Regulatory Affairs Outsourcing

THE FDA GROUP LLC

Introduction

Overview

The FDA Group is an organization that utilizes a proprietary talent selection process of former FDA and industry professionals, amplified by a corporate culture of responsiveness and execution. Headquartered in Westborough, Massachusetts, The FDA Group has over 3,250 resources worldwide, over 250 of whom are former FDA. We have resources in 48 states and 75 countries.

Why is The FDA Group in business?

The FDA Group is in business to enhance the quality of people's lives. Whether it is our clients, employees, contractors, vendors, communities, or the patients who receive the products we touch, our purpose lies in discovering meaningful ways to apply our experience, expertise, and passion for quality in everything we do.

How does The FDA Group do it?

We are able to do this through our proprietary talent selection process and deep-rooted corporate culture built upon 5 Core Values. These Core Values are the heartbeat of our organization and focus on the following concepts:

1. Respond with urgency.
2. Find a way to make it happen.
3. Communicate with radical candor.
4. Be humbly confident.
5. Be easy to work with.

What does The FDA Group do?

Service Areas:

- Quality Assurance
- Regulatory Affairs
- Clinical Operations
- Commissioning, Qualification, and Validation
- Pharmacovigilance

Engagement Models:

- Consulting Projects
- Staff Augmentation
- FTE Recruitment

Regulatory Affairs Outsourcing

The regulatory landscape is constantly changing with new initiatives and guidances from the FDA. Do you feel that the FDA does not understand your development program as well as you would like them to? Are you worried that their expectations keep changing? Are you concerned that your development timelines and costs will be negatively impacted by not being able to reach a reasonable agreement with the FDA?

Imagine if you had a team with the experience and expertise in interacting with US FDA and other global regulatory agencies that could help you bring your novel product idea from concept to an approved product that can be commercialized. The entire process from the first call to the agency to the final approval of your application is a multi-disciplinary and complex process. Our team of former FDA and industry experts can help you navigate the regulatory challenges in bringing your idea for a novel product in front of the regulatory agency to obtain approval to market. You will obtain approval for your product staying within budget and in the shortest possible time thus maximizing the return on investment for your company.

> ***"When we decided to pursue FDA approval for a new medical device, we did not know where to begin. Luckily, some cursory research led me to a call with The FDA Group, LLC. They did an excellent job of explaining the process and keeping me well informed every step of the way. They completed the project early and came in under budget. I would highly recommend The FDA Group, LLC for all your regulatory needs."***

Are you concerned that your regulatory submission is not complete and properly organized and will not be accepted by the FDA at the first attempt? A refusal to receive (RTR) or a refuse to accept (RTA) for an application can have a significant cost in terms of both money and time (delays in product approval and launch) for your development program and your company. Can you afford this preventable cost to your company?

What if you had a team of former FDA and industry experts who understood the importance of time and money to your development program? We always emphasize a right-first-time approach to ensure you stay within budget and timeline. Our experts are meticulously selected to provide a breadth and depth of experience that matches your needs. These experts have a thorough understanding of the regulatory requirements for a complete and well-organized package for FDA submission ensuring right-first-time. Another benefit is a shortened review cycle thus saving valuable time. A good package tells the agencies that you understand your obligations and are serious about complying with their regulations, which builds a favorable impression for your company. You will experience overall faster approval time and prevent unnecessary penalties and other

costs associated with sub-standard submissions. Finally, you will prevent delays in bringing product to market and you will maximize returns on your investment.

> ***"I highly recommend contacting The FDA Group, LLC if your company is in need of regulatory consulting. They have successfully matched the right consultant to the right issue for our business many times. From day-to-day Regulatory Affairs questions and training to significant issues such as recall management and 483 responses, The FDA Group has a pool of consultants to pull from that can assist you both expeditiously and professionally."***

The FDA Group offers a team of Regulatory Affairs professionals who have vast experience working with the US FDA. Our regulatory expertise ensures that regulatory strategies and alternatives are considered at every step to help you gain product registration.

The FDA Group will work with you in both pre- and post-marketing drug safety regulations, regulatory filings, marketing authorization applications, variations and renewals and carefully developed due diligence strategies.

Our Regulatory Affairs services include:

- Review of client technical dossiers and developmental plans
- Research and interpretation of regulations
- Determination of regulatory status
- Pre-submission review of technical documents
- Critical writing and review of documentation
- Clinical trial applications and notifications (IND, IDE, CTX, etc.)
- Marketing Application Support (NDA, BLA, ANDA, 510(k), PMA, etc.)
- Orphan Drug, Treatment Use, and ANDA Suitability petitions

The FDA Group's experience encompasses US FDA clinical trial applications, and registrations of new chemical and biological entities, as well as those products containing established pharmaceutical ingredients (generics and 505(b)(2) products). We develop high-level regulatory strategies to expedite products through clinical trials and into the market, and regularly represent our clients in meetings with the US FDA.

The FDA Group can manage the entire registration process for new medicinal products as well as for generic products. We have extensive experience writing Drug Master Files for product registrations.

The FDA Group's Regulatory Operations supports the production of submissions in both paper ("old" and CTD formats) and electronic formats. Whether you are submitting an original IND, NDA or ANDA, or an amendment, supplement, or variation to an existing application, or converting an existing application to eCTD format, we can publish and deliver an FDA/ICH-compliant submission to meet your needs.

In the ever changing world of regulatory submissions, we work with industry leaders to stay at the forefront of eCTD requirements. By using highly qualified and experienced staff to perform the e-publishing we can offer affordable e-submissions to our client companies, regardless of the size of their company. Our publishing team works closely with the authors to ensure documents are written using industry templates with the appropriate granularity, and to ensure formatting consistency across the dossier. Throughout all stages of submission preparation, consideration is given to the potential lifecycle management of the application to ensure that accommodations to future changes and amendments can be made with little or no disruption to the overall message of the application.

The FDA Group prepares all major regulatory submissions and provides extensive quality control review for all trial related documentation, such as:

- Regulatory Agency and IRB/EC submissions
- Procurement of Import/Export license, as applicable
- Initial submissions, amendments, notifications, and closeout submissions

Working as a collaborative team, our regulatory specialists coordinate all aspects of your trial's document collection and submissions, including:

- Manage all regulatory documentation as part of the start-up, conduct, and close-out phases
- Coordinates clinical trial application filings to regulatory agencies
- Ensures submissions comply with regulations
- Manages submissions and document storage processes
- Stays abreast of all regulations to ensure documentation compliance

Our team of experienced regulatory scientists can write the nonclinical, clinical and CMC sections in CTD and traditional format for your new drug and biologic applications. We have extensive experience writing Drug Master Files for product registrations.