Working Summits on

Particulate in Single-Use Systems

WHY

The bioprocess industry is evolving from stainless steel systems, which are cleaned and steam-sterilized by validated processes immediately before use, to single-use systems (SUS), which are *not* routinely cleaned prior to use. Particles are generated during SUS fabrication, transportation and assembly. Cleaning and sterilizing stainless steel systems reduces the risk of particle contamination and especially endotoxin contamination. However, for SUS, the pharmaceutical manufacturer *outsources* process cleanliness and sterilization to the SUS manufacturer, relying on "clean build" practices that are similar to those for semiconductors, but the bioprocessing industry is still concerned about particulates. Because of this, the SUS community needs to address the paradigm shift from end users being responsible for preparation of equipment to suppliers being responsible, even though end users are still accountable to regulatory authorities. Without addressing this challenge, SUS use will not progress.

WHAT

Please join us at one of our open collegial working summits to discuss the issue of particulate contamination in single-use biopharmaceutical processes. We are looking for participants from the end user, supplier, and testing communities who have experience in this area and have working knowledge to present to the other participants. Space is limited and attendees are asked to provide a brief presentation of their current efforts. These will be shared with the other attendees to provide specifics for the discussions. The meetings will be an open exchange of opinions and ideas regarding the key issues, such as:

- **In which BioProcessing steps is particulate contamination more critical?**
- **Visual inspection methods of SUS: Room for improvement?**
- **Measurement of sub-visible particulates: Best approaches**
- **Measurement of visible particulates: Best approaches**
- **Identification of contamination risks in SUS manufacturing**
- **Approaches for continuous improvement of SUS manufacturing processes**

GOAL

We would like to summarize the current state of the industry and to identify areas which should be addressed to improve the overall quality of BioPharmaceuticals.

SUMMIT DATES

USA Working Summit
13 October 2017
University of Rhode Island
(Kingston, RI)

Europe Working Summit
20 October 2017
ZHAW Zürich University of Applied Sciences
(Wädenswil, Switzerland)

REGISTRATION

Please Contact:
The BioProcess Institute:
info@bioprocessinstitute.com
401-294-9000

SUMMIT LEADERS

James Dean Vogel, P.E.
Director
The BioProcess Institute

Klaus Wormuth, Ph.D
Lead Scientist, Particles
Sartorius Stedim Biotech GmbH

The BioProcess Institute

Sponsors:

BPSA Bio-Process Systems Alliance
Advancing Single-Use Worldwide

Zurich University of Applied Sciences
zhaw