QUICK REFERENCE GUIDE

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

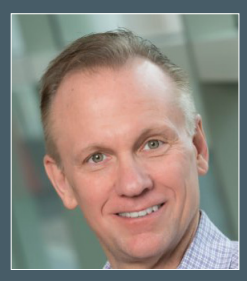
A GUIDE TO FDA MEETINGS

Meetings with the FDA are extremely beneficial to build a relationship that will last many years

Meetings with the US Food and Drug Administration (FDA) help you create a viable regulatory strategy and also ensure your drug is on the best path to receiving market approval. Typically, FDA meetings will only last one hour, and you will only have one chance to get it right, so it's vital they run smoothly so that you meet your objectives.

PharmaLex US expert Mark Lane has laid out a clear step-by-step guide to meeting with the FDA to help you get the most out of your meetings.

EXPERT SPEAKER



Mark Lane, PhD
VP, Principal Consultant, PharmaLex US

Over 25 years experience including small molecules, biologics, biosimilars and medical devices across multiple therapy areas. Understanding what it takes to deliver new drugs to the market, his expertise also includes clinical and regulatory strategy and program, project and portfolio management.

CONTACT US

THERE ARE THREE TYPES OF FDA MEETINGS:

Meeting category determines process and timeline

TYPE A Critical Path meeting
(Meetings are held within 30 days of request)

- Quite rare – addresses issues that resulted in stalled development
- Occurs if put on clinical hold or a "refuse to file" notification is received
- Refuse to file notifications inform the sponsor of deficiencies in an application, allowing companies to take corrective action
- Specific information is required to proceed with your clinical trials

TYPE B Development Path meeting
(Meetings are held within 60 days of request)

- Most typical – to obtain FDA guidance on development at key milestones
- Usually a teleconference or face-to-face meeting although written response only to the meeting questions
- Covers everything from pre-IND to pre-NDA, including end of phase 1 and 2 meetings
- FDA usually grants one meeting per product at each phase of development, be strategic

TYPE C Any other type of meeting **(Meetings are held within 75 days of request)**

Usually for general clinical development and review topics that are out of scope for Type A or B meetings including, for example, early consultations on the use of biomarker as a new surrogate endpoint as the basis for product approval.

ABOUT FDA MEETINGS

- The Center for Drug Evaluation and Research (CDER) covers approvals for prescription, non-prescription & over-the-counter drugs. CBER regulates biologic products
- You are guaranteed FDA interactions at pre-Investigational New Drug (IND), end of Phase II and pre-New Drug Application (NDA) phases
- **Most initial meetings will occur between Pre-clinical and First in Human Clinical Trials**
- A pre-IND meeting offers the chance to get early advice and build relationships with the key meeting goals being to avoid a clinical hold and to discuss the pre-clinical, CMC, and clinical expectations during product development.
  - A clinical hold is notice given to the sponsor to halt or delay a clinical investigation into a new drug on the grounds of safety

THERE IS A FIVE STEP PROCESS TO A SUCCESSFUL FDA MEETING:

Planning the meeting

DETERMINE TIMING of when a meeting is required, work backwards to plan meeting

DEVELOP COMPANY QUESTIONS and positions

SUBMIT MEETING REQUEST and briefing packages (allowing adequate 0 time for preparation)

ENSURE INFORMATION IS ORGANIZED and succinct

PROPER STRATEGY AND FRAMING of questions is critical

ONCE BRIEFING BOOK IS SUBMITTED

CDER WILL HOLD INTERNAL PRE-MEETING prior to sponsor meeting

PRELIMINARY RESPONSES PROVIDED to sponsor usually 1-3 days before meeting

HIGHLIGHTS AREAS FOR DISCUSSION and alerts sponsor to CDER concerns

Rehearse

Conduct **MOCK MEETINGS** internally

DETERMINE PARTICIPANTS' ROLES and responsibilities; who will address each specific topic

PREPARE ANSWERS to likely FDA objections

HOLD A FINAL REHEARSAL to refine strategy after receiving the preliminary FDA responses

Conducting the meeting

ARRIVE EARLY to allow time to pass through Security check point (extensive)

Meetings **KICKED-OFF BY FDA STAFF**, then sponsor controls agenda

DISCUSS FDA PRELIMINARY RESPONSES and their rationale regarding areas of concern

TIME MANAGEMENT is crucial

Before leaving, **SUMMARIZE TO ENSURE MUTUAL UNDERSTANDING** of meeting

Debrief

DEBRIEF WITH THE TEAM immediately post-meeting

SEND ONE COMMUNICATION of outcome and FDA advice to stakeholders

OFFICIAL FDA MINUTES will be received within 30 days. – **REVIEW CAREFULLY** and communicate any important errors or omissions to FDA project manager, no response is **FULL AGREEMENT** of their summary

Implementation

FOLLOW THROUGH on your commitments made during meeting

SUBMIT TIMELY RESPONSES or requests to FDA for clarification

EXECUTE on FDA guidance

ADVISE FDA OF ANY DELAYS or changes from agreements – it helps build the relationship

If applicable, **INFORM OTHER GLOBAL HEALTH AUTHORITIES** of meeting outcome

IT'S CRITICAL TO FOLLOW PROPER ETIQUETTE IN FDA MEETINGS

✓ DO

- **Be polite and prepared**
- **Bring scientists and data**
- **Be clear and truthful**
- **Understand FDA Language**
- **Brief consultants on FDA regulations and expected meeting behaviors**
- **Respect the reviewers' point of view**
- **Know the meeting objectives**

✗ DON'T

- **Be rude, arrogant or emotional**
- **Bury important information**
- **Rely on charm, politics or negotiation**
- **Be confusing, lie or conceal information**
- **Bring lawyers or CEO**
- **Surprise with new data, or change the purpose of a meeting**

ABOUT PHARMALEX

25+ YEARS
OF INDUSTRY EXPERIENCE

OVER 50%
OF OUR PROJECTS ARE GLOBAL

100% COVERAGE
OF ALL PRODUCT CATEGORIES INCLUDING MEDICINAL PRODUCTS, MEDICAL DEVICES, CONSUMER HEALTH AND VETERINARY

40+
HEALTH AUTHORITY MEETINGS PER YEAR WITH EMA/FDA/PMDA

95%
OF OUR PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE WITHOUT MAJOR FINDINGS