CLINICAL/REGULATORY STRATEGY AND SUBMISSIONS

NSF International offers expert FDA regulatory/clinical support and consulting services for pharmaceutical, biologics and biotech companies who need experts to interpret or navigate the intricacies of FDA pharmaceutical and biologics regulations.

We provide regulatory strategies based on your corporate objectives, whether for product development, FDA approval pathways or lifecycle management of marketed pharmaceuticals and biologics. We also prepare or review relevant regulatory documentation, provide temporary regulatory affairs services and can serve as the U.S. agent for pharmaceutical, biologics and biotech companies outside of the U.S. seeking assistance.

In addition to our consultants who bring FDA and industry expertise to your projects, we have a network of subject matter experts across all therapeutic areas who provide our clients with the utmost quality and expertise in any field. In all of our assignments, we seek to balance the compliance requirements with the regulatory requirements for our clients' business needs.

Our regulatory team provides a range of specific services to meet all of your regulatory needs across the product development and marketing continuum. Our services include:

STRATEGIC CONSULTATION

- Provide regulatory consultation for product development and regulatory strategy for new therapeutics and combination products, including assessment of applicability of unique programs and pathways available for approval (e.g. breakthrough therapeutics, orphan drug status eligibility for 505(b)(2))
- Conduct due diligence assessments of early stage start-ups for possible investment or of established companies with a portfolio of approved drugs for possible acquisition/merger
- Advise on FDA expectations for product manufacturing and product specifications: review and preparation of chemistry, manufacturing and control (CMC) programs

REGULATORY SUBMISSIONS AND SUPPORT IN THERAPEUTIC AREAS

> Review and/or preparation of:

  - Investigational New Drug (IND), New Drug Application (NDA), Biological Application License (BLA), Abbreviated New Drug Applications (ANDA) and lifecycle management submissions, such as prior-approval supplements (PAs), all with eCTD format
  - Post-marketing submissions: PAs supplements, annual reports and post-market studies
  - Responses to submission deficiency letters and/or additional information requests

> Provide interim regulatory affairs professionals to fill staffing shortages

PRODUCT DEVELOPMENT AND EVALUATION

> Advise on clinical protocol development

> Provide clinical trial support (e.g. CRO selection and contracting, IRB selection, drug management/ labeling)

> Provide scientific review and medical writing support (e.g. clinical protocol, investigator's brochure, informed consent)

> Provide expertise in non-clinical study design and review

FDA AGENCY INTERACTIONS

> Assist with regulatory agency meeting interactions that includes preparing briefing documents, conducting meeting preparation sessions and conducting the FDA meeting

> Interactions may include: pre-IND, end-of-phase-2 (EOP2), pre-BLA, Type A,Type C and advisory committee meetings

TRAINING

> In-house or on-line training on U.S. regulatory IND, ANDA and/or NDA processes and approval pathways

For more information, visit our website at **www.nsf.org/info/pharmabiotech**, email **uspharma@nsf.org** or call +1 202 822 1850.

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