Prepare to Win at FDA Advisory Committees

We reduce the Pressure

www.ndareg.com
Advisory Committee Meetings

The stakes are sky high at an FDA Advisory Committee meeting. You've spent years developing your product. Now you've got just one chance to make your case for it. And the outcome can make or break your product — even your company.

We can prepare you for the challenges of that day.

NDA affiliate PharmApprove is a pioneer in Advisory Committee preparation. Our rigorous approach — developed over more than 150 public hearings — will help your team and your Briefing Package, presentations and responses to questions make the most compelling case for your product.

Our team of project leaders are industry professionals and communication coaches with decades of scientific communication experience. We will help you prepare your content (“what you say”), and will train you on persuasive and powerful delivery (“how you say it”).

Rigorous preparation is crucial to success. This includes:

- Advisory Committee strategy and key message development
- Clear, concise and compelling communication
- Slide and technology management
- Training and coaching
- Media management
- Practice, practice and more practice

Why choose us?

PharmApprove is the acknowledged leader in US Advisory Committee preparation. We’ve been helping global companies make the best possible case for their products since 1999.

In the past five years alone, we’ve helped over 60 applicants through Advisory Committees in almost every therapeutic area. We’ve also tackled priority reviews, orphan indications, and other complex, high-profile hearings. The result? A “win rate” of over 80%.

If you’re developing a product in the US and Europe, PharmApprove provides unparalleled synergistic support on both sides of the Atlantic.

80% of our projects have resulted in a positive vote.

“Extremely professional, seamless, first-class… I could go on. It could not have been accomplished without your collective efforts.”
How can we support you?

Preparing for an FDA Advisory Committee can take up to six months. But we’ll guide you every step of the way with a full suite of services scaled to fit your specific needs.

Those services include:

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High Stakes Meetings

Preparing to present and defend your product at a meeting with decision-makers is a major challenge for any team. Achieving success with decision-makers requires a clear strategy and focused preparation. Your company needs to deliver a clear and compelling argument supporting your position and be ready to respond confidently when challenged.

We can help you to prepare and succeed in:

- Advisory Committee Meetings
- Oral Explanations
- PRAC public hearings
- Payer Negotiations
- Other critical milestone meetings
A selection of our Experts

Pete Taft
Founder, PharmApprove
Pete provides strategic counsel as well as individual and group coaching services within the pharmaceutical Industry. He has been involved in over 50 Advisory Committee projects over the past 16 years.

Martha Arnold
Principal / Project Lead
Martha brings extensive experience in cross-functional development team activities, working closely with clinical, regulatory and scientific experts to move candidates through all stages of the product lifecycle.

Laurie Smaldone Alsup, MD
COO / CSO, NDA Group
Laurie has 25 years of executive leadership experience in drug development, regulatory strategy, and regulatory approvals across all major therapeutic areas and product technologies.

Lisa Peluso
Director, Coaching
Lisa has coached individuals and provided presentation/Q&A training and workshops to teams in pharma and biotech, and has helped over 45 clinical development teams prepare for FDA Advisory Committee meetings.

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