PALL Biotech

Technical Regulatory Topic

Useful Reference Documents

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Introduction

Particles management for single-use systems (SUS) is not always an obvious consideration. There are currently no standards or regulations directly applicable to SUS. The specification for the SUS used in a pharmaceutical process must be derived from the regulations applicable to the drug product in its final container.

Here is a list of what Pall Biotech feels are the most important regulations and guidance documents on this topic. These references provide deeper insight and help to understand the main elements of this complex and evolving subject in more detail.

Regulations Applicable to the Drug Product in its Final Container

1. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q4B Annex 3(R1) Test for Particulate Contamination: Sub-Visible Particles General Chapter.

2. European Pharmacopoeia (EP) general chapter 2.9.19. Particulate Contamination: sub-visible particles.

3. EP, 2.9.20. Particulate Contamination: visible particles.

4. Japanese Pharmacopoeia (JP), 6.07 Insoluble Particulate Matter Test for Injections.

5. United States Pharmacopeia (USP) <788> Particulate Matter in Injections.

6. USP <790> Visible Particulates in Injections.

7. USP <1790> Visual Inspection of Injections.

Guidance Documents

1. American Society of Mechanical Engineers: Bioprocessing Equipment (ASME-BPE) revision 2016, Part PM (Polymeric and Other Non-metallic Materials), Particulates.

2. ASTM International E3230-20: Standard Practice for Extraction of Particulate Matter from the Surfaces of Single-Use Components and Assemblies Designed for Use in Biopharmaceutical Manufacturing.

   Can be bought on https://www.astm.org/Standards/E3230.htm. Accessed November 7, 2020.

3. Clarke, D., *et al.*, Managing particulates in cell therapy: Guidance for best practice, *Cytotherapy* 2016.

   Freely accessible on https://www.celltherapysociety.org/page/CommunityResources. Accessed November 7, 2020.

4. 2020 Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Process Equipment, Bio-Process Systems Alliance (BPSA), 2020.

   Freely accessible on http://bpsalliance.org/technical-guides/. Accessed November 7, 2020.

Literature References

1. Bukofzer S, Ayres J, Chavez A, Devera M, Miller J, Ross D, *et al*. Industry perspective on the medical risk of visible particles in injectable drug products. *PDA J Pharm Sci and Tech* 69(1) (2015): 123–39.

2. Camposano, D., Mills, A., and Piton, C. A. Single-Use, Clinical-Scale Filling System - From Design to Delivery. *BioProcess International* June 15, 2016. https://bioprocessintl.com/manufacturing/single-use/a- single-use-clinical-scale-filling-system-from-design-to-delivery/

3. Langille SE., Particulate matter in injectable drug products. *PDA J Pharm Sci and Tech* 67(3) (2013): 186–200.

4. Johns J., Golfetto P., Bush T., *et al*. Achieving "Zero" Defects for Visible Particles in Injectables. *PDA J Pharm Sci and Tech* 72 (2018): 640-650.

5. Mathonet S, Mahler H.C, Esswein, S.T., *et al*. A Biopharmaceutical Industry Perspective on the Control of Visible Particles in Biotechnology-Derived Injectable Drug Products. *PDA J Pharm Sci and Tech* 70 (2016): 392-408.

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