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Whitepaper

The Executive's Guide to FDA Meeting Strategy

Expert insights into the world's most valuable pharmaceutical market

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Why this matters now

The US pharmaceutical market was valued at

$634.32 billion in 2024

and is projected to reach

$883.97 billion by 2030

making it the most valuable target for global life sciences companies.

Strategic regulatory engagement represents a key competitive advantage in this high-growth market, not merely a compliance exercise.

Mastering your FDA interactions can accelerate time-to-market, maximize commercial potential and capture greater market share.

Inside the guide

Preparing a drug or device program for FDA evaluation requires more than adherence to regulatory requirements—it demands a strategic, adaptive, and forward-thinking approach.

Meeting selection framework

Understanding the array of FDA meeting types and when to use them

Strategic planning timeline

Key considerations for impactful FDA engagement at each development stage

Preparation playbook

Crafting effective questions and positioning your program for success

Global harmonization strategy

Leverage FDA feedback across international regulatory bodies

The stakes are significant

- Get Agency alignment before making costly development investments.
- Identify and prevent development plan missteps through strategic consultation.
- Address regulatory concerns before they impact your formal submission.
- Transform regulatory milestones into competitive timeline advantages.

Gain first-hand regulatory insights

Drawing on experience guiding over 250 clients, DLRC Group leverages over 1,000 years of cumulative regulatory expertise. With strategic offices across the UK, US, and EU, we share practical approaches for optimizing your FDA meeting strategy in the world's most valuable pharmaceutical market.

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Abstract

Preparing a drug or device program for FDA evaluation requires more than adherence to regulatory requirements—it demands a strategic, adaptive, and forward-thinking approach. This article emphasizes the importance of early, well-planned engagement with the FDA to mitigate development risks and accelerate time to market. As the regulatory landscape shifts towards real-world evidence, digital health solutions, and patient-focused development, Sponsors must cultivate regulatory intelligence, build internal expertise, and remain agile in their development strategies. DLRC Group exemplifies this proactive philosophy, leveraging decades of experience and a deep understanding of FDA processes to guide over 250 clients through successful regulatory submissions, including 31 cleared INDs in the past five years. By prioritizing collaboration, flexibility, and continuous learning, DLRC helps Sponsors transform regulatory challenges into opportunities—positioning their programs for long-term success in a dynamic U.S. healthcare market.

Introduction

Given its place as the world's most valuable pharmaceutical market, gaining access to the U.S. market remains a top priority for pharmaceutical and biotech companies across the globe. However, entering and succeeding in this highly regulated and competitive environment requires more than just a promising or innovative product – though that's a great start. Successfully navigating the U.S. market ultimately demands a well-planned, evidence-based development strategy and a clear regulatory roadmap tailored to the expectations of the U.S. Food and Drug Administration (FDA).

While companies may take a global approach to development – balancing opportunities in markets such as Europe, Japan, and emerging regions like India or China – the FDA's influence and the commercial potential of the U.S. market make early regulatory engagement with the Agency a critical focus. Yet, there is no one-size-fits-all approach: regulatory expectations vary depending on therapeutic area, patient population, novelty of the product, and unmet medical need, among many other factors. FDA guidance documents provide useful frameworks, but in practice, each program is reviewed on a case-by-case basis.

As a result, strategic planning – particularly around regulatory milestones and FDA interactions – can mean the difference between a streamlined path to approval and costly setbacks.

This paper outlines key considerations for preparing your drug or device development program for FDA evaluation, with practical guidance on how and when to engage the Agency. It provides an overview of the meeting types available, insights on aligning U.S. development strategy with FDA expectations, and recommendations for maximizing the value of regulatory interactions. By understanding and navigating the nuances of the U.S. regulatory landscape, Sponsors can reduce risk, accelerate timelines, and increase the likelihood of a successful market entry.

Preparing your Program for FDA Evaluation and the U.S. Market

The U.S. remains the largest pharmaceutical market, with an estimated value of $634.32 billion in 2024 and an expected growth rate of 5.72% compound annual growth rate (CAGR) to reach $883.97 billion by 2030. As such, pharmaceutical companies focus on accessing and expanding their presence in the U.S. as one of the key countries in their drug development plans.

Regulatory considerations for drug development programs are often unique. They will vary significantly depending on factors such as the type of drug, the severity of the target disease, and/or the patient population's needs. For example, FDA requirements for a common metabolic disease will differ considerably from those for a neurological rare disease. Although the FDA has issued a wide range of guidelines to ensure the safety and efficacy of new drugs, every development program will be assessed on a case-by-case basis. As a result, the importance of building a well-informed and data-driven drug development plan and regulatory pathway cannot be overstated.

Key development milestones such as proof-of-concept in relevant animal models, start of the first-in-human (FIH) study, or the completion of the Phase 2 clinical study will shape the regulatory pathway for your drug development plan. As discussed later in this article, the FDA offers Sponsors several opportunities to interact and seek advice through different types of meetings, depending on the stage of development of your product. It is essential to plan carefully and be prepared for these interactions, since they can often tip the balance towards a successful or failed drug development plan. Some strategic considerations for FDA engagement are summarized in Table 1.

Table 1:
Strategic Considerations for FDA Engagement

Main Considerations	Key questions	Strategic approach
Timely engagement	• Is this the right time to engage with the FDA? Is it too early, or too late? • Has enough data been generated to support the proposed plans?	• Engage early and regularly with the agency to build rapport and receive valuable input, but make sure you have a clear plan backed up by stage-appropriate data
Understand the regulatory framework	• Are the proposed approaches in line with relevant guidelines? • If not, has an appropriate justification been included to support your approach? • Are there any FDA programs that could expedite your development?	• Familiarize with relevant FDA and ICH guidelines to include strong rationale to your company positions • Constantly gather regulatory intelligence to monitor changes in regulations that may impact your drug development plan • Be aware of FDA requirements to access expedited programs that can facilitate your development program, such as fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation
Understand FDA's hot topics and research areas	• What are other competitors doing in the same therapeutic space? • Are there any new restrictions or data expectations?	• Familiarize with where to find FDA intelligence • It can be helpful to refer to recent precedent (regulatory approvals and other information in the public domain) in seeking to convince FDA of your position
Comprehensive data package	• Is the data adequate to provide complete and robust responses from FDA? • Has the data been QCed against source documents?	• Gap analysis • Make sure that sufficient data is provided to allow for a sound response from the Agency
Overly prepare for the meeting	• Have we rehearsed rebuttals to FDA's potential comments? • Have we clarified key points from the briefing book?	• Anticipate potential questions and be readily prepared to answer them • Schedule several rehearsals with your teams to ensure the presentation is clear and concise

Understanding the FDA Regulatory Landscape

Key Considerations for Interacting with the Agency

Meeting with FDA is an essential aspect of navigating the U.S. regulatory landscape, giving Sponsors the opportunity to ensure their development program meets Agency expectations and to seek advice and feedback where guidance is limited or unclear. These interactions should be planned with care so that the recommendations provided are actionable and do not cause undue disruption or delay to the Sponsor's program. Once a Sponsor has decided to interact with the FDA, they must select the most appropriate type of meeting. There is an array of potential options that could apply, depending on the product type, stage in development, questions to be asked, circumstances under which the meeting is requested, and if the program has any special designations. When selecting a meeting type, the Sponsor should also consider how the interaction would feature in their overall development timeline and goals, including plans for subsequent interactions with the Agency and Health Authorities in other regions. Sponsors should also think about the logistics of the interaction and which meeting format (e.g. teleconference, videoconference, face-to-face in person, written responses only) would be most appropriate. FDA meeting types run on different timeframes, and Sponsors should carefully factor this into their planning to ensure that they are prepared to meet Agency expectations for the procedure and make the most of the opportunity for engagement. An understanding of the nuances of Agency interactions is imperative for a productive meeting that could de-risk a development program—rather than the opposite.

Formal Meetings Relating to Drugs and Biologics

To discuss the development of drugs and biologics (including cellular therapy and human gene therapy products) with the Agency, Sponsors should engage with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) as appropriate. Table 2 details the types of meetings available and goals for meeting dates, as established by the Prescription Drug User Fee Act (PDUFA) and various reauthorizations thereof (see also draft guidance from FDA). For all meetings, Sponsors are expected to provide a briefing package with sufficient information for the Agency to answer the questions asked. The timing for when the briefing package must be received varies by meeting type; in some cases (e.g. Type A, D, and INTERACT meetings) this must be submitted at the time of the meeting request. For a productive interaction with FDA, Sponsors must submit the briefing package according to the specified timeline; otherwise, the meeting may be cancelled.

Sponsors are generally entitled to one FDA meeting per development milestone, such as IND filing or the end of a phase 2 trial(s). These milestone meetings are classed as Type B (Table 2). Before requesting a Type B meeting, Sponsors should consider whether their program is sufficiently developed to warrant the interaction. For instance, a Type B meeting for end-of-phase 2 would be only appropriate once there is summary safety and efficacy data from the trial(s) available for Agency review. For a Type B pre-IND meeting, the Agency will expect questions on a program that has a clear development plan, with rationale to support the proposed IND-opening trial.

For novel products in the early stages of development, a separate type of meeting known as an INTERACT (Initial Targeted Engagement for Regulatory Advice on CDER and CBER Products) may be a prudent first interaction.

INTERACT meetings are a forum for advice and feedback on early preclinical studies conducted thus far and additional data that should be collected in advance of an IND filing. Eligibility for an INTERACT meeting can be difficult to determine, but having a regulatory partner can limit the unnecessary time and resource expenditure that comes from requesting an improper meeting. As with any FDA interaction, for a productive INTERACT, Sponsors should ensure the questions asked are specific and pertain to topics where there is not already clear guidance.

Beyond INTERACT or Type B meetings, Sponsors can request additional types of interactions with FDA over the course of product development. The purpose of a Type D meeting, for instance, is to discuss a narrow range of topics, and questions are limited to five. Such an interaction may be useful for asking follow-up questions, with additional background information, on a topic discussed in an earlier pre-IND (Type B) meeting, even before the IND filing. In contrast, Type A meetings are defined by a certain set of circumstances—a stalled development program (e.g. a program subject to a clinical hold). The last category, Type C, is for interactions that do not fall under the other meeting types (see Table 2 for examples). A Type C meeting could be used, for instance, as a follow up to a previous interaction with FDA where the number of questions would be beyond the scope of a Type D meeting.

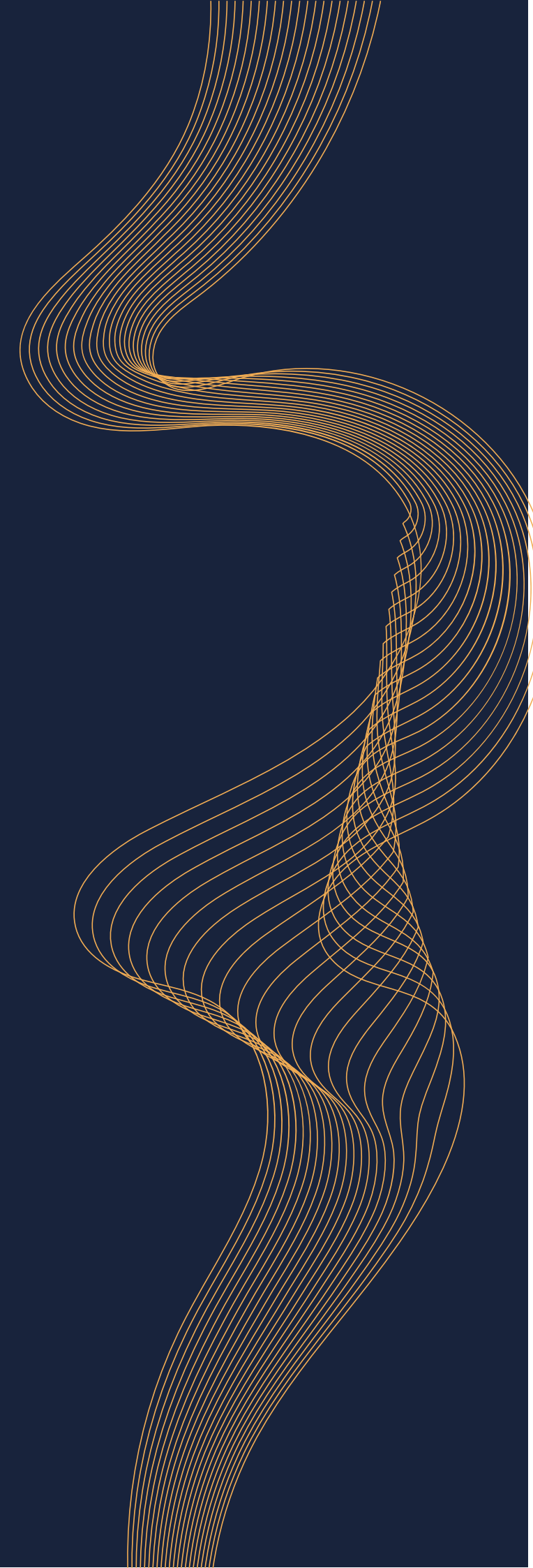
If the Sponsor's development program has been granted a special designation, such as Fast Track or Breakthrough Therapy, there is more flexibility with and opportunity for Agency interactions. Furthermore, additional types of meetings exist for Sponsors developing particular types of products, such as complex generic products, over-the-counter monograph drugs, and biosimilars.

Interacting with FDA is a valuable opportunity to de-risk a development program, and Sponsors should be strategic in the timing and number of meetings requested (see, "Maximizing Value from Interactions").

Table 2:
Strategic FDA Meeting Framework for Drugs and Biologics

Meeting Type	Purpose	Examples	Days to meeting /WRO	Typical BP Expectations*
A	Progress a stalled development program	• Dispute resolution meetings • Clinical hold discussions	30	Submit at time of MR
B	Discuss development program in advance of major milestones	• Pre-IND meetings • Pre-NDA/BLA meetings • Pre-EUA meetings • Development program discussions for BT and RMAT-designated products	60	No later than 30 days before meeting/WRO
B (EOP)		• Certain end-of-phase 1 meetings • End-of-phase 2 meetings	70	No later than 50 days before meeting/WRO
C	Any meeting other than a Type A, B, B (EOP), D, or INTERACT	• Advisory committee meeting • Preliminary BTD Advice meeting • Pre-Orphan meeting • Discuss new potential surrogate endpoints as basis for product approval	75	No later than 47 days before meeting/WRO; submit at time of MR for surrogate endpoint discussions
D	Discuss narrow set of issues at key decision points	• Follow-up question on a new issue • Specific question on a trial design aspect	50	Submit at time of MR
INTERACT	Discuss early development challenges for novel product	• Discuss choice of preclinical model • Discuss CMC issues prior to FIH study	75	Submit at time of MR

Table 2. FDA meeting types for drugs and biologics. *See FDA guidance on PDUFA meetings for exceptions. BLA, Biologics License Application; BP, briefing package; BT(D), Breakthrough Therapy Designation; CMC, Chemistry Manufacturing and Controls; EOP, End of Phase; EUA, Emergency Use Authorization; FIH, First-in-human; IND, Investigational New Drug; INTERACT, Initial Targeted Engagement for Regulatory Advice on CDER and CBER Products; MR, Meeting Request; NDA, New Drug Application; RMAT, Regenerative Medicine Advanced Therapy; WRO, Written Response Only.



Formal Meetings Relating to Medical Devices

To discuss the development of medical devices, Sponsors should engage with the Center for Devices and Radiological Health (CDRH) or CBER (when devices are regulated as biological products). Formal meetings are generally organized through the Q-submission (Q-Sub) program, with meeting types and goal dates established as part of the Medical Device User Fee Amendments and various reauthorizations thereof (see Table 3 and draft guidance from FDA). The Agency recommends only one Q-Sub is submitted for review at a time.

Pre-submissions (Pre-Subs) are a key type of Q-Sub, as the primary means by which Sponsors can seek advice and feedback in advance of an intended premarket submission. Pre-Subs can be requested as needed throughout the course of development. Of note, all information necessary to support the questions asked must be provided in the Pre-Sub when submitted to FDA.

Another type of Q-Sub is a PMA Day 100 Meeting, to which Sponsors of high risk (Class III) devices are entitled following the submission of their Premarket Approval application (PMA); the meeting can be requested in the cover letter to the application, and is intended to discuss the application's review status.

Beyond those detailed in Table 3, there are additional types of Q-Subs reserved for products in the Breakthrough Devices Program or Safer Technologies Program (STeP). Similarly, an Interaction for a Designated Breakthrough Device and a STeP Interaction Submission could involve a sprint discussion or a review of a Data Development Plan (DDP). An additional option afforded to Breakthrough Devices is Clinical Protocol Agreement. The timing of these interactions is more flexible and is negotiated by the Sponsor and FDA.

Table 3:
Strategic FDA Meeting Framework for Medical Devices

Meeting Type	Purpose	Examples	Days to meeting/ WRO	Method of Feedback
Pre-Submission (Pre-Sub)	Obtain FDA feedback prior to an intended premarket submission	• Discuss planned nonclinical and clinical studies	70–75	Meeting or WR
Submission Issue Request (SIR)	Discuss proposed approach to address formal issue letters	• Discuss marketing submission hold letter • Discuss CW hold letter • Discuss IDE letter	21 or 70 (depending on if SIR is received within 60 days of issue letter)	Meeting or WR
Study Risk Determination (SRD)	Request FDA determination on the risk level of planned medical device study	N/A	90	Formal Letter
Informational Meeting	Share information with FDA without expecting feedback	• Provide overview of device development • Familiarize FDA with a new technology	90	Meeting
PMA Day 100 Meeting	Discuss review status of PMA	N/A	100 days (from filing date)	Meeting
Interaction for Designated Breakthrough Device	Request feedback on device development and clinical protocols for Breakthrough Devices	• Sprint Discussion • Discuss Data Development Plan • Clinical Protocol Agreement	Negotiation between Sponsor and FDA	Meeting or Formal Letter

PMA, Premarket Approval Application; WR, written responses.

The Importance of Regulatory Intelligence and Monitoring

When planning interactions with FDA, it is important to keep abreast of changes in the U.S. regulatory landscape. Amongst the current trends and regulatory shifts, there is an increasing emphasis on real-world evidence, adaptive trial design, and patient-centric endpoints. For instance, proposals for admission into the Rare Disease Endpoint Advancement (RDEA) Pilot Program require Sponsors to indicate how patient input will be considered; those admitted into the Program are afforded another route to meet with the FDA, for discussion of endpoint development. In addition, digital health and innovative product pathways are an increasing focus for the Agency.

Keeping track of these trends is not only essential for the meeting at hand, but for the U.S. regulatory strategy and product development plan at large.

Maximizing Value from Interactions

How do you ensure you get the best feedback possible from these interactions? As described above, there are key points common to most products' development when a meeting is expected, but other meetings will be highly product-dependent. In many cases, the purpose of the meeting and the scope of discussion is defined by the development stage and type of interaction requested.

For example, the focus of some typical milestone meetings may be:

Pre-IND meetings

Presenting background information on the active ingredient including manufacturing and pre-clinical data, planned development strategy, identifying relevant clinical studies including discussion to support a move to first-in-human trials.

End-of-Phase 2 meetings

Review of Phase 1/Phase 2 data to determine the safety of proceeding to Phase 3, to evaluate the Phase 3 plan and protocols and the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

Pre-NDA/BLA meetings

Discussion around format and content of the anticipated application, including labelling and Risk Evaluation and Mitigation Strategies (REMS), if applicable, presentation of data, dataset structure, acceptability of data for submission, as well as the projected submission date of the application.

A range of other interaction types, already described in this article, offer the chance to address other specific objectives whether that is defining a pathway for a novel product early in its development (INTERACT), a dispute resolution (Type A) or a discussion of breakthrough designation (Type A/B). The questions and supporting documentation should be defined with the outcome in mind.

Therefore, the first step of planning an interaction with the FDA is to consider the overall regulatory strategy for the product. This should be mapped out early in development, prior to submission of the IND, but with sufficient flexibility to accommodate any new information that arises during the drug development process. Below are five critical areas to consider when preparing to engage with FDA.

1 Tips for Planning

When should the interaction take place? Allow sufficient time to prepare adequately, not only to ensure there is sufficient time to create a package of suitable quality (this might be your first chance to make an initial impression on their assessment team) but also to ensure that the package contains sufficient data to allow FDA to provide meaningful review – consider requesting a later meeting date if there are missing data or pending analyses that will be critical to the objectives of the FDA interaction. Note that the FDA expects sponsors to adhere to meeting management goals regarding timing of requests, submission of briefing packages, and response to any FDA Preliminary Responses.

The scope of FDA interactions can cover all disciplines so in the case of a meeting, a choice of attendees must be agenda-driven: what are the key areas for discussion? The company attendees may need to be in the position to make decisions on behalf of the company: they must be adequately informed and sufficiently empowered. Depending on meeting scope, these may include regulatory, medical/scientific, R&D, and commercial departments, external consultants, and key opinion leaders in the space. Since 2023, FDA has been transitioning back to offering a face-to-face format for meetings, although hybrid or completely virtual meetings are possible to request and may allow a wider attendance. At least core meeting attendees should consider being physically present; in DLRC's experience, this strengthens the interaction and improves discussion opportunities. It also reduces the risk of misinterpreting written advice.

FDA attendees will be defined on the basis of the company's request, and on the agenda and list of questions shared with the meeting request. Self-evidently, if you request an agenda change, alter the attendee list or wish to add new topics, the FDA must be notified.

2 Question Development

Provide the questions to the FDA with the initial meeting request, accompanied by a short rationale for context. You should follow up with the full company position and supporting data as part of the briefing package prior to the meeting – it is usually helpful to develop the questions and the briefing package in parallel.

- Craft questions that fit into the overall meeting aims and will elicit actionable guidance. The questions that work well in health authority meetings are often a clear proposal that can be ratified.
- Ensure the company position provided in the briefing pack is clearly defined, justified, and consistent with overall messaging. The supporting information must be sufficient for FDA to be able to answer fully and effectively.
- Take account of FDA published guidance already in place. This lends credibility and in practice the FDA may refuse to grant a meeting if they consider the answers are already available.

- Avoid too many or complex questions – a smaller number of well-crafted questions with a clear purpose is better. In general FDA requests no more than 10 questions to allow sufficient time for discussion.

- Use the questions to anticipate potential FDA perspectives and concerns. Take account of current hot topics. In this way the company position can be developed and presented proactively rather than trying to respond when FDA raises a concern

3 Preparation for a Face to Face or Virtual Meeting

The most successful meetings are those where the company has allowed sufficient time for rehearsal and preparation. This facilitates a smooth meeting flow, allows agreement of who is speaking and who is well placed to respond to FDA comments during the meeting.

During the preparation phase it is also essential to plan for potential questions. As a team you should rehearse responses, develop contingency plans and agree back-up positions in case FDA disagrees with the position presented. If you already have an agreed alternative position available to present to FDA this may allow consensus during the meeting.

It is helpful in this respect to take account of the FDA preliminary response to the briefing package, usually provided 2 to 5 days before the meeting. Respond to any comments in writing before the meeting where possible. This shared assessment of the outstanding issues can help steer the focus areas for discussion in the meeting itself.

4 Do's and Don'ts for the Meeting Itself

Do:

- ✓ Arrive in sufficient time
- ✓ Expect to drive the agenda – time management will be important
- ✓ Prioritize the key focus areas identified in the preliminary response
- ✓ Expect to listen more than you speak
- ✓ Summarize understanding and final agreements at the end of the meeting

Dont:

- ✗ Conceal important information
- ✗ Change the agenda or introduce significant new data

The FDA meeting is not only an opportunity to clarify the specific agenda items, but an important way of building a relationship with the FDA assessment team that may last several years.

5 After the Meeting, What's Next?

We recommend debriefing as soon as possible after the meeting. The FDA will provide formal meeting minutes, but it is best practice for the company to also provide its meeting minutes to the FDA within 1-2 business days. You will receive the official FDA minutes within 30 days. Review them carefully and contact the FDA with any clarifications. Ensure you follow up on any commitments made in the meeting.

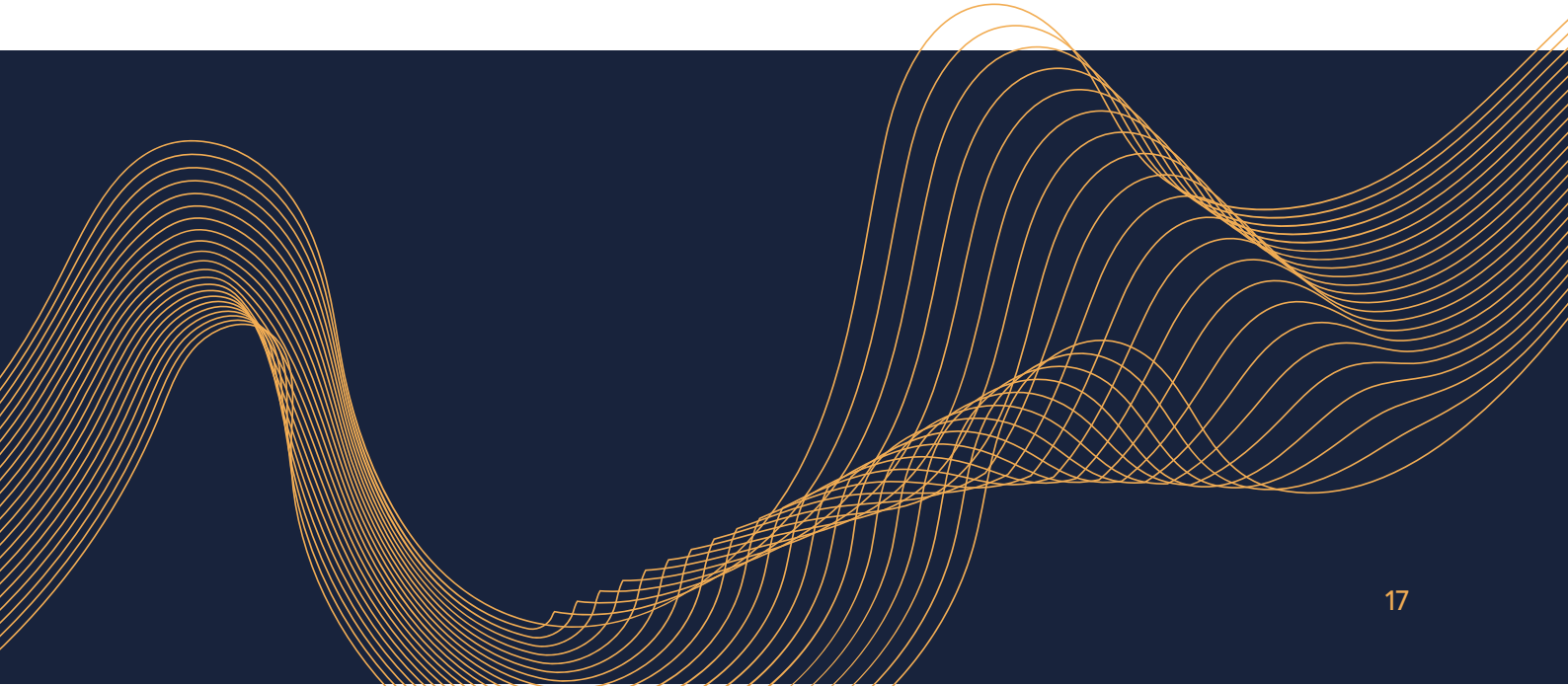
What if you didn't get the answers from an FDA interaction that were needed? FDA has introduced written follow-up opportunities. These are only intended for clarification of the FDA advice given, although FDA might answer additional questions at their discretion. Any clarification request should be submitted within 20 days of receipt of the meeting minutes or written advice.

The FDA interaction is an important milestone in product development and for maximum benefit, the advice gained should be followed. Things don't always go to plan so where there are unexpected changes from the agreed plan or delays to the development timeline, notify FDA: the ongoing relationship will be an important one.

You can and should also share the FDA feedback with other health authorities to facilitate a harmonized global development. Increasingly, other regulators are invited to observe FDA meetings, and companies are looking to hold joint FDA meetings with other regulators such as the Parallel Scientific Advice (PSA) program that is shared with the European Medicines Agency. In the context of globalized medicines development and supply chains and an increase in joint regulatory assessment procedures, early alignment on development strategy obtained through scientific advice from FDA and other regulators is an important win.

Lastly, positive and actionable FDA feedback offers a practical demonstration to investors and funders of Agency buy-in. A positive meeting outcome can be an important selling point for companies making program decisions.

And perhaps one of the most prudent tips of all – enlisting the support of regulatory experts. Sponsors can benefit greatly from a regulatory consultant's expertise in FDA interactions, as these teams can help anticipate Agency expectations, craft persuasive arguments, and identify potential risks or opportunities early in development. Sponsors generally have quite limited access to FDA and thus a limited opportunity to build the relationship and make their case for four to approval, but with the help of an experienced regulatory consultant, Sponsors can make the most of their chances.



Conclusion & Future Considerations

Successfully preparing a drug or device program for FDA evaluation requires more than regulatory compliance—it demands foresight, flexibility, and a strategic approach to development and engagement. The FDA offers multiple structured opportunities for Sponsors to seek advice and alignment throughout the lifecycle of a product, and these interactions, when leveraged effectively, can significantly reduce development risk and streamline the path to market. As the U.S. regulatory landscape continues to evolve – with increasing focus on real-world evidence, digital health, and patient-centric development – Sponsors must remain proactive in monitoring emerging trends and regulatory shifts. Building in-house expertise, investing in regulatory intelligence, and maintaining a flexible mindset are key to navigating uncertainty and adapting plans in real time. Early, well-prepared, and intentional engagement with FDA not only facilitates smoother regulatory review but also enhances overall program credibility and efficiency. By taking a thoughtful, data-driven approach to development planning and Agency interaction, Sponsors can position their programs for long-term success in the U.S. market. Looking ahead, the most successful development strategies will be those that anticipate change, embrace collaboration, and treat regulatory engagement as a critical driver – not a barrier – of innovation.

Expert Support for Your FDA Regulatory Success

Facing the complexities of FDA interactions shouldn't stand between your innovative product and the world's most valuable pharmaceutical market. While this whitepaper outlines key strategies for successful FDA meetings, many organizations discover that partnering with specialized regulatory experts delivers substantial advantages throughout the submission process.

What Expert Support Means for Your Program:

Reduced Risk

Benefit from insights gained through hundreds of successful FDA submissions, including 31 cleared INDs in the past five years alone.

Accelerated Timelines

Avoid costly delays by anticipating FDA concerns before they arise, with proactive strategies tailored to your specific product and development stage.

Resource Optimization

Focus your internal team on core development activities while regulatory specialists manage the intricate details of FDA engagement.

Enhanced Meeting Outcomes

Transform potentially challenging interactions into strategic opportunities that advance your program.

When to Consider Specialized Support:

- Your program involves novel technologies or regulatory pathways
- You have limited internal FDA meeting experience
- Your timeline to market is critical for commercial or funding objectives
- Previous FDA interactions didn't yield expected outcomes
- You're balancing global regulatory strategies and need U.S.-specific expertise

The difference between regulatory compliance and regulatory excellence often lies in the approach to Agency engagement. By partnering with experts who understand both the letter and spirit of FDA expectations, you position your program not just for approval, but for long-term success in the dynamic U.S. market.

DLRC Group's collaborative approach places your program's success at the center of our engagement, ensuring that each FDA interaction moves your innovation confidently toward patients who need it most.

Meet the Authors

Catherine Flynn

Principal Regulatory Consultant, DLRC

Catherine is a longstanding consultant with DLRC having joined in October 2008, and has 25 years' experience in the pharmaceutical industry, including 20 years in regulatory affairs. Focusing primarily on regulatory CMC, she supports clients at all stages of the product lifecycle from early phase development (Scientific Advice, IMPD, INDs) to MAA and post-approval procedures. Catherine has worked on a wide variety of product types ranging from small molecule generics to herbal medicines and biologics; recent examples include a novel herbal extract, mRNA vaccine, monoclonal antibodies and inhalation products. She has a particular interest in strategy for established active substances, UK post-Brexit strategy, sterile manufacture and the GMP interface.

Maggie Rahman

Senior Regulatory Consultant, DLRC

Maggie is a Senior Regulatory Consultant at DLRC and joined the company in September 2024. Maggie is a global regulatory professional with experience across many therapeutic areas including oncology, immunology and cardiology. She has extensive expertise in early development strategy, health authority interactions and IND applications with both small molecule and biologics programs. Maggie has a proven track record of providing tailored solutions that support product development and commercialization goals.

Luis López-Navas

Regulatory Consultant, DLRC

Luis joined DLRC in May 2021 after 4 years at Andalusian Network for Design and Translation of Advanced Therapies where he had some exposure to non-clinical regulatory. He has worked on a large range of EU and US projects including briefing documents, Scientific Advice, PIPs/iPSP, ODDs, INDs, labelling and MAAs. Luis has a Master in Manufacturing of Advanced Therapy Medicinal Products, specialization as Qualified Person, a MSc in Tissue Engineering and a BSc & MSc in Biotechnology (5-year programme).

Amanda Buckingham

Senior Regulatory Associate, DLRC

Amanda joined DLRC in 2024 with a background in the discovery and development of medicinal products cultivated at the academic research bench, university spin-outs, and big pharma. Leveraging her PhD in Molecular Medicine (Cambridge), Amanda has quickly applied her scientific knowledge and strategic thinking to a range of complex client projects, spanning therapeutic areas such as rare disease, virology, neurology, and oncology. As a Senior Regulatory Associate and Project Lead, Amanda has gained expertise in managing and maximizing value from health authority interactions for a diverse range of products, including medical devices. She has performed gap analyses for development programs and formulated regulatory roadmaps with an eye for efficient path to market.

Rose Prizzi, PharmD

Regulatory Associate, DLRC

Rose Prizzi, PharmD, is a Regulatory Associate at DLRC who joined the company in November of 2023. Rose brings specialized expertise in oncology, immunology, and infectious disease. With a strong foundation in regulatory strategy, she has supported a broad range of projects across the drug development lifecycle, including Biologics License Applications (BLAs), Investigational New Drug (IND) submissions, and numerous Pre-IND (PIND) meetings. Rose also has experience supporting regulatory activities for clients operating within the EU and work with the EMA. Her academic background includes a Doctor of Pharmacy (PharmD), which underpins her scientific and clinical understanding of therapeutic development. Rose is dedicated to providing strategic, transparent, and communicative regulatory support to her clients, helping them navigate complex regulatory pathways with confidence and clarity.

Ready to optimize your FDA meeting strategy?

Contact DLRC Group to discuss how our award-winning regulatory support can transform your approach to FDA engagement.

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