

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.



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.



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.



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 30 clinical development teams prepare for FDA Advisory Committee meetings.

High Stakes Meetings

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Preparing to present and defend your product at high stakes meetings is a major challenge for any team.

Achieving success in these venues 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



NDA Germany
T +49 (0)89 3585 4000
E munich@ndareg.com



NDA Sweden
T +46 (0)8 590 778 00
E stockholm@ndareg.com



NDA Switzerland
T +41 (0)78 951 9929
E zurich@ndareg.com



NDA UK
T +44 (0)1372 860 610
E london@ndareg.com



NDA USA
T +1 609 583 1990
E usa@ndareg.com



pharmapprove
a member of the NDA Group

Prepare to Win at FDA Advisory Committees



We reduce the pressure

Advisory Committee Meetings

The stakes are incredibly high at a 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 one of the pioneers in Advisory Committee preparation. Our rigorous approach — developed over 20 years and more than 150 hearings — will help prepare your Briefing Package, presentations and Q&A responses so that together they will make the most compelling case for your product.

Our team of principals — leading industry professionals with decades of regulatory experience — will help you prepare your content (“what you say”), while our communications coaches — the best in the industry — 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 both US and European clients make the best possible case for their products since 1999.

In the past five years alone, we've helped over 60 clients 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 83%.

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

83%

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 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:

Strategy Development

- Advisory Committee Strategy
- Advisory Committee Intelligence
- Mock Panel Recruitment
- Working Session and Mock Panel Facilitation

Scientific Messaging

- Storyline
- Briefing Document
- Core Presentation
- Q&A Responses

Training & Preparation

- Presentation Development
- Presentation Coaching
- Q&A Training
- Slide Creation, Indexing & Retrieval
- Full A/V Production

Project Execution

- Team Organization
- Project Management
- Meeting Logistics
- Open Public Hearing Coordination