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Nota di contenuto	PHARMACEUTICAL MANUFACTURING HANDBOOK Regulations and Quality; CONTRIBUTORS; CONTENTS; PREFACE; SECTION 1 GOOD MANUFACTURING PRACTICES (GMP) AND OTHER FDA GUIDELINES; 1.1 Good Manufacturing Practices (GMPs) and Related FDA Guidelines; 1.2 Enforcement of Current Good Manufacturing Practices; 1.3 Scale-Up and Postapproval Changes (SUPAC) Regulations; 1.4 GMP-Compliant Propagation of Human Multipotent Mesenchymal Stromal Cells; SECTION 2 INTERNATIONAL REGULATIONS OF GOOD MANUFACTURING PRACTICES 2.1 National GMP Regulations and Codes and International GMP Guides and Guildelines: Correspondences and Differences; SECTION 3 QUALITY; 3.1 Analytical and Computational Methods and Examples for Designing and Controlling Total Quality Management Pharmaceutical Manufacturing Systems; 3.2 Role of Quality Systems and Audits in Phatmaceutical Manufacturing Environment; 3.3 Creating and Managing

a Quality Management System; 3.4 Quality Process Improvement; SECTION 4 PROCESS ANALYTICAL TECHNOLOGY (PAT); 4.1 Case for Process Analytical Technology: Regulatory and Industrial Perspectives 4.2 Process Analytical Technology; 4.3 Chemical Imaging and Chemometrics: Useful Tools for Process Analytical Technology; SECTION 5 PERSONNEL; 5.1 Personnel Training in Pharmaceutical Manufacturing; SECTION 6 CONTAMINATION AND CONTAMINATION CONTROL; 6.1 Origin of Contamination; 6.2 Quantitation of Markers for Gram-Negative and Gram-Positive Endotoxins in Work Environment and as Contaminants in Pharmaceutical Products Using Gas Chromatography-Tandem Mass Spectrometry; 6.3 Microbiology of Nonsterile Pharmaceutical Manufacturing; SECTION 7 DRUG STABILITY 7.1 Stability and Shelf Life of Pharmaceutical Products; 7.2 Drug Stability; 7.3 Effect of Packaging on Stability of Drugs and Drug Products; 7.4 Pharmaceutical Product Stability; 7.5 Alternative Accelerated Methods for Studying Drug Stability: Variable-Parameter Kinetics; SECTION 8 VALIDATION; 8.1 Analytical Method Validation: Principles and Practices; 8.2 Analytical Method Validation and Quality Assurance; 8.3 Validation of Laboratory Instruments; 8.4 Pharmaceutical Manufacturing Validation Principles; INDEX

Sommario/riassunto

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines.