

# Contents

## Part I Formulation Approaches for Sterile Products

<b>1 Basic Principles of Sterile Product Formulation Development .....</b>	<b>3</b>
Martin A. Joyce and Leonore C. Witchey-Lakshmanan	
<b>2 Molecule and Manufacturability Assessment Leading to Robust Commercial Formulation for Therapeutic Proteins.....</b>	<b>33</b>
Ranjini Ramachander and Nitin Rathore	
<b>3 Polymer- and Lipid-Based Systems for Parenteral Drug Delivery.....</b>	<b>47</b>
David Chen and Sara Yazdi	
<b>4 Formulation Approaches and Strategies for PEGylated Biotherapeutics .....</b>	<b>61</b>
Roger H. Pak and Rory F. Finn	
<b>5 Considerations for the Development of Nasal Dosage Forms .....</b>	<b>99</b>
Jason D. Ehrick, Samir A. Shah, Charles Shaw, Vitthal S. Kulkarni, Intira Coowanitwong, Samiran De, and Julie D. Suman	
<b>6 Formulation Approaches and Strategies for Vaccines and Adjuvants .....</b>	<b>145</b>
Kimberly J. Hassett, Pradyot Nandi, and Theodore W. Randolph	

## Part II Process, Container Closure and Delivery Considerations

<b>7 Challenges in Freeze-Thaw Processing of Bulk Protein Solutions .....</b>	<b>167</b>
Hari R. Desu and Sunil T. Narishetty	
<b>8 Best Practices for Technology Transfer of Sterile Products: Case Studies .....</b>	<b>205</b>
Leonore C. Witchey-Lakshmanan	

<b>9</b>	<b>Transfer Across Barrier Systems: A New Source of Simplification in Aseptic Fill and Finish Operations</b> .....	227
	Benoît Verjans	
<b>10</b>	<b>Challenges and Innovation in Aseptic Filling: Case Study with the Closed Vial Technology</b> .....	249
	Benoît Verjans	
<b>11</b>	<b>Contemporary Approaches to Development and Manufacturing of Lyophilized Parenterals</b> .....	275
	Edward H. Trappler	
<b>12</b>	<b>Advances in Container Closure Integrity Testing</b> .....	315
	Lei Li	
<b>13</b>	<b>Pen and Autoinjector Drug Delivery Devices</b> .....	331
	Ian Thompson and Jakob Lange	
<b>Part III Regulatory and Quality Aspects</b>		
<b>14</b>	<b>Particulate Matter in Sterile Parenteral Products</b> .....	359
	Satish K. Singh	
<b>15</b>	<b>Appearance Evaluation of Parenteral Pharmaceutical Products</b> .....	411
	Erwin Freund	
<b>16</b>	<b>Sterile Filtration: Principles, Best Practices and New Developments</b> .....	431
	Herb Lutz, Randy Wilkins, and Christina Carbrello	
<b>17</b>	<b>Intravenous Admixture Compatibility for Sterile Products: Challenges and Regulatory Guidance</b> .....	461
	Manoj Sharma, Jason K. Cheung, Anita Dabbara, and Jonathan Petersen	
<b>18</b>	<b>Basics of Sterilization Methods</b> .....	475
	Gregory W. Hunter	
<b>19</b>	<b>Avoiding Common Errors During Viable Microbial Contamination Investigations</b> .....	501
	Kenneth H. Muhvich	
<b>20</b>	<b>Validation of Rapid Microbiological Methods (RMMs)</b> .....	513
	Jeanne Moldenhauer	
<b>21</b>	<b>Validation of Moist and Dry Heat Sterilization</b> .....	535
	Jeanne Moldenhauer	
	<b>Index</b> .....	575

Sterile Product Development  
Formulation, Process, Quality and Regulatory  
Considerations

Kolhe, P.; Shah, M.; Rathore, N. (Eds.)

2013, XVI, 585 p. 89 illus., 67 illus. in color., Hardcover

ISBN: 978-1-4614-7977-2