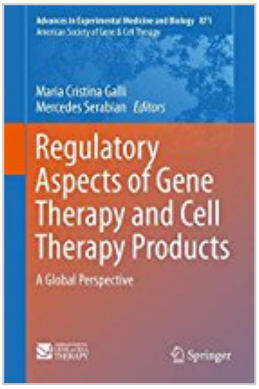

Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective (Advances in Experimental Medicine and Biology)

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This book discusses the different regulatory pathways for gene therapy (GT) and cell therapy (CT) medicinal products implemented by national and international bodies throughout the world (e.g. North and South America, Europe, and Asia). Each chapter, authored by experts from various regulatory bodies throughout the international community, walks the reader through the applications of nonclinical research to translational clinical research to licensure for these innovative products. More specifically, each chapter offers insights into fundamental considerations that are essential for developers of CT and GT products, in the areas of product manufacturing, pharmacology and toxicology, and clinical trial design, as well as pertinent "must-know" guidelines and regulations.

Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective is part of the *American Society of Gene and Cell Therapy* sub-series of the highly successful *Advances in Experimental Medicine and Biology* series. It is essential reading for graduate students, clinicians, and researchers interested in gene and cell therapy and the regulation of pharmaceuticals.

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Editorial Review

From the Back Cover

Medical literature for health care practitioners on the evaluation and treatment of breastfeeding issues has been disjointed, conflicting, and difficult to find. The field of breastfeeding medicine itself is nonexistent?there are no "breastfeeding doctors" who are specifically trained to understand this complex and interactive process. While much of the literature about breastfeeding describes how it "should" work, there is currently nothing available to explain why it often fails and how to treat it.

Clinician's Guide to Breastfeeding: Evidence-based Evaluation and Management is written for health care practitioners who work with breastfeeding mothers; physicians, nurses, nurse practitioners, and lactation consultants. It provides clear information and clinically tested strategies to help professionals guide new mothers to breastfeed successfully. The first of its kind to consider the entirety of the breastfeeding experience, *Clinician's Guide to Breastfeeding* is written by Dr. Linda D. Dahl, a leading expert on the subject. It is a comprehensive review of breastfeeding, covering objective analyses of ideal or "normal" nursing, as well as the evaluation and treatment of abnormal nursing, including case studies to illustrate the treatment decision-making process.

About the Author

Maria Cristina Galli holds a University degree in Biological Sciences and a PhD in Molecular Medicine; currently she is in-staff senior researcher, Cell Biology and Neurosciences Department, Istituto Superiore di Sanità, Roma, Italy. Her main expertise is in regulatory sciences for translational medicine supported by scientific education and research experience in experimental oncology, cellular biology, and molecular immunology. Dr. Galli spent more than twenty years as a basic researcher in experimental oncology, cellular biology, and molecular immunology, and wrote or co-wrote sixty publications in international journals. Over the past two decades, she has been active in the field of translational medicine as quality assessor for gene therapy and biotechnology medicines in national as well as European procedures; she has also been active for most of this time as GMP and GLP inspector. Dr. Galli was a member of CAT-EMA for three years and for four years served as vice-chair/chair of CAT-EMA Gene Therapy Working Party, in which she has participated since its first meeting. She is currently co-chair of the ATMP platform in the European infrastructure for translational medicine EATRIS-ERIC.

Mercedes Serabian holds an MS degree in Toxicology from American University and is a Diplomat of the American Board of Toxicology (DABT). She currently serves as Chief of the Pharmacology/Toxicology Branch in the Office of Cellular, Tissue, and Gene Therapies (OCTGT) in the Center for Biologics Evaluation and Research (CBER) at the USFDA. She is responsible for overseeing the pharmacology/toxicology review, regulation, and policy development for cellular and gene therapy products submitted to FDA. She provided expert pharmacology/toxicology advice on FDA guidance documents such as cancer vaccines, cellular therapies for cardiac disease, cartilage repair/replacement products, long-term follow-up of subjects administered gene therapy products, and viral shedding. Ms. Serabian championed the *Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products*, outlining FDA recommendations on preclinical data to support clinical studies of cellular and gene therapy products. She has participated in several expert working groups under the International Conference for

Harmonisation and has presented to outside parties on preclinical regulatory considerations for cellular and gene therapy products intended for administration in clinical trials.

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