REGULATORY CONSULTING FOR PHARMA BIOTECH

NSF International offers expert FDA regulatory / clinical support and consulting services for pharmaceutical and biotech companies that need experts to interpret or navigate the intricacies of FDA pharmaceutical and biotechnology 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 or serve as the U.S. agent for pharmaceutical and biotechnology for foreign companies seeking assistance.

Our experts possess comprehensive knowledge of the regulatory requirements and a wealth of experience. All efforts are directed by senior staff members with former positions in both the FDA and industry, who have many years of experience interacting with the FDA and other regulatory agencies.

OUR SERVICES

NSF provides regulatory solutions and strategic input across a wide variety of therapeutic areas.
Our services include:

- 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))
- Due diligence assessments of early stage start-ups for possible investment or established companies with a portfolio of approved drugs for possible acquisition/mergers
- Advice on product manufacturing and product specifications: review and preparation of chemistry, manufacturing and control (CMC) programs
- Assistance with regulatory agency meeting interactions that includes preparing briefing documents, organizing meeting preparation sessions and leading FDA meetings. These include pre-IND, end-of-phase-2 (EOP2), pre-BLA, Type A, Type C and advisory committee meetings

- Expertise in non-clinical study design and review
- Assistance in clinical protocol design and clinical trial support (e.g. CRO selection and contracting, IRB selection, drug management/labelling)
- Scientific review and medical writing support (e.g. investigator's brochures, informed consents)
- In-house or online training on U.S. regulatory IND and NDA processes and approval pathways
- Review and/or preparation of Investigational New Drug (IND), New Drug Application (NDA), Biological License Application (BLA) and Abbreviated New Drug Applications
- Abbreviated New Drug Application (ANDA) a nd lifecycle management submissions, such as prior-approval supplements (PASs), all with eCTD format
- Interim regulatory affairs professionals to fill staffing shortages

OUR COMMITMENT

NSF maintains a commitment to outstanding service and quality. We focus on achieving your business objectives through the use of sound science and proven expertise. NSF can assist across a wide range of therapeutic areas, product classifications and regulatory pathways. We are uniquely positioned to offer an integrated regulatory approach for your product's development or product portfolio with expertise in CGMP, ICH, GCP and regulatory requirements.

NSF provides your company:

- Widely recognized senior professionals with former leadership positions in both the FDA and industry
- Detailed knowledge of industry best practices that spans from early stage pre- clinical and clinical development to post-marketing approval
- Regulatory expertise across many product types: biologics (e.g. vaccines, recombinant proteins), small molecules, combination products, biosimilars, OTC and generic drugs
- Access to a broad network of global subject matter experts across many therapeutic areas
- An integrated approach that covers the complete product lifecycle from a regulatory and manufacturing (CMC) perspective

NSF INTERNATIONAL | PHARMA BIOTECH

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