ABOUT THE BOOK:

To tackle the rising burden of disease, disability and premature deaths, the demand for newer and better treatment is more than ever. Drug registration is a critical step for the introduction of medicines in a country. There has been a great deal of international interaction and cooperation in the area of public health, particularly since the conception of the Millennium Development Goals. However, international cooperation vis-à-vis mechanisms to achieve shared goals of public health are still very limited. Regulation of drugs, more specifically drug registration, is one such neglected area. This report, the first-of-its-kind, based on extensive desk and field research in 4 Indian states—Maharashtra, Karnataka, Gujarat and Telangana—and 7 countries—USA, UK, Switzerland, Germany, South Africa, Singapore and Indonesia—incorporates views of more than 150 stakeholders to identify lessons as well as opportunities for the Government of India in its effort to address challenges of drug regulation in particular, and public health more generally, in the country.

PRAISE FOR THE BOOK:

“Through a thoughtful review of various countries’ drug registration procedures, this report summarizes international cooperation initiatives, and various opportunities critical in reestablishing India as a leader in pharmaceutical development. This report will be vital for government and private sector efforts to modernize India’s drug registration processes.”
— Mark Barnes, J.D., LL.M
Barbara Bierer, M.D.,
Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard University

“This is an excellent and timely report from an expert group that should be very useful to the Indian government as it considers possible improvements in its systems for review and approval of drug products.”
— Richard Kingham
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