



Managing particulates in cell therapy: Guidance for best practice

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Abstract

The intent of this article is to provide guidance and recommendations to cell therapy product sponsors (including developers and manufacturers) and their suppliers in the cell therapy industry regarding particulate source, testing, monitoring and methods for control. This information is intended to help all parties characterize the processes that generate particulates, understand product impact and provide recommendations to control particulates generated during manufacturing of cell therapy products.

KeyWords: cell therapy, disposable, injectable, parenteral, particle, particulate

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