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2.4.1 Comparability of Plasmid Gene Therapy Products; 2.4.2 Mixed Plasmid Preparations; 2.4.3 Plasmid Molecular Structure; 2.5 Biosafety Issues and Environmental Risk Assessment; References; 3 From Bulk to Delivery: Plasmid Manufacturing and Storage; 3.1 Introduction; 3.1.1 Gene Therapy; 3.1.2 DNA Vaccination; 3.2 Manufacturing of Plasmid DNA; 3.2.1 Bacterial Cultivation; 3.2.2 Plasmid DNA Purification; 3.2.3 Innovative Aspects in Plasmid Manufacturing; 3.3 Quality Control of Plasmid DNA Vectors; 3.3.1 Proteins, Ribonucleic Acid, and Lipopolysaccharides; 3.3.2 Chromosomal DNA; 3.3.3 Plasmid Identity; 3.3.4 Plasmid Topology (Structural Homogeneity); 3.4 Plasmid Stability during Storage and Application; 3.4.1 Long-Term Stability of Plasmid DNA; 3.4.2 Lyophilization for Long-Term Storage; 3.4.3 Stability during Application; 3.5 Future Developments; References; 4 Minimized, CpG-Depleted, and Methylated DNA Vectors: Towards Perfection in Nonviral Gene Therapy; 4.1 Introduction; 4.2 The Mammalian Immune System as a Barrier to Nonviral Gene Delivery; 4.3 Strategies to Minimize DNA Vectors; 4.3.1 Excision of a DNA Fragment Containing a Transgene Expression Cassette from Plasmid DNA; 4.3.2 Intramolecular Site-Specific Recombination Within a Bacterial Plasmid; 4.3.3 Synthesis of Minimized DNA Vectors by PCR; 4.3.4 Improvement of Minimized DNA Vector Yield and Purity; 4.4 Depletion of CpG Dinucleotides in the Bacterial Vector Backbone; 4.5 Methylation of CpG Dinucleotides in Plasmid DNA; 4.6 Towards an Ideal Nonviral Vector; 4.7 Conclusion; References; 5 Localized Nucleic Acid Delivery: A Discussion of Selected Methods; 5.1 Foreword; 5.2 Nucleic Acid Delivery - What For? 5.3 Nucleic Acid Delivery - How?

Sommario/riassunto

With its focus on a completely novel class of pharmaceuticals, this book collates the hitherto scarce literature about DNA drug formulation keenly desired by biotechnologists, molecular biologists and pharmacists, as well as those working in the biotechnological and pharmaceutical industries. As such, this volume presents a wide range of gene delivery systems needed for different therapeutic applications. It fills the gap between research and clinical trials and describes pharmaceutical fundamentals for the development of efficient DNA pharmaceuticals.
