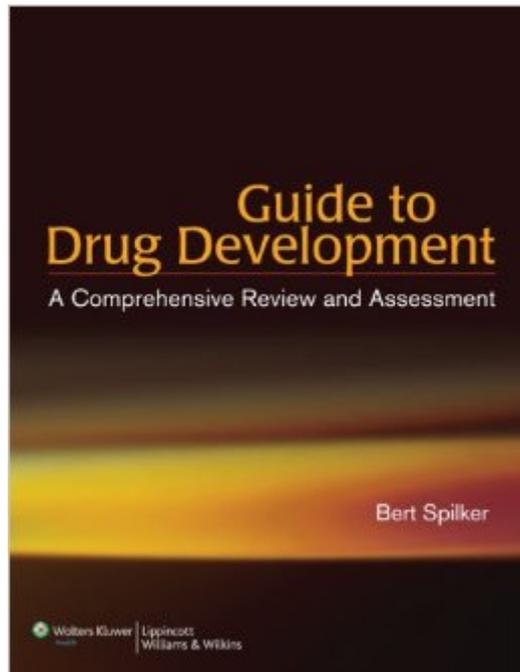# Guide To Drug Development: A Comprehensive Review & Assessment

Synopsis

Written by one of the foremost authorities on clinical trials, drug development, and regulatory affairs, Guide to Drug Development is a comprehensive review of the principles and activities involved in developing new drugs, devices, and other medical products. The book covers many topics not discussed in any other textbook and includes timely discussions on electronic clinical trials, registries of clinical trials, data mining, computer simulations and modeling, and changing regulatory standards. Each chapter includes practical tips, lessons, guides, firsthand stories, quotes from experts, and three to six questions for group discussion. The last three chapters present twelve case studies each on clinical trials, regulatory affairs, and management of drug development. Spilker's Guide to Drug Development will be the standard reference text for everyone working on or studying drug discovery or development, in industry, academia, hospitals, government, and independent laboratories.

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