Oral Explanation Preparation

Deliver your Best

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**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. We support applicants throughout the MAA process, developing strategy, creating a regulatory roadmap, and providing overall submission support.

Our team provides independent and strategic insight into how best to address the scientific concerns of the regulators in writing.

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 will review and refine those responses. The goal is to address any issues in writing but also lay the groundwork should you need to support your position in person at an Oral Explanation.

An OE defines “high-stakes”: Time is tight, and you're expected to provide a clear, concise and targeted response to major objections of the CHMP.

NDA/PharmApprove helps your team prepare to win.

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**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 challenging regulatory interactions in Europe and have developed a highly effective process that quickly enables internal teams to focus on what is most critical.

Our service offerings include:

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

Our unique process supported by our regulator experts has an exceptional track record of predicting the questions and responses during the hearing. Leveraging these insights we are able to provide optimal preparation to teams, letting them enter this high-pressure situation confident and well-informed; teams with the best possible chance to achieve a positive outcome.

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**Over 12 successful years of Oral Explanation Preparation with more than 100 teams prepared.**
How can we support you?

Our Strategic Leads, ex-regulators and scientific communications coaches work together to support your team. We will analyze the issues, pressure test responses and prepare your team to deliver convincingly.

We offer a full range of OE preparation services:

### Organizing
- Developing a timeline
- Planning and facilitating team meetings *(in person or via video/teleconference)*
- Providing operational support for meeting day

### Strategic Messaging
- Identifying key content
- Developing messaging strategy
- Developing and organizing backup slides
- Q&A Preparation

### Leveraging Experience and Expertise
- Explain the “theatre” of the OE
- Prepare a formal/core presentation, including script and slides
- Identify and preparing responses to anticipated questions
- Scenario plan and prepare for potential negotiations at the OE
- Coach presenters and Q&A responders
- Set up rehearsals before SMEs knowledgeable in the OE process *(but naive to your compound)*

### High Stakes Meetings

Prepared by pharmapprove

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

**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.

**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.

**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.

**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.

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