



## PHARMACEUTICAL & MEDICAL DEVICE ADVISORY COMMITTEE MEETING PREPARATION & MANAGEMENT SERIES

Regulatory professionals must know what it takes to “tackle” advisory committees head-on!

### WEBINAR OVERVIEW:

Millions of dollars are at stake for medical device and pharmaceutical companies whose new product is subject to an FDA Advisory Committee meeting; any misstep can affect the likelihood and timing of getting a product approved. The preparation and management of an advisory committee meeting is one of the most important events in the life cycle of the product and needs to be approached as such. Teams may not realize that it takes more than simply being knowledgeable about the science; it also takes STRATEGY, KEY MESSAGING... INTELLIGENCE... and a lot of PRACTICE to appropriately communicate to the committee the benefits of a product and what it provides to public health. Please join us for this informative webinar series on the nuts and bolts of preparing for and implementing a successful FDA Advisory Committee meeting program for your product.

### Course 1:

**Tuesday January 13 - 12 PM EST**

#### Ad Com Preparation: Best Practices

- Message is key
- Issue identification and preparation
- Picking the right presenters
- Building an effective timeline and managing for success
- Ensuring internal and external alignment
- Practice, practice, practice! (Mock Rehearsal Programs)
- Before the meeting; Advisory Committee Member Research

### Course 2:

**Thursday January 15 - 12 PM EST**

#### Content Development

- Briefing Book
  - Outline construction – core team, sub team review
  - Content inclusion, not just a “data dump”
  - Focus on major issues and address them head-on
  - Key message must resonate throughout
  - Must align with oral presentation
- Presentation Slides
  - Core presentation ‘shell’ construction – determining presentation flow/storyline
  - Content inclusion – determining what should be presented vs. what should only be in briefing book vs. what should be back-up
  - Key message must resonate throughout
  - Making presentations visually impactful
  - Providing sufficient detail without overwhelming the listener

### WEBINAR PRESENTER:



**Steven M. Weisman, Ph.D.**

*Head of Clinical & Regulatory Support*

**INNOVATIVE SCIENCE SOLUTIONS  
LLC**



**INNOVATIVE SCIENCE SOLUTIONS, LLC**  
SCIENTIFIC CONSULTANTS TO INDUSTRY and COUNSEL

Steve Weisman, Ph.D. is the Head of Clinical and Regulatory Support practice at Innovative Science Solutions (ISS), a firm that provides worldwide scientific consulting for the pharmaceutical, biotechnology, and medical device industries. ISS has over fifteen years of experience in developing regulatory strategies including support for FDA Advisory Committee meetings. Dr. Weisman organizes and leads more advisory committee meetings per year than even the largest pharmaceutical companies. He has also organized and presented at numerous symposia, FDA advisory committee meetings, and other regulatory venues, worldwide. He manages the FDA advisory committee process for many of the largest pharmaceutical concerns and represents companies before regulatory authorities in major markets around the world.

Prior to founding ISS, Dr. Weisman ran the Pharmaceutical and Food practices at a major scientific consulting firm in Washington, DC. Before that, he served as Global Director of Medical and Clinical Affairs at Bayer, Director of Strategic Research at Sterling Winthrop, and held similar positions at Hoffman La Roche and Procter & Gamble.

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### **Course 3:**

**Tuesday January 20 - 12 PM EST**

#### **Anticipating and Responding to Questions**

- Advisory Committee Member Research
  - Determine member knowledge and understanding of issues to understand their perspective
  - Understand the committee members' 'hot buttons' (Are they mostly patient-oriented? Are they all about the data?)
  - Understand how the committee members have voted in the past and what kinds of questions they are likely to ask
  - Model likely questions and effective responses
- Q&A Practice; Preparation and Delivery

### **Course 4:**

**Thursday January 22 - 12 PM EST**

#### **How to Find the Best External Support**

- Request for Proposals (RFPs) from 3rd Party Vendors
  - Accurate outline of program objectives (i.e. knowing how often team wants to interact, how many mocks team wants/is able to have)
  - How to assess and choose the right support vendor for your advisory committee
  - Timeline for effective review and engagement
  - Value of references
  - Considering the various options and picking the one most relevant to the team's needs
- Utilizing 3rd Party Vendor to Engage Appropriate and Effective KOLs
  - Identify experts in relevant scientific field(s)
  - Perform initial reach-outs (availability/interest)
  - Begin contract process
  - Dealing with Sunshine Act and compliance related issues
  - Keeping control with outside KOL involvement



#### **TARGET AUDIENCE:**

##### **JOB TITLES:**

Regulatory Affairs  
Regulatory Operations

##### **INDUSTRIES REPRESENTED:**

Pharmaceutical  
Biotechnology  
Medical Device

#### **WEBINAR LOGISTICS:**

Webinars are conducted utilizing GoToMeeting software that is easy to use and allows presenters to move through presentation slides while audience members watch from their laptops. Each presentation is intended to run for 45 minutes to one hour of presentation followed by dialogue in the form of Q&A from audience members, facilitated by the Q1 moderator. Questions from the audience can be submitted prior to the presentation, during, or at the conclusion, depending on the preferences of the attendees and presenter.

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