FACET LIFE SCIENCES

FLAGSHIP REGULATORY & DEVELOPMENT SERVICES

Facet Life Sciences is an award-winning regulatory strategy and product development organization that enables small organizations to design and build streamlined product development strategies and implement the right tactical plans to bring therapies to patients in need. Whether your organization plans to take your product "all the way" to FDA approval/clearance or simply to reach the next regulatory milestone, Facet can help.

The Facet Life Sciences services team is comprised of development, regulatory affairs, and regulatory writing experts who have advanced scientific degrees with a combined hundreds of years of experience in the pharmaceutical, biologics, biopharmaceutical, and/or device industry. We do everything a large pharmaceutical company regulatory affairs department does but have transformed how it's done. Our goal is to help small organizations efficiently and effectively speed their great science and innovative products to and through FDA.

FDA meetings, regulatory strategies, gap analyses, and IND/NDA/BLA/510k submissions are "bread and butter" for us. Because we only work with small organizations, we also provide broader development support including selection and management of partners for nonclinical and clinical studies and product manufacturing. Through a network of partners who also understand the business drivers and entrepreneurial mindset of a small organization, we provide a comprehensive solution for our clients.

Your goals are our goals and your success is our success. This mindset drives every aspect of our relationships with clients.

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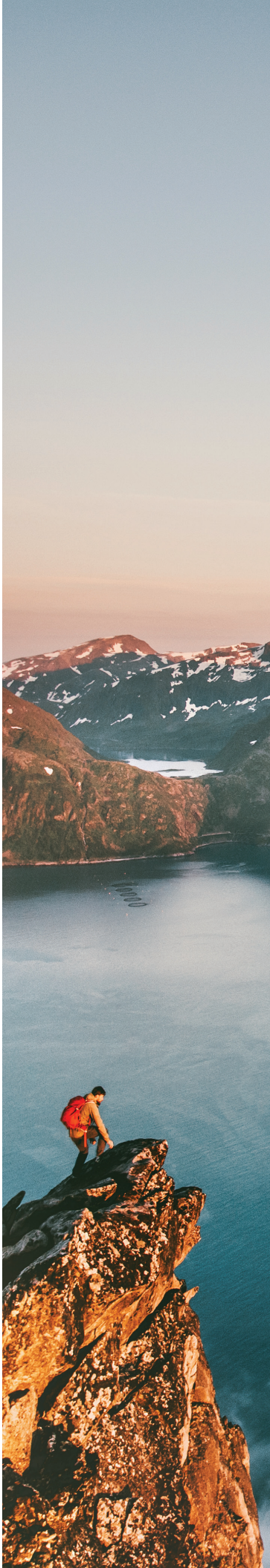
TOP REGULATORY SERVICES PROVIDER 2023
Facet Life Sciences
AWARDED BY Life Sciences Review



OUR EXPERTISE

Gap Analysis

Are you looking at your next regulatory milestone (e.g., pre-IND meeting, IND, NDA, BLA) and asking whether you are ready? Are you concerned that you are doing too much or, might have have gaps in your development program and want a second opinion from a group that "has been there and done that" before you go to FDA?

A gap analysis is a great way to obtain an independent evaluation of readiness to a particular regulatory or development milestone. Facet provides an objective evaluation of a product in the context of a company's stated goal (e.g., NDA submission). The gap analysis is a strategic evaluation from a development, medical, regulatory, and commercial perspective. Gaps from a development, medical, regulatory, and commercial perspective are identified, and potential risk mitigation is suggested. Timelines and estimated costs to the stated goal are included. We review your product progress and objectively identify where you are in regulated development (a "You are Here" assessment).

FDA Meetings

Do you need answers to specific questions from FDA about your development program or your upcoming application? Are you not sure you need an FDA meeting or are uncertain what the benefits of an FDA meeting would be to your program?

We can help you decide if an FDA meeting is right for you and if so, what questions we should be asking FDA. We prepare compelling meeting requests to ensure that our clients secure the meetings they desire and prepare background packages that result in clear answers from FDA in the preliminary written comments. If you do choose to hold a face-to-face meeting or teleconference with FDA, Facet's group of scientific regulatory experts can serve as emcee, scientific subject matter expert, scribe, or simply coach to help you to be the champion of your own meeting.

Facet provides support for all types of FDA meetings with CDER, CBER, OGD, and CDRH, and has a track record of success in securing the desired meeting as well as obtaining clear and actionable outcomes.

U.S. Agent

Are direct interactions with FDA outside your comfort zone? Do you want your initial contact person with FDA to be an experienced regulatory expert who has worked with FDA for decades? By using Facet as your US Agent you can leverage our expertise to foster a strong and productive relationship between you and FDA.

Facet serves as a strategic US Agent for over 60 Sponsors for products in development under CBER, CBER, CDRH, and OGD.

For organizations that do not have a US presence, a US Agent is required to bring an investigational or marketed drug, biologic, or combination product into the US. For companies that have a US presence, a contract US agent can be particularly desirable when US regulatory expertise is not available in house or resources are limited.

We do not believe in a "post office box" style of US Agent support because we understand that successful interactions with FDA can make all the difference when trying to move a program forward, especially for smaller companies that don't already have an established relationship with FDA. Facet regulatory strategists are also scientists, and our backgrounds and experience enable us to better interpret FDA questions and feedback in the context of your scientific development program. The combination of strong scientific foundations and decades of regulatory affairs experience enables us to help you put your best foot forward with FDA to develop novel regulatory strategies and solutions for development challenges.

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Strategic Regulatory & Development Guidance

One of the most important goals for small organizations is to make rapid progress on a development candidate in the context of limited resources and in house expertise. Facet works as an integral part of your core team to provide expert scientific and regulatory recommendations to help you achieve your regulatory and business milestones within a tight timeframe and budget. We know there are many ways to develop medical products and we believe in aggressive, science-based, and creative approaches. We believe the right development pathway for a particular product being developed in a small organization depends on a wide variety of factors, including the organization's goals and objectives, risk tolerance, and financial support. Facet's development plans include detailed recommendations for the right complement of nonclinical studies and stage-specific CMC requirements. Development plans can also include detailed descriptions of the necessary clinical studies and recommendations on protocol designs; patient populations (inclusion/exclusion criteria); efficacy, safety, PK/PD, and other endpoint selection; and regulatory routes/milestones.

Medical Writing of Submission Documents

Facet's award-winning regulatory experts author, QC, format and finalize documents for regulatory submissions, including but not limited to cover letters, nonclinical, clinical and chemistry sections, protocols and CSRs, investigator brochures, and product labeling. We also author orphan designation requests, breakthrough therapy designation requests, rare pediatric disease/tropical disease designation requests, and small business waivers. All our documents are written by scientifically trained regulatory strategists with both the company product strategy and the FDA reviewer in mind, ensuring your documents have both the content and context to enable an efficient FDA review.

Regulatory & Scientific Review of Submission Documents

Many of our clients are scientific experts who understand their product well and want to tell their product's story to FDA but have never written a submission document before. Scientific writing for FDA's review is different than writing a grant or publication. Facet helps these scientific experts in 2 ways: 1) we provide organizations with templates designed for FDA submissions that include instructions for authoring, and 2) we review regulatory submission documents prepared by you or a third party for scientific integrity and regulatory compliance. Facet can give you peace of mind with a scientific and regulatory compliance review of submission content to ensure you are telling your best product story!

Regulatory Submission Leadership

Facet provides strategic and tactical team leaders who champion your regulatory submission project from inception to submission to the FDA. We look for ways to improve impact, save time, and avoid obstacles. Preparing a regulatory submission with the reviewer in mind is critical to everything we do. A successful application is one that allows us to proceed to the next stage of development as efficiently and effectively as possible. We strive for clear and concise applications and prepare all our submissions with the goal of progressing forward with few or no questions from the FDA. Although the date of submission of a regulatory application can be important, speeding a product through review to clearance/approval to get that product to patients is our primary focus!

We also know that small organizations often need a full-service solution. Facet offers a broad array of supplemental services through our partners, including submission publishing, patent support, biometrics, medical affairs, CRO/CMO selection and oversight, GXP audits and pre-approval inspection readiness, and ex-US regulatory affairs support.

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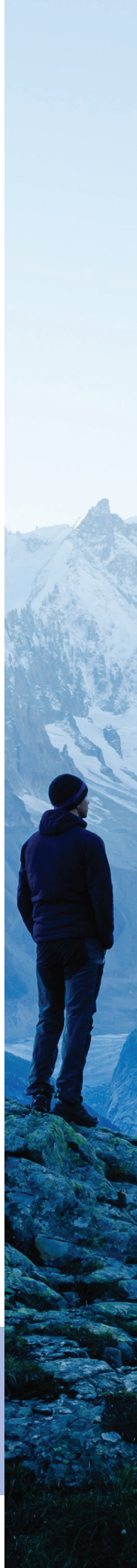

APPLICATION TYPE EXPERIENCE

Facet's FDA application experience incudes (but is not limited to):

- 505(b)(1) NDA
- 505(b)(2) NDA
- 505(j) ANDA
- IND (non-commercial)
- IND (commercial)
- Pre-IDE
- 510(k)
- PMA
- De Novo
- Orphan and small business
- Drug-device combination
- Biologic-device combination

THERAPEUTIC AREA EXPERIENCE

Facet has worked in virtually every therapeutic area including:

Allergy, cardiovascular/renal, dermatology, diagnostic and therapeutic radiopharmaceuticals, GI, immunology, infectious disease, neurology, oncology, ophthalmology, pain, psychiatry, reproductive health, ultra-rare diseases

DOSAGE FORM EXPERIENCE

Facet has experience with the following dosage forms:

Capsules, creams, gels, liposomes, medical gases, microdose powders, monoclonal antibodies, parenterals (liquid, lyophilized, powder fill), overencapsulation, patches, powders, synthetic and semi-synthetic drug substances, tablets (IR and ER), toothpaste, suppositories, swabs, vaccines.

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