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There is no secret recipe for a successful FDA meeting, and Drs. Spilker and Kennedy do not use a single model or approach. Their experience will lead to an optimal approach to achieve your meeting objectives. The difference between successful and unsuccessful meetings is often the quality of the planning for these meetings.

They have created two approaches to help you achieve success.

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**Brief Bio Sketches**

**Dr. Spilker** recently retired as Sr. Vice President of Scientific and Regulatory Affairs, PhRMA. He was President and co-founder of Orphan Medical, Inc. He has worked at Pfizer, Philips-Duphar, Sterling-Winthrop, and Burroughs Wellcome in medicine, development and management. He served on the Steering Committee for ICH, and has received numerous honors including the FDA Commissioner’s Special Citation. He is Clinical Professor of Pharmacy Practice at the Univ. of Minnesota and Adjunct Professor of Medicine and Pharmacy at the UNC in Chapel Hill. He is the author of 15 books on clinical trial methods and the processes of drug discovery and development. His medical training in pharmacology and internal medicine was at Cornell Medical College, SUNY Downstate, UCSF, University of Miami, and Brown University.

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