

A selection of our Experts



Steffen Thirstrup, Professor
Director and Medical Advisor,
NDA Regulatory Advisory Board

Former Head of Division, Medicines Assessment and Clinical Trials at the Danish Health and Medicines Authority with expertise in clinical development and regulatory strategy. Steffen held several significant roles including 5 years as CHMP member.



Dave Gilbert
Regulatory Strategy and Drug
Development Expert

Former Head of European Regulatory Affairs and Head of EMEA Liaison and Regulatory Intelligence at leading Pharma companies. Expertise in strategic regulatory affairs, drug development, orphan drugs, conditional approvals and EU procedures.



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 is an expert in preparing teams for High-stakes Interactions. She brings extensive experience in crossfunctional development team activities to move candidates through all stages of the product lifecycle.

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



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Oral Explanation Preparation



When Delivery Matters

Oral Explanation Preparation

An Oral Explanation can literally determine the fate of your product.

An Oral Explanation (“OE”) is one of the last opportunities you have to overcome any major objections the CHMP may have about your product. Time is tight, and you’re expected to provide a clear, concise and targeted presentation that directly addresses the issues, then answer any and all questions the panel may have.

Careful preparation, of course, is the key. And that’s what NDA provides.

We’ll support you throughout the MAA process, developing strategy, creating a regulatory roadmap, and supporting the submission. Should an OE be required, our teams provide independent and strategic insight into how best to address the scientific concerns.

We’ll first help you address the issues in writing. Then, if you need to address the CHMP in person, we’ll help you create targeted arguments, rehearse your speakers, “pressure test” your case with mock panelists, and drill you on Q&A.

In short, prepare to win.

“It was a pleasure to get your feedback on my presentation. Thank you for the support during the coaching. You made me believe I could do it and made me do it better than I expected.

Preparation is really the key.”

Mid-sized Pharma

Why choose us?

Applying our deep regulatory experience, we can assess your compound’s situation and accurately predict your likely regulatory interactions in the EU.

We know because we’ve been there before.

We have prepared hundreds of teams for Oral Explanations. Through our long experience we have developed a highly effective process that quickly and efficiently prepares you to *win*.

Our service offerings include:

- Disciplined meeting management
- The development of a compelling formal presentation
- Intensive rehearsal “in role”
- Wide ranging Q&A response rehearsals
- Presentation and Q&A coaching

Our process is adapted from the highly successful approach that our PharmApprove team has taken to Advisory Committee preparation in the United States, where over 83% of our projects have resulted in positive votes.

How can we support you?

Of course, the best way to prepare for an Oral Explanation is to avoid having one in the first place! That means crafting the strongest possible 120 Day Responses.

NDA’s scientific and communications experts can review and refine those responses. We’ll then offer one or more of the following OE preparation services, customized to fit your particular need:

- Organizing the team
- Developing a timeline
- Explaining the “theatre” of the OE
- Identifying key content
- Developing messaging strategy
- Preparing a formal/core presentation, including script and slides
- Identifying and preparing responses to anticipated questions
- Scenario planning and preparing for potential negotiations at the OE
- Developing and organizing backup slides
- Presentation coaching for presenters and Q&A responders
- Planning and facilitating team meetings (*in person or via video/teleconference*)
- Rehearsals before SMEs knowledgeable in the OE process (*but naive to your compound*)
- Operational support for meeting day