

REGULATORY & CLINICAL STRATEGY SERVICES



Devices, Drugs, Biologics and Combination Products

NSF offers comprehensive expert FDA regulatory and clinical strategy support and consulting services for medical device, pharmaceutical, biotech and in-vitro diagnostics companies. The NSF regulatory team provides a range of specific services to meet all your regulatory needs across the product development and marketing continuum.

Our services include:

STRATEGIC REGULATORY CONSULTATION

- > Develop regulatory strategies for pathway to market approval/clearance
- > Formulate response strategy to FDA regulatory inquiries
- > Define regulatory strategy for post-approval changes (e.g., new indication, tech transfer, change in specifications, etc.)
- > Conduct regulatory due diligence assessments for possible acquisitions

PHARMA AND BIOTECH

- > Develop viable U.S. and EU regulatory, clinical, non-clinical, and CMC development strategies that may include orphan drug, fast track, breakthrough therapy, and/or accelerated approval pathways
- > Advise on regulatory approval pathway (BLA, NDA, ANDA, 505(b)(2), drug/biologic/device combination products)

MEDICAL DEVICES

- > Develop streamlined regulatory strategies based on product classification, submission type, predicate device recommendations, applicable regulations, standards, and guidance documents
- > Advise on primary regulatory clearance/approval pathways and programs (510(k), PMA, HDE, de novo, IDE), as well as other unique programs, such as breakthrough designation, accessory classification requests, early feasibility studies, etc.



REGULATORY SUBMISSIONS SUPPORT

Preparation and/or review of:

- > eCTD compliant IND, NDA, BLA, ANDA, DMF, and lifecycle management submissions
- > IDE, 510(k), de novo, PMA, HUD/HDE, combination product pre-RFD/ RFD, 513(g), device master files, and Q-submissions
- > Post-market submissions
- > Responses to submission deficiency letters and/or additional FDA information requests

NON-CLINICAL AND CLINICAL PRODUCT DEVELOPMENT

- > Device safety and performance testing plans, protocols, and reports (e.g., human factors evaluations, labeling comprehension studies, etc.)
- > Provide expertise in non-clinical study design and review
- > Provide clinical study design and clinical trial support (e.g., scientific review and medical writing support of clinical protocols, clinical study reports, investigator's brochures, informed consent forms, ISS/ISE etc.)

FDA INTERACTIONS

Conduct and support regulatory agency meetings, including preparing briefing documents/meeting requests, conducting meeting preparation sessions, and facilitating the FDA meeting

- > Pre-IND, end-of-phase-2 (EOP2), pre-BLA/NDA, Type A, Type C and advisory committee meetings, emerging technology program meetings
- > Q-Submissions
- > Advisory panels, including mock panels
- > Serve as U.S. agent

TRAINING

- > Customizable in-house or online medical device and pharma
- > Regulatory process and regulation training

For more information visit www.nsf.org, email healthsciences@nsf.org or call +1 202 822 1850.

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