PHARMALEX

FDA MEETINGS AND HEALTH AUTHORITY INTERACTIONS

Meetings with the leadership and review staff of the US Food and Drug Administration (FDA) are one of the most important resources available to sponsors seeking agency approval in the US. PharmaLex recommends holding face-to-face and teleconference meetings with FDA throughout the product development timeline. FDA encourages these discussions starting early in the development process (Pre-IND) so that sponsors can become aware of concerns and be able to address potential issues before IND, NDA or BLA submission. Timely meetings with the FDA have proven to dramatically increase the probability of cost efficient development and final FDA approval.

PharmaLex assists you every step of the way, ensuring a highly professional interaction with the FDA. We assist with overall meeting strategy, including identification of appropriate regulatory questions, authorship of meeting materials (request letter, meeting package), and correspondence with the FDA. Depending on your needs, we conduct rehearsals prior to the meeting, lead or participate in the FDA meeting and prepare sponsor meeting minutes.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- **Meeting Strategy**
  We help to decide when and how best to approach the FDA, formulating the right questions to maximize the opportunity for collaborative discussion.
- **Authoring Meeting Documents**
  We provide all levels of authorship, from review to full support of FDA meeting requests and supportive meeting packages, in accordance with FDA guidance requirements.
- **Coaching and Rehearsals**
  We ensure the meeting team is adequately prepared for discussion with the FDA, reviewing meeting etiquette and finalizing overall message strategy.
- **FDA Responses**
  We use our regulatory expertise and meeting experience to interpret FDA requests and responses in order to ensure meetings are run efficiently and sponsors obtain necessary feedback critical for their development programs.
- **Implementation**
  We support project teams in designing and implementing post-meeting strategies to address FDA meeting feedback.

50+ FDA Meetings (Type A, Type B, Type C and BSUFA) in past 3 years

200 + Original IND submissions and IND Amendments in past 3 years

25+ Fast Track and Breakthrough Therapy Designations

30+ US Orphan Product and EU Orphan Designations

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

APPROVAL / AUTHORISATION

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

The PharmaLex Group now has over **1000** employees, with **33** offices in **21** countries and more than **600** satisfied clients worldwide.

Stay **one step ahead** of essentials requirements needed by health agencies. Our knowledge accelerates your business sucess...

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

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