

News Release

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BERT SPILKER & ASSOCIATES, LLC ANNOUNCES THE LAUNCH OF
THE SPILKER REPORT™
UNIQUE PUBLICATION FOCUSES ON SHORTENING DRUG DEVELOPMENT TIME.

BETHESDA, MD - Both the length of time and the associated cost it takes for a new drug to reach those it will benefit have become a serious problem which is inhibiting the development of therapies that society sorely expects, needs and demands. Now, to tackle these issues, **THE SPILKER REPORT**™, a new publication from one of the world's foremost authorities on drug development, addresses topics of import in the drug development arena.

Each monthly issue, crucially relevant to the pharma and biotech industries, device manufacturers, regulatory agencies, as well as sophisticated investors, venture capitalists and business journalists, comprises eight columns covering regulatory, clinical, and management topics. The content presents insights, ideas, tips and suggestions targeting ways to shorten the time for developing pharmaceutical products by improving approach, methods and efficiency. Each month readers will gain insights and benefits in how to improve efficiency and shorten development time for biotech or pharma drugs, devices and diagnostic products.

In this era of increasing pressures to develop drugs, biologicals, devices and diagnostics as rapidly as possible, it is essential to consider every idea and approach that may improve efficiency and shorten time to availability. **THE SPILKER REPORT**™ is written with this in mind and presents observations and lessons collected and learned over a 30-year career in the industry by Dr. Spilker, the world's leading author on multinational drug companies and clinical trials.

The first issue will launch January 2003, and may be previewed at:
www.spilkerreport.com

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Monthly topical columns include:

Regulatory Affairs

Commentaries, Practices & Tips

Enhancing Your Meetings with Regulatory Agencies

Case Studies & Exercises: *Highlighting actual regulatory experiences*

Clinical Trials

Strategies, Practices & Tips

Case Studies & Exercises: *Highlighting actual clinical experiences*

Management Issues

Specific approaches & ideas to improve efficiency

Reflections: *Current pharmaceutical issues*

Case Studies & Exercises: *Highlighting actual management experiences*

Dialogue Forum

Questions from Readers & Responses from Dr. Spilker

Comments from Readers

Information on subscription options for **THE SPILKER REPORT**™ is available by calling 1-800-490-5676 or by e-mailing sprr@kable.com

Dr. Spilker comments "I have learned about many strategies and approaches to drug development that are effective, and decided to pass on this information. My 15 books focus on principles and practices and **The Spilker Report**™ focuses on tips and strategies that companies can apply and use in a variety of situations. A single idea can save a company months or years &, possibly, \$millions."

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About Dr. Bert Spilker

Bert Spilker, PhD, MD, FCP, FFPM, is well known as the author of 15 books on clinical trial methods and the processes of drug discovery and development. These books are considered by many as the standard references on clinical trials and drug development.

He was most recently the Senior Vice President of Scientific and Regulatory Affairs for PhRMA (Pharmaceutical Research and Manufacturers of America) based in Washington, DC. He was President and cofounder (in 1993) of Orphan Medical, Inc., a public pharmaceutical company that develops and markets important medical products for patients with uncommon diseases. He has received numerous honors including the FDA Commissioner's Special Citation for work in the orphan medicine area. He has worked at four major pharmaceutical companies for over 20 years (Pfizer, Philips-Duphar, Sterling-Winthrop, and Burroughs Wellcome) in medicine discovery, development, and management. He has received numerous honors including the FDA Commissioner's Special Citation for work in the orphan medicine area. He is Clinical Professor of Pharmacy Practice at the University of Minnesota and Adjunct Professor of Medicine and Clinical Professor of Pharmacy at the University of North Carolina in Chapel Hill. His medical training in pharmacology and internal medicine was at Cornell Medical College, State University of New York (Downstate Medical Center), University of California at San Francisco, University of Miami Medical School (Ph.D. to M.D. Program) and Brown University Medical School.

Additional information is on www.bertspilker.com

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