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Nota di contenuto	DNA Pharmaceuticals; Preface; Contents; List of Contributors; Abbreviations; 1 DNA Vaccines - An Overview; 1.1 Rationale for DNA Vaccines; 1.2 Preclinical Proof of Concept; 1.3 Clinical Trials; 1.4 Second-Generation Vaccines; 1.5 Conclusions; References; 2 DNA as a Pharmaceutical - Regulatory Aspects; 2.1 Introduction; 2.2 Quality Requirements for DNA used as a Gene Therapy Product; 2.2.1 Introduction; 2.2.2 Production and Purification; 2.2.2.1 Raw Materials; 2.2.2.2 Antibiotics; 2.2.2.3 Solvents; 2.2.2.4 Fermentation; 2.2.2.5 Purification; 2.2.3 Cell Banking System Procedures 2.2.3.1 Generation and Characterization of Master and Working Cell Banks 2.2.4 Product Characterization and Quality Criteria; 2.2.4.1 Identity; 2.2.4.2 Purity; 2.2.4.3 Adventitious Agents; 2.2.4.4 Potency; 2.3 Safety Studies for Clinical Trials; 2.3.1 General Considerations; 2.3.2 Conduct of Preclinical Safety Studies; 2.3.2.1 Regulations; 2.3.2.2 Design of an Appropriate Toxicology Program; 2.3.2.3 Single- and

Repeat-Dose Toxicity Studies; 2.3.2.4 Safety of the Formulated Plasmid DNA; 2.3.2.5 Specific Safety Considerations; 2.3.2.6 Choice of Animal Model; 2.4 Special Issues
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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
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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.
