



Preparing for an FDA ADVISORY COMMITTEE MEETING

Facing an FDA Advisory Committee (AdComm) is a stressful moment for any drug team. After presenting a short, convincing argument for approval, the team must answer a barrage of questions from a panel whose vote could spell the success or failure of their product, or company.

Some think preparing for an AdComm involves an intensive few weeks of work before the hearing. In fact, smart preparation actually begins four to five months in advance, as there is much work to be done.

Teams must be built, external experts engaged, timelines created, and roles assigned. A briefing package and a series of presentations (on efficacy, safety, etc.) must be written and sharpened. Hundreds, sometimes thousands, of slides must be created, and the answers to dozens of questions must be rehearsed in “mock panels” designed to expose the team to lifelike hearing situations.

Such in depth preparation is all the more important given that Advisory

Committee meetings continue to grow in both frequency and importance.

More than 50 to 60 AdComms are held each year and recent legislation and guidances virtually ensure that these numbers will increase. The 2007 FDA Amendments Act (FDAAA) mandates an AdComm for any new molecular entity, while the 2008 Guidances for the Public and FDA Staff on Convening Advisory Committees encourage consideration of a hearing if a drug is controversial or of public interest, or if special expertise is needed to evaluate it.

Moreover, ever since Vioxx, there’s been an increasing focus on safety and risk management by both the agency and the panels: the FDAA, in fact, mandated the creation of a risk communications committee.

Appreciating the growing importance and complexity of Advisory Committees, teams about to face one might remember Henry Ford’s wise counsel on preparation: “Before everything else, getting ready is the secret of success.” Indeed . ■

REGISTER FOR DIA’S NEW TRAINING COURSE ON THIS TOPIC!

Preparing for a US FDA
Advisory Committee
Meeting

**October 20, 2011
Horsham, PA**

For more information, visit the
DIA website at www.diahome.org,
select Training,
Find an Educational Offering,
and search ID 11442

The Steps to Preparing for
a Successful FDA Advisory
Committee Meeting

**November 14, 2011
11:00am-12:30pm ET**

DIA # 11251