THE BASICS OF REGULATORY STRATEGY

DRIVING DEVELOPMENT OF DRUG PRODUCTS FROM PRE-IND THROUGH MARKETING

Regulatory strategy encompasses the adaptations a sponsor makes to move its product from development to marketing approval. Implementing a regulatory strategy at the start of the program, before filing for an investigational new drug (IND), is crucial because it allows you to devise a development plan, a document for a path forward that describes the specific steps and action required to successfully meet the regulatory strategy objectives. The development plan examines the hurdles and mitigates any risks, challenges, or issues the drug might face. Pre-IND meeting requirements include submission of a development plan with the meeting package; this item can be used to drive the team to map out a plan. Additionally, communicating the strategy to the FDA via a draft Package Insert (PI) or by other means (typically in a meeting) will apprise the agency of your strategic thinking.

A well thought out strategy should include outstanding issues or questions, background information, regulations and/or guidance documents, strategic advice, past precedents (if any), and recommendations on implementation. The ultimate goal of the drug development plan is to include all studies that you will need for a marketing application, based on a well thought out regulatory strategy. Waiting until the end of Phase II or during NDA preparation to implement a strategy, only to discover that you need to conduct additional clinical studies (such as QT prolongation) to support the filing or claims, is costly in terms of both time and money. A well-developed strategy early on will highlight potential drug development issues, any change in regulations that may need to be discussed with the FDA, and allows for creation of novel approaches to drive drug development from the pre-IND stage through marketing approval.

It is important to keep in mind that the FDA, when reviewing your marketing application, will look at all aspects of the strategy described to see whether you addressed the necessary components of a successful drug development program, incorporated the regulations, guidance documents, and past precedents. If your team does not take the time to put together a strategy, the FDA will—which could result in a refuse to file or complete response letter.

PRA's Regulatory Affairs department plays a vital role in developing a sponsor's regulatory strategy and development plan. PRA is able to conduct an initial Gap Analysis of a client's development strategy and propose a plan that is sustainable throughout the regulatory life cycle.

Our Global Regulatory Affairs group offers extensive experience and support to the sponsor in research and evaluation of the regulatory items that lead to an overall approval strategy, as follows:

■ Health authority (reviewing division)	■ Classification
■ Approval route	■ Regulatory hurdles
■ Regulatory submissions needed	■ Supporting documentation
■ Meetings with regulatory authorities/ scientific advice	■ Total Product Profile (TPP)
■ Special Protocol Assessments (SPA)	■ Pediatric Study Plan (PSP)
■ Regulatory risks and mitigations	■ Marketing exclusivity expected
■ Approval options (fast track, priority, accelerated approval, orphan)	■ Global marketing applications and requirements - In what countries should marketing applications be submitted for the product and what are the documentation requirements?

Regulatory staff are experienced in all types of FDA meetings and negotiations that have expedited drug development. This group has 20+ years of combined experience in attending meetings with the FDA, along with extensive experience writing briefing documents.

CONTACT

For further information or to discuss any aspect of PRA's services in the field of regulatory submissions, please contact your PRA Business Development Manager.

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