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Reviews

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(Justina Kunze)

THE BIOLOGICS AND BIOTECHNOLOGY HANDBOOK FOR ENGINEERS (PAPERBACK)



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Createspace Independent Publishing Platform, 2017. Paperback. Condition: New. Language: English . Brand New Book ***** Print on Demand *****. This book provides a wide ranging overview of key themes and technologies used in Biotechnology. It is written from an engineers perspective and focuses on understanding the key subject areas including facility requirements, clean utilities, equipment validation, aseptic processes, Chapter 1: Facilities Introduction Contamination Control Material Flow Material Transfer Disinfection and Cleaning Agents GMP Zoning Environmental Grade A (Aseptic) Environmental Grade B Environmental Grade C Environmental Grade D Chapter 2: Clean Utilities Compressed Air Water Systems Water for Injection Clean Steam HVAC Chapter 3: Sterile Manufacturing Operations Unit Operations Raw materials Upstream Processing Filling Operations Container Closure Integrity Isolator Barrier Systems Decontamination Agents Containment Steam Sterilisers Chapter 4: Depyrogenation What is Depyrogenation? Pyrogens Endotoxins and Depyrogenation Biological Indicators for Dry Heat Control of Materials In-Process Controls Cooling Failure of Depyrogenation Chapter 5: Cleaning and Disinfection Cleaning Validation PICS/s Guidance on limit Test Methods Cleaning Process Design Piping Utilities Chapter 6: Process Development Vial Washers Depyrogenation Tunnels Isolators Chapter 7: Physical Processes Fluid Flow Classification of Fluids Mixing Vessel Geometry Heat Transfer Chapter 8: Equipment Validation Depyrogenation Tunnels (Equipment Validation) Isolators (Equipment Validation) Steam Sterilisers (Equipment Qualification) Chapter 9: Performance Qualification Depyrogenation Isolators Steam Sterilisers Chapter 10: Data Integrity The Lifecycle of Data System Categorisation Chapter 11: Test Method Validation Basics Chapter 12: Ethylene Oxide Sterilisation Sterilisation and Parametric Release Sterilisation Conditions Packaging Systems Pure ethylene oxide sterilizers Ethylene Oxide Sterilisation Cycles Biological indicator (BI) placement Chapter 13: Single Use Technology Introduction Extractables and Leachables Biocompatibility Chapter:14 Extractables and Leachables Introduction Extractables Explained Leachables Explained.



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