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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 Banks2.2.4 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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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.