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Sterile Product Development: Formulation, Process, Quality ...

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.

Sterile Product Development Formulation Process

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2 Chapter 13 - Formulation of Parenteral Products Objectives This chapter provides an overview of the development of injectable (parenteral) drug products. Injectable drug products are relatively specialized and diverse, depending on both the location and type of disease to be treated in a patient. Developing an optimized formulation around a

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• Product development, including formulation, package, and process development. • Manufacturing, including basic teaching on all the primary unit operations involved in the preparation of sterile products and the underlying importance of contamination control and compliance to current good manufacturing practice.

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As these complex APIs and formulations become more common, there is an increased need for sterile operations, much of which is being addressed by contract manufacturers (Figure 1).In general, there are two ways to manufacture a sterile drug product: Terminal Sterilization: A process that involves filling and sealing product containers under high-quality environmental conditions, then ...

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Chapter 13 Formulation Development of Parenteral Products

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