BIOPHARMAGLOBAL

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The Benefits of Working With **BioPharma Global**

BioPharma Global is a full-service FDA and EMA regulatory affairs consulting firm specializing in orphan products treating rare diseases and non-orphan products which treat indications with unmet medical needs. We offer services such as writing orphan drug designation (ODD) applications and other expedited review program applications such as Fast Track (FT) and Breakthrough Therapy (BTD) designations application submissions, provide support for meetings with the FDA and EMA (e.g., Pre-IND meetings), IND preparation using the eCTD format, electronic submissions to the agency, in addition to providing comprehensive consulting on projects for regulatory strategy, gap analysis, and regulatory roadmaps.

We operate in a very client-focused fashion, maintaining a completely customer-centric and transparent process through the entirty of our projects.

BIOPHARMA GLOBAL

Full-service FDA and EMA regulatory affairs consulting.

Specializing in orphan products treating rare diseases and non-orphan products which treat indications with unmet medical needs.

- 100+ years combined experience
- 100's of successful projects

NOT A CRO

An Independent "Set of Eyes" for Your Regulatory Needs

BioPharma Global focuses exclusively on matters pertaining to regulatory affairs. **Unlike Contract Research Organizations (CROs) which could also provide regulatory services, BioPharma Global does not have a vested interest in managing other aspects of clinical trials thus avoiding any potential conflicts of interest.** Utilizing an independent regulatory affairs consulting firm provides the necessary "checks and balances" resulting in objective guidance with respect to regulatory strategy. However, it should be noted, that BioPharma Global regularly partners with CROs and can provide CRO recommendations to sponsors, if needed.

KEY DIFFERENTIATORS

Former FDA Staff & Complimentary Data Review

BioPharma Global differentiates itself from other regulatory affairs providers in two important ways. First, our team is comprised of globally recognized experts in rare diseases and other under-served disease areas. Specifically, our team consists of former FDA staff and a variety of scientists with many successful FDA interactions and other expedited program submissions to their credit. Collectively, our regulatory affairs staff has a combined hundred plus years of experience. We do not limit our expertise to any specific area, as our experienced staff works across various therapeutic areas and indications. Second, BioPharma Global is very transparent with prospective clients. For example, **we offer a complimentary top-level data review to assess whether our team sees a regulatory path forward.** It should be noted that in the event the data review does not reveal a current regulatory path forward, we provide tangible feedback with clear guidance on next steps (e.g., what non-clinical or clinical studies need to be conducted). Our preliminary data reviews are popular with sponsors and are conducted in a timely and objective manner.

FDA/EMA submission success rate is **100%** when clients follow our guidance.

A Reputation For Success

Our team has submitted hundreds of applications for FDA and EMA Orphan Drug Designation, Rare Pediatric Disease Designation, Fast Track Designation, Breakthrough Therapy Designation, and other expedited programs. Importantly, our **FDA/EMA submission success rate is 100% when clients follow BioPharma Global's instructions.**

Relationship-Focused

BioPharma Global focuses on providing quality advice and building strong relationships with our clients through a highly iterative process. We collaborate with our clients for each project by fostering a robust communication pipeline, ensuring no details, documents, or intentions are overlooked. We believe in building long-term relationships with our clients, of which many have chosen to pursue multiple projects with us as they continue through their drug development pipeline.

Competitive Pricing

BioPharma Global uses a project-based, fixed-price model, translating into reduced client risk, very competitive fees, and lower costs for our clients. We employ a project-based model, so our clients are clear on a defined scope of work and a not-to-exceed cost budget.

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Are you interested in learning how BioPharma Global can assist in your drug development efforts?

Please Contact us today to connect with our expert team regarding your regulatory affairs needs.