NSF Health Sciences Medical Devices

The right people. The right solution. The first time.™

Clinical & Regulatory Strategy and Submissions Consulting

NSF Health Sciences Medical Devices' regulatory team provides a range of specific services to meet all of your regulatory needs across the product development and marketing continuum. Our consultants bring FDA and industry expertise to your projects, and our network of subject matter experts, across all therapeutic areas, provides you with quality and expertise where you need it.

- Strategic consultation
  - Regulatory strategy: product classification, submission type, predicate device recommendations, applicable standards and guidance documents
  - Emerging regulatory issues: mobile medical applications, combination products
  - Due diligence
- Regulatory submissions and support
  - Pre-market submissions: IDE, 510(k), de novo, PMA, amendments, technical file/design dossier for European CE marking
  - Post-marketing submissions: PMA supplements, 510(k)s for changes, annual reports and post-market studies
  - Responses to submission deficiency letters and additional information requests
  - Expertise for specific therapeutic or diagnostic areas
- Product development - documentation and evaluation
  - Preclinical testing: safety and performance testing plans, protocols and reports
  - Risk analysis: dFMEA, pFMEA, fault tree analysis and safety assurance cases
  - Design and development plans and traceability matrices

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- FDA and European agency interactions
  - Informational, pre-submission and submission issue meetings
  - Competent authority scientific briefings
- Advisory panel preparation and support
  - Project management from start through meeting date
  - Mock Panel practice sessions
  - Expert recruitment and management
  - Panel Materials development and review
  - Q&A practice and support
  - Dispute resolution and administrative appeal
- Clinical study design and evaluation and SR/NSR determinations
  - Patient population identification and endpoint selection
  - Protocol development support
  - Statistical analysis plans
  - Report, manuscript and publication development
  - Human factors evaluations and labeling comprehension studies
- Training
  - FDA and EU classification of medical devices
  - CE marking and U.S. marketing authorization pathways
- Global regulatory filings and global strategies

For more information about NSF Health Sciences Medical Devices, visit our website at www.nsf.org/info/medicaldevices.

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