Biotech

Technical Regulatory Topic

New BPSA 2020 Particulates Guide

Particle Management in Single-Use Systems

Document Number:	PMPE5
Revision Number:	1.00
Date:	07-JUL-20
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Introduction

In May 2020, BPSA (Bio-Process Systems Alliance) released a new version of its technical guide on particulates[1] from single-use systems (SUS) (1), providing a significant update to the original version. It is the output of a group of experts, including single-use systems (SUS) suppliers and end-users, all of whom are members of the BPSA.

Scope of the BPSA Particulates Guide

This 30+-page document provides a detailed overview as well as recommendations to suppliers and end-users of SUS for how to best manage particles from single-use systems. It describes current industry best practices and concludes with a list of considerations for further improvement.

Content of the BPSA Particulates Guide

This guide is intended for people who are new to single-use technologies as well as for people with experience in using SUS.

Increased implementation of SUS and increased awareness of particles from SUS has led to substantial progress since the publication of the first version of the BPSA technical guide on particulates in 2014. All sections of the particulates guide have been revised, reflecting the evolution of the industry approaches.

It is recognized that achieving zero particles is impossible, and that the goal is to continue to reduce the levels of particles as much as possible, and, therefore, the associated risk.

A large section is devoted to the risk associated with particles from SUS and the key factors impacting the risk assessment.

1 Particulates, particulate matter and particles are considered as equivalent terms by the regulators. Particles is used in the text above, unless otherwise mentioned in a referenced document, like the BPSA technical guide.

Another large section is associated with the control and testing of SUS. Visual inspection of SUS is a key element of the control strategy. However, due to limitations explained in the guide, the visual inspection should be complemented by more sensitive destructive testing performed on a statistical sampling of the production. This consists of liquid extraction of SUS, plus particle counting. Details are given illustrating how to verify the performance of the extraction method. Counting methods are compared, and recommendations made for the one best adapted to monitor all types of particles in SUS ("sub-visible" and "visible" particles).

With an end-to-end perspective, the key elements to be considered to control and minimize particles during both the SUS manufacturing process and the biopharmaceutical process are detailed.

The impact of the detection of particles in the SUS at different steps of its lifecycle is explained, with the associated consequences in terms of typical deviation levels, immediate actions and mitigation plans.

Finally, the document provides a summary of the key elements that should be in place for a robust management of particles, as well as items for further improvements.

It is a key guidance document to facilitate the collaboration between suppliers and end-users on this arduous topic, as well as between the SUS assembler and other suppliers upstream in the supply chain.

References

(1) "2020 Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Process Equipment". Can be downloaded on BPSA website: https://bpsalliance.org/technical-guides/