**Don’t be afraid of the FDA**

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. It is the US Agency responsible for the regulation of drugs and biologics, including, vaccines for humans, blood and blood products and cellular and gene therapy products.

As the United States remains the largest pharmaceutical market in the world, any drug development program will require a close interaction with the FDA to ensure your development rationale is sound and that the design of your studies is fit-for-purpose.

Although a first contact with the FDA might sometimes feel intimidating, an early interaction will prove very valuable. Your first interaction with the FDA will likely be a pre-IND meeting. *Sensu-stricto* a pre-IND meeting is not required, it is however highly recommended to engage with the FDA in a pre-IND meeting for the following reasons:

**Early Feedback from the FDA** - The most valuable benefits of the pre-IND meeting are to receive early feedback directly from the FDA on your development program and to gain an understanding as to what the FDA’s expectations are for your drug.

**Fine-Tuning of your Development Strategy** – Taking the feedback in the FDA into account, offers you the opportunity to fine-tune your program development strategy, potentially saving time and money.

**Relationship Building** – The pre-IND meeting is also the opportunity to start building a working relationship with the FDA and individuals within the Agency that will be your contact persons.

In preparation of your pre-IND meeting, you will need to prepare a briefing package. In this briefing package you will provide background information on your compound and prepare the list of questions. When preparing these questions, there a few things you need to keep in mind:

- FDA meetings are most effective when they are focused on specific scientific or regulatory issues, such as clinical trial design, pharmacology studies, toxicology studies, acceptability of novel formulations, dosing limitations, data requirements for an IND application, etc.

- Speculative and open-ended questions are difficult to address; meetings are typically most productive when questions are focused and specific. Questions for the FDA should be posed in such a way that the agency can either agree or disagree with the question.

As the briefing package forms the basis of a successful meeting, it is important that it is well worked out. Taking advantage of the valuable input that can be gained from pre-IND meetings is essential for the further development of the drug and may reduce the drug’s time to market and ensure that the proposed studies are designed to provide useful information. Sponsors who are forthcoming with potential issues of concern during the drug development process will benefit from input provided by the regulatory agency.

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*If you are interested to learn more about how our Regulatory Affairs department can support your development activities, please contact Venn life Sciences at getintouch@vennlife.com.*