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Rosen, Pablo Gurman, Noel Elman, 2025-01-31 This book provides a unique knowledge source of the FDA's regulatory processes to anyone interested in the development and approval of biomedical products. Navigating the FDA Regulatory Processes will be of particular importance for those innovating in biomedical devices, pharmacological therapies, and combination products, who are interested in considering regulatory affairs early on in product development. The authors offer a comprehensive exploration of FDA regulations, providing industry insights and guidance for navigating the complexities of drug and device development. The book offers concrete examples, industry perspectives, and historical context, ensuring clarity and aiding in successful understanding of the requirements for regulatory compliance. Readers will also gain a thorough understanding of FDA regulatory processes, from securing approvals to navigating expedited pathways. Lastly, the book provides unique insights into the FDA approach for emergency preparedness, including discussing the recent COVID-19 pandemic. Biomedical industry personnel, engineers, scientists, entrepreneurs, medical doctors, students, and anyone interested in the development and approval of medical products in the US will find this book useful and essential.

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