Filtration Strategies
- Primary Packaging

3. CLINICAL RISKS OF PARTICLES

- Underlying Mechanism / Mode of Action of Particle Toxicity
- Consequences of Particles to Tissue Function and the Immune-System
- Long-Term vs. Short-Term Clinical Consequences of Particles in Patients
- Risk Assessment of Different Injection Routes (e.g. I.M., Sub-Q, I.V., Intraocular)
- Risk Assessment of Visible vs. Sub-Visible vs. Nanoparticles
- Bio-Distribution of Visible vs. Sub-Visible vs. Nanoparticles
- Strategies to Minimize Risk of Particles in Patients
- Strategies to Monitor Particle Risk In Vivo

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Markus Lankers, *rap.ID, Chair*

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Melanie Decker, *PDA Europe*

The Conference will be held at the elegant Sofitel Berlin Kurfürstendamm, situated in the heart of Berlin City West.

VENUE

Sofitel Berlin Kurfürstendamm
Augsburger Strasse 41
10789 Berlin | Germany
https://goo.gl/MfWijL

- Classification of Patient Groups at Risk for Particle Harm, e.g. Critical Care Patients
- Potential Costs for the Healthcare System due to Particle Associated Clinical Consequences
- Particles arising from Primary Packaging, e.g. Glass, Silicone and other Components
- Particles arising from Incompatibilities/ Precipitation during Y-Site Administration
- Particle Load of Brand vs. Generic Products

4. PHARMACOVIGILANCE AND PATIENT SAFETY

- Clinical Risk Assessment vs. Patient Risk Assessment
- Quality Standards Regarding Particle Load in Hospitals
- Reporting of Adverse Effects arising from Particles
- Protein Particles and Immune Response
- Cleaning of Primary Packaging for Injectables

5. PARTICLE IDENTIFICATION & SOURCE ANALYSIS

- Particulate/Foreign Material Identification
- Assessment of the Different Sources of Particle Load/ Overview
- Investigation of Unclear/Unexplained Particles
- Validation of Particle Reduction Effectiveness

6. INSPECTION PROCESS

- Fundamental Investigations into Inspection Processes
- Development and Control of Manual Inspection Processes
- Definition and Classification of Defects
- Challenges of Difficult to Inspect Products (e.g. Lyophilized, Suspensions, Viscous Solutions, Large Molecule, Pre-Filled Syringes, Flexible Bags)
- Use of Acceptance Sampling and AQLs

SUBMISSIONS RECEIVED MUST INCLUDE THE FOLLOWING INFORMATION:

- TITLE
- PRESENTER'S NAME AND CONTACT DETAILS
- PRESENTER'S BIOGRAPHY (APPROX. 100 WORDS)
- ADDITIONAL AUTHORS (IF APPLICABLE)
- KEY OBJECTIVES OF TOPIC
- 2-3 PARAGRAPH ABSTRACT, SUMMARIZING THE TOPIC

Paper abstracts and posters must be non-commercial in nature, describing current, modern and innovative approaches in the entire chain of **parenteral drug manufacturing** and related products.

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. A more detailed draft presentation will be due for committee review one month prior to the conference to ensure scientific nature of the content. Abstracts not selected for a 30 minute podium presentation may be eligible as a scientific poster during the conference. Please note that additional presenters / authors or poster presenters will be subject to a registration fee.

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

Deadlines

Abstracts of papers for presentation: **4 May 2017**

Poster abstracts: **26 August 2017**

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

TO EXHIBIT:

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