



Gene Therapy Technologies, Applications and Regulations: From Laboratory to Clinic

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Gene Therapy Technologies, Applications and Regulations From Laboratory to Clinic Edited by Anthony Meager Division of Immunobiology, The National Institute for Biological Standards and Control, South Mimms, UK The development of gene-based technologies has been rapid over the past decade and has consequently resulted in a surge of interest in human gene therapy, the deliberate transfer of genes to somatic cells to cure or alleviate disease symptoms. Hundreds of clinical protocols involving variously designed vectors for efficient gene transfer have been developed. However, the use of such complex 'gene medicines' containing potentially heritable genes has raised numerous concerns regarding quality, efficacy and safety. Encompassing recent developments in the field and addressing current concerns this book:

- * surveys many of the current technologies for preparing vectors for use in gene therapy protocols
- * reviews the application of gene-mediated therapies to a range of medical conditions
- * considers the regulatory aspects of gene therapy including product quality and safety requirements
- * appraises the transfer of technologies from laboratory to clinic with regard to the attendant requirements and facilities for:
 - * good laboratory practice (GLP) conditions in the R&D laboratory
 - * large-scale production methods and good manufacturing practice (GMP)
 - * current in-process and final product testing

Written by international experts knowledgeable about many aspects of human somatic gene therapy, this book will be an essential guide for those embarking on gene therapy technologies relevant to specifications of production and testing of products (and procedures) required to meet existing regulations, including quality, efficacy and safety considerations.

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