

Regulatory Agency Representation

Meetings with regulatory agencies are invaluable in better understanding Agency expectations about the data necessary to support regulatory actions. The questions a sponsor asks, the way in which they are asked, and the discussions around those questions can reduce the data burden and smooth the path to clinical study or product marketing approval or clearance.

Regulatory Solutions

Strategic, Execution and Project Management support for the submission lifecycle of drug, biologic, or regenerative products and vaccines, from pre-IND through licensure including the creation of and adherence to project timelines, monitoring of project resources, tasks, and budget, integration of multiple functional experts for application review and maintenance, attendance at FDA-Sponsor meetings, and experience with regulatory agency requirements and guidance.



FDA Meeting Preparation & Engagement

- Represent clients in interactions with FDA and EMA
- Assist with preparations for Agency Advisory and milestone meetings
- Provide clients with an 'Agency style' review of submissions
- Advise on regulatory options and potential pathways

Every interaction with the Agency is a crucial moment for your development program, and Agency meetings represent a culmination of compiled and scheduled work. Strategies, timelines, costs and complexity are all organized through this interaction — the stakes are high, and the outcomes are extremely important. It all comes down to strategic communication. Every facet of FDA meetings and submissions — from the information your company is providing, to scientific research and the tone and articulation of that information — must be conducted flawlessly.

DSI will compose your communications for submissions and perform all preparation for these meetings. From experience, we know the nuances at play when expressing understanding of laws and issues, and how to analyze and interpret data accurately to present it clearly and concisely through written documents and in-person meetings.

- Pre-IND, EoP2 and other FDA meetings that involve CMC and compliance strategy
- Pre-NDA/BLA meetings and other pre-approval meetings

Agency meetings play a critical role in any sponsor's development strategy. They provide sponsors the opportunity to seek out critical agency feedback, identify gaps in required data, and come to agreement on whether the development studies that have been conducted are enough for FDA review. These meetings also provide sponsors the opportunity to educate the Agency about their product – so reviewers have a basis of background and understanding once the Marketing Application is submitted.

This background is particularly helpful with new compounds that are being developed with cutting edge technology or innovative mechanisms of action, which may not be familiar to agency officials. That said, it takes experience, preparation and planning to ensure sponsors get the ultimate benefit from each meeting.

High-level suggestions;

1. Understand the three main types of FDA meetings, and the purpose for each
2. Make sure you have the right people at the FDA meeting table
3. Practice, preparation, and punctuality are key
4. Don't let time get away from you.

Perhaps most importantly, remember that FDA reviewers are people, just like you. And they really do want to help you and your product move forward. Extending the common courtesies of being on time, well prepared and organized can go a long way in ensuring that you leave each meeting with all the information you need to further develop your drug. And tapping regulatory experts – with proven experience in communicating with the Agencies – to lead and help you plan for meetings with the agency can also give you the peace of mind of knowing that your time together will be well spent.

You should leave an Agency meeting with answers to critical questions and an understanding of the expectations. To the best extent possible, any meeting with the FDA or EMA should end in clarity and whoever is working on your project must ensure this happens.

To achieve your goals at a meeting, the interaction must be carefully planned and executed flawlessly, leaving the Agency with a good impression of your product and company. This requires experts with prior regulatory experience who know the appropriate time to request a meeting, what is needed to prepare the necessary paperwork, what to expect when meeting with the Agency, and what steps should be taken post-meeting.

As frequent advocates for companies before the FDA and in Europe, DSI takes your product and combines our knowledge of science, drug development, ethics, and regulations to prepare for each meeting.

We will guide you step-by-step through FDA meetings during each phase of the development process including:

- [Pre-IND Meeting](#) 
- [End of Phase 2 Meeting](#) 
- [Pre-NDA/BLA Meeting](#) 

Pre-IND Meeting

After much planning and strategizing, you are ready to begin testing your drug in humans but are unsure that your rationale is sound and that the design of your development studies is valid. The necessary next step is a Pre-IND Meeting, which will facilitate communication with the Agency and provide the advantage of early feedback on your drug development program.

Important Considerations About Pre-IND Meetings

Although they are not required, Pre-IND Meetings are highly recommended by both the FDA and DSI. Among the many advantages of attending a Pre-IND Meeting, is the fact that it gives the FDA the opportunity to confirm its requirements regarding the drug development process. The earlier this is done, the better it will ultimately be for the applicant, reducing the amount of time and money that must be spent.

The following are a few things to consider when planning a Pre-IND Meeting:

- The most effective Pre-IND meetings for CMC are focused on specific regulatory and/or scientific issues (e.g., clinical trial material design, toxicology and pharmacology material bridging, drug development decisions and timing).
- The goal of a Pre-IND Meeting is to receive confirmation from FDA that the drug development plan and future clinical trials are acceptable to the Agency. As such, it is critical for sponsors to remember that complete transparency is necessary to obtain the maximum value from the meeting.
- When used in an appropriate manner, Pre-IND Meetings can reduce a product's time to market, certifying that the proposed studies have been designed to return useful and necessary information.

Benefits of Having a Pre-IND Meeting Consultant

Many companies entering the Pre-IND stages are "first-timers", making it even more important that these initial conversations with the Agency are well planned and rehearsed. DSI will help you prepare for this meeting using a few proven steps:

- Formulate questions to the FDA that are prefaced by supportable information, ending with a simple question to the division, such as "Does the FDA agree?" The questions are sent to the FDA with the Pre-IND Meeting request.
- Prepare the briefing package, making sure it includes an overview of your product, describes the purpose of the meeting, and that it includes appropriate nonclinical, clinical setting, and manufacturing information.
- Conduct a pre-meeting teleconference to make sure you are 100% ready to face the FDA. During this teleconference we will review possible challenges by the FDA and prepare your responses.
- Hold a meeting dry run the day before your Pre-IND Meeting to reinforce objectives of the meeting and finish preparations of our arguments to potential questions or concerns from the FDA.

DSI: Pre-IND Meeting Experts

DSI will provide you with guidance through the entire Pre-IND process – from the initial meeting request all the way through preparation and execution of the meeting itself. We will manage the timing and quality of IND submissions and regulatory interaction. Our goal is to help you meet this critical milestone.

End of Phase 2 Meeting

The time will come when you need to review and obtain agreement from the FDA on your Phase 3 plan and development protocols and an End of Phase 2 meeting is necessary. During this meeting you need to effectively present your Phase 3 and submission strategy and ensure that you are aligned with the FDA prior to the start of Phase 3.

Preparation for End of Phase 2 Meeting

To move you to the next clinical trial phase, DSI will diligently work with you to prepare for the End of Phase 2 meeting. With your input, we will:

- Request the End of Phase 2 meeting
- Develop the End of Phase 2 briefing package to be sent to FDA in advance of the meeting
- Determine meeting objectives and agenda, and script the participants
- Conduct a meeting rehearsal
- Attend the meeting with you, and summarize results in formal notes
- Conduct a debriefing session to discuss accomplishment of meeting objectives and finalize meeting minutes to be sent to the FDA

DSI: Continuing to Phase 3

Our team of experts will work closely with you to ensure your End of Phase 2 meeting with the FDA delivers the feedback necessary so you may continue with your Phase 3 clinical trials.

Pre-NDA/BLA Meeting

You and your firm have spent thousands of hours and millions of dollars assuring your product is safe and effective. Now, you need to make sure it will receive FDA approval. The key to achieving this is a perfectly executed Pre-NDA/BLA Meeting.

When you leave your Pre-Marketing Meeting you should have an understanding of the FDA's expectation for content and formatting of the submission, and a firm estimation of your product application's readiness for filing and likelihood of approval.

During the Pre-NDA Meeting, you must make the most of the opportunity to solicit comments and clarification from the FDA on the acceptability of:

- Pivotal data, including late-breaking data (ie stability, validation) that might become available for submission during the FDA's review of the marketing application.
- CMC information and the extent of accruing stability data.
- Content of the agreements made prior and any commitments made.

When is a Pre-NDA Meeting needed?

Developing and submitting an NDA/BLA requires significant investments of both time and money. As such, when preparing to submit your marketing application it is in your best interest to assure that your

application does not land cold at FDA. At the same time, it is in the FDA's best interest to be aware of upcoming work so it can be prepared with the required resources. The Pre-NDA/BLA Meeting allows each party to accomplish its objective. Although a Pre-NDA Meeting is not a requirement, we would not recommend submitting a marketing application without first meeting with the Agency. Drug development rarely goes exactly as planned and keeping communication open with the Agency increases your chances of achieving success the first time around. Accordingly, we advise anyone that is preparing to submit a marketing application to schedule and attend a Pre-Marketing Application Meeting.

Benefits of Having a Pre-NDA/BLA Meeting Consultant

Partnering with a consulting firm when preparing for and conducting a Pre-NDA Meeting with the FDA offers several benefits. We have the necessary experience and knowledge to ensure that your Pre-NDA Meeting goes as smoothly as possible, leaving you in a position to succeed. By partnering with DSI, some of the benefits you will receive include:

- We have been working with the Agency for more than 25 years and have prepared for and attended countless meetings with the FDA and EMA. As such, we know what is needed to achieve a successful interaction with the Agency and are uniquely qualified to help you achieve this.
- Diversity of knowledge. DSI's scientific and regulatory experts specialize in a variety of disciplines and stay abreast of changing trends and current events. In short, we bring a unique and extensive range of knowledge and skills to the table, which is what you need to achieve a successful Pre-NDA/BLA Meeting with FDA.
- The key to completing your Pre-NDA/BLA Meeting successfully is adequate preparation. However, this can be tricky if you are unsure of what is needed. That is why DSI is here to help. Due to the abundance of meetings that we have attended, we know what is required and can help ensure that you are as prepared as possible for anything the Agency may throw your way.

DSI: NDA/BLA Regulatory Experts

DSI will guide you through the Pre-NDA/BLA process by working with you to develop a clear, concise strategy, deliver complex information, and carefully execute all responses to the FDA. Our goal is to make your product successful. In addition, we will attend the Pre-NDA/BLA Meeting with you and hold a post-meeting debriefing session to discuss meeting takeaways, lessons learned, and next steps.

WHAT CAN DSI DO FOR YOU?

Regulatory Affairs

- Regulatory Agency Representation
- Regulatory Strategy Development
- Management and Preparation of Regulatory Submissions
- Responses to Regulatory Challenges
- Breakthrough Therapy Designation Requests
- Gene and Cell Therapy Product Review

CMC

- Integrated CMC Development
- Materials Characterization and Formulation Development
- Process Development, Optimization, And Validation
- Analytical Method Development, Optimization, and Validation
- Stability Program Design and Management

QA

- Design, Implementation, and Remediation of Quality Systems
- Compliance, Vendor Qualification, and Mock Pre-approval Audits (Mock-pais)
- Management of Compliance Situations