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WHITEPAPER

PRE-IND MEETINGS DON'T OVERLOOK THIS KEY OPPORTUNITY FOR EARLY FDA FEEDBACK

Andrew S. Verderame, MBA, RAC
Partner, PharmaLex US Corporation
andrew.verderame@pharmalex.com

Andrew is a leader in our US-based Regulatory staff providing FDA-specific guidance and consulting services. He has over 30 years of involvement in the pharmaceutical industry, including positions of increasing responsibility in pharmaceutical production management, Regulatory CMC, US Regulatory leadership, and as Global Head of Regulatory therapeutic area teams. He has led over two hundred meetings with FDA, managed multi-site regulatory teams for both large and small pharmaceutical companies, and has presented to FDA Advisory Committees with successful outcomes.

An expert at building constructive FDA relationships, he was the first industry representative ever invited to speak at the internal FDA Project Manager Forum. He also held senior Regulatory affairs positions at Bayer and EMD Serono, where he led the approval of a novel best-in-class auto-injector drug/device combination product.

Introduction

After years of research, fundraising, and initial pre-clinical testing, you believe you are ready to begin studying the safety and efficacy of your new drug in humans. However you, your financial backer or your licensing partner has questions on whether your scientific rationale is sound, your pre-clinical studies are robust and whether the design of your initial human study(ies) will be accepted by the FDA.

The first step in the US on your path towards eventual approval is a pre-IND Meeting, which will facilitate communication with the FDA and provide the advantage of early feedback on your development program. This first meeting establishes the tone of your Agency relationship, and as one of the desired outcomes, you want the Agency to gain respect for your company and your science.

Pre-IND Meetings - Some Of The Basics

Pre-IND Meetings are recommended by the FDA to help eliminate surprises during the initial review of the IND. Even though this Agency touchpoint is not required, we at PharmaLex **almost always** recommend taking advantage of the Pre-IND Meeting opportunity.

Among the many advantages of conducting a Pre-IND Meeting are the chances to discuss and agree on the topics that can prevent clinical holds, the ability to showcase your company and product to the FDA Review Division to generate enthusiasm, and the opportunity for FDA to provide early confirmation of its requirements for the indication under discussion. Of course preparing for the meeting consumes time and resources, but this early FDA engagement often leads to significant benefits for the sponsor, potentially reducing the amount of time, effort and money spent on unproductive areas of development.

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The following are necessary considerations when planning a Pre-IND Meeting:

- The most important goal of a Pre-IND Meeting is to receive feedback from FDA on issues that could cause a clinical hold for your program. Gaining clarity on any potential safety issue on your pre-clinical findings, manufacturing/formulation plans, and your IND opening study must be your first priority.
- Once this first objective is satisfied through appropriately phrased questions and the company positions have been justified, discussing the drug development plan and future clinical trials with the Agency is acceptable.
- When used in a correct manner and with the appropriate expectations, well-conducted Pre-IND Meetings have the ability to reduce a product's time to market, with the sponsor able to clarify that the initially planned studies will generate the necessary data that FDA will need to approve your product.

How can PharmaLex US Regulatory and Development Consultants Help?

It is incredibly important that the initial conversations with the FDA are well planned and rehearsed. This is even more critical if this is the first time your company has ever been to the FDA. PharmaLex US experts can assist you to:

- Ask the right questions to the FDA – this is the most important part of the meeting request, as FDA will review the questions to determine if a meeting will be granted. The right questions, coupled with the correct amount of supporting information in the Pre-IND Meeting request, gives your company the best chance for FDA greeing to hold a meeting.
- Act as your FDA Agent – is your company still maturing and your regulatory group is small or non-existent, or are you a firm based outside the US without a US regulatory presence? PharmaLex can act as your expert communicators to FDA.
- Prepare the meeting briefing book – preparations should begin on the briefing book at the same time that you begin the meeting request. Usually, your package is due to FDA 30 days before the meeting, and it needs to include the appropriate pre-clinical/clinical/manufacturing/regulatory information for FDA to be able to thoroughly consider your questions and generate thoughtful responses.
- Electronically publish and submit to FDA on your behalf – PharmaLex is a full service regulatory consultancy; you can rely on our experienced regulatory operations team to compile well-structured, submission-ready electronic documentation and seamlessly submit to FDA. Beginning earlier in 2018 all pre-IND communications to FDA must be submitted electronically through the secure FDA gateway.
- Conduct pre-meeting teleconference rehearsals – you need to be ready to face the FDA. PharmaLex and your staff will prepare for all possible Agency objections and prepare your responses.
- Hold a final face to face rehearsal after receipt of the Agency preliminary comments – FDA typically provides preliminary replies to your questions 24-48 hours before the scheduled meeting. PharmaLex will lead in the final discussions and preparations based on the FDA comments, further refining the strategy and agenda, and reinforce the objectives of the meeting.
- Act as the Regulatory Lead – PharmaLex staff have led hundreds of FDA meetings. We will professionally open and close the meeting, engage FDA in the scientific discussions and ensure that your critical meeting time while at the FDA is maximized to the fullest.

PharmaLex: Let Our Pre-IND Meeting Expertise Work For You

PharmaLex US will efficiently guide your team through the entire Pre-IND process – from the initial planning for the meeting request completely through to the preparation and conduct of the meeting itself. Companies often botch this incredible opportunity - learn from our industry veterans how to assure that you get the answers needed to make key development program decisions, and the strategies for how NOT to unintentionally sabotage this critical milestone meeting.

DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex can quickly supply the widest range of **highly-skilled market leading experts** to our clients. We work with you to identify and overcome any challenges, but remain sufficiently flexible to respond and adapt to your evolving needs. Our **experienced team** spans all geographies, helping you to **accelerate your products or accelerate access to much needed resources,** and to stay one step ahead of essential requirements needed by health agencies worldwide. Our **knowledge accelerates** your business success.

Put simply, our approach transcends all of our work, providing you with our expertise and ability to achieve quicker timelines, or...

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Pharmacopimediology, & Risk Management worldwide. Our global teams of experts can take you through early strategic planning activities and nonclinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.

PHARMALEX IN NUMBERS

700+
SUBJECT MATTER EXPERTS WITH A UNIQUE BLEND OF EXPERTISE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS

50%
OF OUR PROJECTS ARE GLOBAL

contact@pharmalex.com
www.pharmalex.com