USP Workshop on the Control and Determination of Visible and Sub-visible Particulate Matter in Biologics

June 26-27, 2017

CALL FOR ABSTRACTS

Overview

The U.S. Pharmacopeial Convention (USP) invites you to submit abstracts for oral presentations at the USP Workshop on the Control and Determination of (Sub)Visible Particulate Matter in Biologics, to be held at the USP Headquarters Meetings Center in Rockville, MD on June 26-27, 2017.

Regulations direct drug product manufacturers to exclude foreign matter and minimize foreign particle content. Particles can originate from the environment, packaging materials, formulation ingredients, interactions between product and packaging, or be inherent to the product. For inherent species, or the expected formulation-related particle species, which techniques may be most appropriate? This workshop will be a forum for discussing the control and determination of undesired visible and sub-visible particulate matter and also characterization of inherent particle species in biopharmaceuticals.

We are seeking abstracts on the following topics:

Current Public Standards

- Compendial
- Regulatory

Particulate Matter Control

- Particles and patient safety risk, both extraneous and inherent
- Mitigating risk of particle content
- Raw material control
- Packaging and manufacturing component control
- Manufacturing process control
- Silicone oil use and control
- Setting appropriate control limits
- Particulate matter monitoring of manufacturing arenas and product

Particulate Matter Determination

- Detection issues related to product class (e.g. cell therapy, vaccines, lyophilized products)
- Gaps and challenges with analytical methods
- Detecting and quantifying particles ≤10 µm
- Analytical methods use: quality control vs. product development
- Challenges with the visual inspection process and technologies
- Particulate isolation, characterization and identification
- Particulate differentiation: Inherent vs extrinsic or intrinsic
- Setting appropriate product limits
- Particle size standards/Test set

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Submission Timeline:

- **Submission Deadline:** December 1, 2016
- **Notification of Acceptance/Denial:** January 15, 2017

Submission Instructions:

A. FORMAT YOUR ABSTRACT
Please send your abstract to USP in either Microsoft Word or PDF format.

B. PROOFREAD
Be sure to *proofread* your submission to confirm that it contains all the information you want to include before submitting your abstract.

C. PRESENTING AUTHOR AND ADDITIONAL AUTHORS
When listing your authors, you must designate a presenting author. It is recommended that the presenting author also be the submitter of the abstract. All correspondence will be sent to the submitter. The authors can be listed in any order you designate.

D. SUBMIT YOUR ABSTRACT
Send your abstract submission to Renee Stake at rms@usp.org.

F. ASSISTANCE
If you have any questions or are experiencing difficulties in the submission process, contact:

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