FACET LIFE SCIENCES

FLAGSHIP REGULATORY & DEVELOPMENT SERVICES

The Facet Life Sciences services team is comprised of development, regulatory affairs, and regulatory writing experts who have advanced scientific degrees with hundreds of years of experience in the pharmaceutical, biologics, biopharmaceutical, and/or device industry.

Facet Life Sciences can help you to formulate an effective development plan and strategies to execute on that plan. Your goals are our goals and your success is our success. This mindset drives our partnerships with clients.

OUR EXPERTISE

1

U.S. Agent

For companies that do not have a US presence, a US Agent is required to bring investigational or marketed product into the US. For companies that have a US presence, a contract US agent is desirable when regulatory expertise is not available in house or resources are limited. Facet effectively serves as US Agent for over 60 Sponsors. US Agent services include strategy, planning and regulatory/scientific support for all types of FDA meetings with CDER, CBER, and CDRH.

2

Gap Analysis

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).

3

Strategic Regulatory & Development Guidance

We generate or review a carefully designed regulatory plan (clinical, nonclinical, CMC and procedural activities) that must be accomplished to meet a specific corporate goal for a company's product.

4

Medical Writing of Submission Documents

Facet's regulatory experts author, QC, format and finalize documents for regulatory submissions, including but not limited to cover letters, nonclinical, clincal and chemistry sections, protocols and CSRs, investigator brochures, and product labeling. We also author orphan designation, breakthrough therapy designation and small business waiver requests. All our documents are written with the FDA reviewer in mind.

5

Regulatory & Scientific Review of Submission Documents

Facet can give you peace of mind with a scientific and regulatory compliance review of submission content that was prepared by you or by a third party.

6

Regulatory Submission Leadership

Facet provides strategic and tactical team leaders who champion your regulatory submission project from inception to submission to the FDA. They look for ways to save time, avoid obstacles and make your product shine!

Facet offers a broad array of supplemental services through our partners, including Submission Publishing, Phase 1-3 Clinical Trial Execution , Biometrics, cGMP Audits, Manufacturing Audits and Patent Support.

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

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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For More Information About Facet And How We Can Support You, Please Contact Us!

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