Enhancing Your Meetings with FDA™

A Service of Spilker/Kennedy Consulting

Your Key to More Successful Meetings with FDA

Two internationally known and respected experts in regulatory and clinical affairs,

Bert Spilker, PhD, MD and Bill Kennedy, PhD apply their talents, experience and skills to help you have more successful FDA meetings. Whether you are preparing for a pre-IND, End of Phase II, Pre-NDA or Advisory Committee meeting, Drs. Spilker and Kennedy can help you plan for and conduct these critical interactions with FDA. Their service is intended to maximize the performance of your company and your staff, not replace it.

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.

Abbreviated Program

This is a limited program in terms of visits to your site, number of interactions and rehearsals. If you are rapidly approaching the big day or you have extensive experience and seek some polish to your presentations, this approach may be the right one for your company. Both Dr. Spilker and Dr. Kennedy participate equally in this program. The fee is $12,000 plus expenses. Additional time is billed at $400 per hour per person.

Custom Program

A special program can be readily developed to address your individual needs with a full range of services that can be made available for you. Each service is available with Dr. Spilker and/or Dr. Kennedy to further enhance possible variations. Fees can be based on hourly or daily rates, and expenses are additional.

Brief Bio Sketches

Dr. Spilker recently retired as Sr. Vice President of Scientific and Regulatory Affairs, PhRMA. He was President and cofounder 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.

Dr. Kennedy retired as Vice President, Regulatory Affairs, Zeneca in 1999. Prior to that he worked for Searle, KaliPharma, Berlex and Pfizer. He earned his PhD in Pharmacology at SUNY at Buffalo, and served on the faculty at Yale Medical School. He is a past Chairman of the PhRMA Regulatory Affairs Committee. He was the PhRMA Chief Negotiator for FDAMA, and co-Chair of PhRMA's PDUFA III Steering Committee.

For further information call Dr. Spilker at (301) 718-5150 or Dr. Kennedy at (302) 542-2986, or visit either of our Web sites (www.bertspilker.com or www.consultkennedy.com).

Whether your company is large or small, the expertise and experience of Drs. Spilker and Kennedy can add value to your meetings with the FDA.

Enhancing Your Meetings with FDA™

Your Key to More Successful Meetings with FDA

Two internationally known and respected experts in regulatory and clinical affairs,

Bert Spilker, PhD, MD and Bill Kennedy, PhD apply their talents, experience and skills to help you have more successful FDA meetings. Whether you are preparing for a pre-IND, End of Phase II, Pre-NDA or Advisory Committee meeting, Drs. Spilker and Kennedy can help you plan for and conduct these critical interactions with FDA. Their service is intended to maximize the performance of your company and your staff, not replace it.

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.

Abbreviated Program

This is a limited program in terms of visits to your site, number of interactions and rehearsals. If you are rapidly approaching the big day or you have extensive experience and seek some polish to your presentations, this approach may be the right one for your company. Both Dr. Spilker and Dr. Kennedy participate equally in this program. The fee is $12,000 plus expenses. Additional time is billed at $400 per hour per person.

Custom Program

A special program can be readily developed to address your individual needs with a full range of services that can be made available for you. Each service is available with Dr. Spilker and/or Dr. Kennedy to further enhance possible variations. Fees can be based on hourly or daily rates, and expenses are additional.

Brief Bio Sketches

Dr. Spilker recently retired as Sr. Vice President of Scientific and Regulatory Affairs, PhRMA. He was President and cofounder 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.

Dr. Kennedy retired as Vice President, Regulatory Affairs, Zeneca in 1999. Prior to that he worked for Searle, KaliPharma, Berlex and Pfizer. He earned his PhD in Pharmacology at SUNY at Buffalo, and served on the faculty at Yale Medical School. He is a past Chairman of the PhRMA Regulatory Affairs Committee. He was the PhRMA Chief Negotiator for FDAMA, and co-Chair of PhRMA's PDUFA III Steering Committee.

For further information call Dr. Spilker at (301) 718-5150 or Dr. Kennedy at (302) 542-2986, or visit either of our Web sites (www.bertspilker.com or www.consultkennedy.com).

Whether your company is large or small, the expertise and experience of Drs. Spilker and Kennedy can add value to your meetings with the FDA.

A Service of
Spilker/
Kennedy
Consulting

Enhancing Your Meetings with FDA™

A Service of Spilker/Kennedy Consulting

Your Key to More Successful Meetings with FDA

Two internationally known and respected experts in regulatory and clinical affairs,

Bert Spilker, PhD, MD and Bill Kennedy, PhD apply their talents, experience and skills to help you have more successful FDA meetings. Whether you are preparing for a pre-IND, End of Phase II, Pre-NDA or Advisory Committee meeting, Drs. Spilker and Kennedy can help you plan for and conduct these critical interactions with FDA. Their service is intended to maximize the performance of your company and your staff, not replace it.

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.

Abbreviated Program

This is a limited program in terms of visits to your site, number of interactions and rehearsals. If you are rapidly approaching the big day or you have extensive experience and seek some polish to your presentations, this approach may be the right one for your company. Both Dr. Spilker and Dr. Kennedy participate equally in this program. The fee is $12,000 plus expenses. Additional time is billed at $400 per hour per person.

Custom Program

A special program can be readily developed to address your individual needs with a full range of services that can be made available for you. Each service is available with Dr. Spilker and/or Dr. Kennedy to further enhance possible variations. Fees can be based on hourly or daily rates, and expenses are additional.

Brief Bio Sketches

Dr. Spilker recently retired as Sr. Vice President of Scientific and Regulatory Affairs, PhRMA. He was President and cofounder 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.

Dr. Kennedy retired as Vice President, Regulatory Affairs, Zeneca in 1999. Prior to that he worked for Searle, KaliPharma, Berlex and Pfizer. He earned his PhD in Pharmacology at SUNY at Buffalo, and served on the faculty at Yale Medical School. He is a past Chairman of the PhRMA Regulatory Affairs Committee. He was the PhRMA Chief Negotiator for FDAMA, and co-Chair of PhRMA's PDUFA III Steering Committee.

For further information call Dr. Spilker at (301) 718-5150 or Dr. Kennedy at (302) 542-2986, or visit either of our Web sites (www.bertspilker.com or www.consultkennedy.com).

Whether your company is large or small, the expertise and experience of Drs. Spilker and Kennedy can add value to your meetings with the FDA.