Sterile Product Development: Formulation, Process, Quality and Regulatory Considerations

Publication Date: 2013-10-31

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This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book:

• Formulation approaches that discuss variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines;

• 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 hurdles for sterile product closures; and

• Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations microbial contamination investigations and validation of rapid microbiological methods and dry and moist heat sterilizers.

Scientists and researchers in industry and academia, process and product development engineers will find this book as a useful resource to gain insight into the current industry practices and evolving regulatory expectations for sterile product development.

ISBN: 978-1-4614-7977-2

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