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Biotechnology: Law, Business, And Regulation



Synopsis

BIOTECHNOLOGY: LAW, BUSINESS, AND REGULATION offers comprehensive analysis on the advancement of a biotech discovery into a commercial product, making it easy for you to identify legal issues as they arise in the R & D and commercialization process; anticipate forthcoming legal and regulatory challenges; and develop an effective strategy for efficient commercialization. Real product and industry examples are used throughout the handbook and pending legislation is discussed and analyzed. This is the first book to pull together all the legal issues associated with the burgeoning biotechnology industry. The author explains and analyzes the current dimensions of biotechnology law, with in-depth attention to:~ the markets for biotech products ~ patent protection ~ confidentiality and other intellectual property issues ~ government-supported cooperative R & D agreements ~ corporate securities issues ~ clinical trial agreements, including informed consent, liability, and insurance issues ~ FDA regulation and tracks to speed product approval and commercialization ~ legal implications of foreign R & D ~ public health and policy considerations ~ legislation prohibiting discrimination on the basis of genetic information ~ and ethical norms of the scientific and medical communities.

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Customer Reviews

I am finding "Biotechnology: Law, Business, and Regulation" to be a truly useful collection of information and references. This single book provides a comprehensive legal and business perspective to the development of medical products derived from biotechnology. Topics covered include: academic research, patents, raising capital, alliance agreements, technology transfer, and

government regulations. The book is well organized with a user-friendly and detailed table of contents, index and glossary. It is packed with a collection of practical information which I am finding to be extremely useful in winding through the complex collection of laws, regulations, guidelines and industry practices associated with this field. Two of the many attractive features of the book are: 1) the update subscription service provided by the publisher and 2) the CD-ROM which includes copies of the book's appendices, approximately seventy documents in pdf format which can be viewed using Acrobat™ Reader, on Mac or PC computer systems. The CD-ROM alone, with full text copies of references such as the FDA Modernization Act, the Bayh-Dole Act, the Belmont Report and lists of venture capital firms, universities and trade associations, is worth the price of the book. "Biotechnology: Law, Business, and Regulation" is a valuable resource that will greatly assist those involved in the commercialization of new medical products. I would recommend this book to professionals in the business of developing new drug products whether traditional pharmaceuticals or biotechnology-based products.

This is an outstanding piece of scholarship that manages to bring together in a logical way the legal, business and regulatory aspects of this rapidly-advancing field. This encyclopedic work is an invaluable resource for academics, legal practitioners, regulators and students. It is the best guide to biotechnology law available worldwide. It is a model that will be replicated from other countries and regions of the world

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