

# **Preparation for FDA Advisory Panel and Other FDA Meetings**

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# Session Objectives

FDA and Sponsor and Perspective on  
How to Prepare for Meetings:

- Elements for Success
- Best Practices
- Pitfalls to Avoid

# What Session Will Cover

- Regulations and Requirements
- Basics of Advisory Committees and Other Meetings:
  - Purpose
  - Membership
  - Function
- Step-by-Step “How To”

# Role of Regulatory Affairs

- Leader
- Planner
- Strategist
- Tracker
- Facilitator
- Team Member
- Coach

*One of the Keys to Successful Meetings*

# Key Success Factors

- Early Planning
- Establishing Strategy
- Preparation
- Tracking

***Despite This, Not All Meetings Result in the Sponsor's Desired Outcome***

# Program

- Preparation Strategies for FDA Meetings
  - FDA Perspective – **Kim Colangelo**
  - Sponsor Perspective – **Susan Mondabaugh, Ph.D.**
- Break
- Preparing for Advisory Committee Meetings
  - FDA, CDER's Advisors & Consultants Staff (ACS) Perspective – **Igor Cerny, Pharm.D.**
  - Sponsor Perspective – **Robert Kirsch, Ph.D.**
- Questions