FDA CLINICAL & REGULATORY CONSULTING SERVICES

From Pre-Submission Consulting with FDA, to FDA Advisory Committee Meetings, NDA, PMA and BLA Group Meetings

3D Communications prepares companies for high-stakes regulatory communications.

A regulatory meeting is the wrong time for an original thought! 3D has developed a full range of services specifically designed and proven to help teams communicate in a credible and persuasive way to FDA and EMA.

3D's seasoned team of communications, scientific, and regulatory experts have used our proven process across more than 250 pharma, biotech, and device projects.

The result: You get an experienced team, a winning track record, and a proven process that is customized to your needs.

When success is the only option, partner with 3D.

PRE-SUBMISSION

- Analyze clinical data and perform gap assessment
- Help set regulatory strategy
- Guide clinical dossier content including CO, SCE/ISE, SCS/ISS
- Develop communication strategy and key messages

ADVISORY COMMITTEE PREPARATION

- Review and analyze clinical data
- Set regulatory strategy for FDA Advisory Committee meetings
- Profile Advisory Committee members
- Develop messages, presentations, slides, briefing materials, Q&As
- Identify KOLs to serve as mock Advisory Committee members
- Conduct realistic mock rehearsals to test regulatory strategy and presentations
- Identify speakers for the open public hearing
- Coach team members to be effective presenters and address challening questions for FDA meetings
- Utilize 3D's Remote Q&A Technology Suite to enable real-time practice anywhere in the world

3D Communications