

Pre-IND Meeting Preparation Checklist

Determining whether a Pre-IND meeting is the right move, and how to make it count if it is.

The Question Before the Checklist

A Pre-IND meeting is not a formality to check off. It is a limited, valuable opportunity to get FDA's written position on specific questions before committing resources to an IND-enabling program. Requesting one too early wastes it. Requesting one too late means proceeding on assumptions the agency might not share.

The threshold question: do we have specific, answerable questions where FDA's input would change what we do next? If the honest answer is "we want general feedback," the program likely isn't ready yet, and a meeting request should wait.

Part 1: Readiness Assessment

Before drafting a briefing document, assess readiness against these questions.

- ☐ Is the regulatory pathway (e.g., IND under 21 CFR 312, applicable product classification) reasonably well understood, even if not finalized?
- ☐ Do we have enough nonclinical or CMC data to ask a specific question rather than a general one?
- ☐ Have we identified the two or three decisions that most affect program cost or timeline, where FDA's position genuinely changes our path?
- ☐ Is there a credible case that FDA's answer could redirect the program, rather than simply confirming a plan already locked in?

If most of these are "not yet," the better use of time is closing those gaps first (see the CMC Gap Assessment Framework) rather than requesting a meeting.

Part 2: Question Design

FDA meetings are most productive when questions are specific, decision-relevant, and answerable in the format FDA actually uses to respond.

Weak question: "Is our overall development plan acceptable?" This invites a noncommittal answer and doesn't test any specific assumption.

Strong question: "Does the Division agree that the proposed nonclinical toxicology package, consisting of [specific studies], is sufficient to support initiation of a Phase 1 study in [specific population]?" This is answerable, and the answer changes what the sponsor does next.

For each proposed question, test it against:

- Does this ask FDA to affirm or redirect something specific, rather than asking for open-ended input?
 - If FDA disagrees, do we have a real alternative path, or would disagreement stall the program regardless?
 - Is this actually a regulatory question, or is it a technical question we should resolve internally first?
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Part 3: Briefing Document Structure

The briefing document is the primary tool that shapes the meeting. FDA reviewers prepare from it, and the quality of the meeting largely reflects the quality of this document.

1. **Background and product overview** — concise, focused on what's relevant to the questions being asked, not a full program history.
2. **Summary of data to date** — organized around what supports each specific question, not organized department by department.
3. **Proposed development plan** — enough detail that FDA can evaluate whether it's reasonable, without overloading the document with information that doesn't bear on the questions asked.
4. **Specific questions for FDA** — stated plainly, in the order that reflects their actual priority to the sponsor.
5. **Appendices** — supporting data, kept separate from the narrative so the core document stays readable.

Common failure mode: a briefing document that reads as a comprehensive program summary rather than a focused case for specific questions. Reviewers have limited time; unfocused documents get unfocused answers.

Part 4: Meeting Logistics and Follow-Through

- ☐ Meeting request submitted with enough lead time for the applicable review timeline
 - ☐ Internal alignment reached on questions and fallback positions **before** the briefing document is finalized, not during meeting prep
 - ☐ Presenters assigned per question, with a single person owning the overall narrative
 - ☐ A realistic view on what happens if FDA's answer is unfavorable — this should be discussed internally before the meeting, not reacted to afterward
 - ☐ Meeting minutes drafted promptly and reconciled against FDA's official minutes when received
 - ☐ Action items from the meeting assigned owners and timelines within the following week
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What Good Preparation Actually Buys

The value of a Pre-IND meeting is proportional to how specific and consequential the questions are. A well-prepared meeting can save months of program time by redirecting an approach before resources are committed. A poorly prepared one produces a transcript nobody can act on.

This checklist reflects a general approach to FDA interaction planning developed through regulatory and CMC work supporting IND submissions and an FDA advisory committee submission for a cell therapy program. Applied here as a demonstration of methodology; no proprietary or client-specific information is represented.

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