

Preparation for FDA Advisory Committee Meetings

Robert M. Kirsch, RAC
Vice President, Regulatory Affairs
TolerRx Inc.
Cambridge, MA

Agenda

- “Standard” FDA Meetings
 - Part of Everyday Life for Regulatory Affairs
- Advisory Committee Meetings
 - For Many, A “Once in a Lifetime Opportunity”!
(For Some, More Than Once)

Standard FDA Meetings

- Confidential Discussion
- Audience → FDA
- Pre-IND, End-of-Phase 2, pre-NDA / BLA
- Driven by Sponsor-Generated Questions
- Variety of Topics at Various Stages of Product Development
- Guidance on FDA / Sponsor Meetings

Advisory Committee Meeting

- Very Different Forum – **Public Discussion**
- Audience → Advisory Committee Members (Independent Experts Selected by FDA)
- Driven by FDA-Generated Questions
- Clinical / Statistical Discussions of Safety & Efficacy

Advisory Committee Meeting

- **Balanced Presentation of Issues**
 - Sponsor Presents Position; Q&A
 - FDA Presents Position; Q&A
- **Open Public Hearing (e.g., Patient Groups)**
- **Committee Deliberations**
- **Committee Votes on Questions Posed by FDA**

Advisory Committee Meeting

First Steps (1)

- Identify the Appropriate **Team Composition**
 - Team Leader (e.g., Regulatory Affairs)
 - Potential Presenters
 - Data Experts (e.g., Clinicians, Statisticians)
 - Outside Experts / Consultants (e.g., KOL)
 - Other Support (e.g., Medical Writers, Administrative Assistants, IT)
- Establish Clear **Roles and Responsibilities**

Advisory Committee Meeting

First Steps (2)

- Need for **Intensive** Preparation – Not Like Any Other Meeting!
 - Block Out Calendars (Months to Prepare!)
 - Arrange Off-site Preparation Meetings (e.g., Several Multiple-day Meetings)
 - No Interruptions (e.g., No Cell Phones, e-mail, or PDAs)
- **CRITICAL** – Determine Your Company's Discipline!
 - Internal Preparation or Off-site With Consultants

Advisory Committee Meeting

Know Your Data!

- Understand the FDA's Point of View, Concerns, and Issues
 - “Why an Advisory Committee?”
 - NCE, New Drug Class, Public Health Issues, Use of Surrogate Endpoints
 - Review Product File's Regulatory History (e.g., Letters, Telephone Records)
- Take a Fresh Look at **All** the Data

Advisory Committee Meeting

Know Your Data!!

- Are There Perceived or Potential. . .
 - Safety Issues?
 - Efficacy Issues?
 - Statistical Issues?
- Know Your Position on Every Issue

Advisory Committee Meeting

Know the Audience – Do Research!

- Varying Disciplines
 - Practicing / Academic Physicians, Nurses
 - Statisticians
 - Consumer and Industry Representatives
- Varying Levels of Specific Disease Understanding
 - Obtain Biographies of Committee Members
 - Obtain Transcripts of Previous Meetings and Voting Records
 - Obtain Literature and Publications
- Varying Levels Of Product Understanding
 - Investigator in Product's Clinical Study vs No Knowledge of Product

Advisory Committee Meeting Information Package

- Target the Audience
 - Find Balance Between “Lecturing” and “Educating”
- Scientific Discussion of Data Supported by Peer-Reviewed Literature, as Appropriate
- Discuss FDA’s Position / Issues and Provide Scientifically-Based Explanations
- Clear, Concise, Unambiguous
- Releasable to Public
 - Don’t Include Proprietary Information

Advisory Committee Meeting Presentation

- Target the Audience
- Use Information Package as Basis for Preparing Presentation
- Address FDA's Position / Issues and Present Scientifically-Based Responses
- Be Clear; Keep to the Point
 - The Panel Has Reviewed the Information Package in Advance

Advisory Committee Meeting Q&A Preparation

- Most Difficult Part of the Meeting and Requires **Most Preparation**
- Anticipate Every Question (>50 Questions)
 - Review FDA's Information Package
 - Generate Questions From Issues Identified by FDA and by the Team
- Write a Response to **Every** Question

Advisory Committee Meeting

Q&A Preparation

- Develop Backup Slides, as Necessary, to Support Responses (Hundreds of Slides)
- Use Data Experts as Backup Slide Callers
- Presenters and Data Experts Memorize the Responses and Related Backup Slide Call Numbers

Advisory Committee Meeting

Practice, Practice, Practice!!

- **Again, Practice at Offsite Location (No Interruptions) – Recommend at Least 4 Sessions of 3 to 4 Days Each**
- **Conduct Several Mock Advisory Sessions**
- **Videotape Practice Sessions and Review Performance**

Advisory Committee Meeting

Practice, Practice, Practice Some More!

- Utilize Slide Presentation Technology With Multiple Laptops, Preview and Main Screens
- Effectively Manage Stress and Differences of Opinion
- Manage Public Relations, Internal Relations and Senior Management Expectations

Advisory Committee Meeting

The Day Before

■ Dos

- Dry-Run of Presentation
- “Light” Q&A Practice
- Keep It Fresh
- Early to Bed!

■ Don'ts

- Drastically Change Presentation
- Change Responses to Questions

Advisory Committee Meeting Conclusions

- Planning and Practice Are Key
- One of the Highest Visibility and Important Events for a Company

However

- Also a Chance for a Company to Shine!