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Basic Principles of Sterile Product Formulation Development.-
... Nitin Rathore, Ph.D, is a Principal Scientist in Drug Product Process Development at Amgen Inc., Thousand Oaks, California. His group is involved with the development of liquid and lyophilized protein drug products.

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2 Chapter 13 □ Formulation of Parenteral Products Objectives

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Developing an optimized formulation around a

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□ Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing ...

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