ZENBIOMED

Your partner for best in-class services & solutions in Regulatory Affairs

We provide training, strategic consulting, staffing & project-based solutions for our clients

Seasoned consultants with decades of real-life industry experience in Regulatory assessment, strategy & submission through the entire device lifecycle

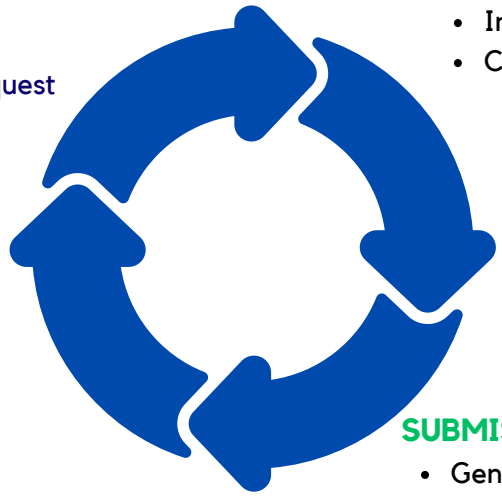
CONCEPT & PLANNING phase

- Regulatory Strategy
- Clinical Strategy
- Pre-Sub (Q-Sub) with FDA
- Breakthrough Device Designation Request

PERFORMANCE EVALUATION phase

- Review of Analytical & Clinical Protocols/Reports
- Investigational Device Exemption
- Clinical Evidence from Scientific Literature

START



POST-MARKET phase

- Reports: PMS related Reports
- Post-Market Change Control Management
- Medical Device Reporting (FDA)/Vigilance (EU)
- Clinical Evidence from Real World Data (RWD)

SUBMISSION phase

- Generation of Regulatory Submission package
- Interaction with Regulatory Bodies
- Prelaunch activities: UDI creation, Registration & Listing,

16185 Los Gatos Blvd #205,
Los Gatos, CA 95032

info@zenbiomed.com

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KEY AREAS OF EXPERTISE

Regulatory Strategy, Planning & Roadmap

- Regulatory framework in specialized areas such as CDx, LDTs, Combination Products, POC devices, SaMD, & Digital Health products
- Risk Classification of devices under different Regulatory jurisdictions
- IVDR & MDR transition
- Identification of predicates, assessment of substantial equivalence
- Assessment of Risk and IDE strategy
- Interpretation of Significant Change to a device
- De Novo pathway (Special Controls)
- Modular PMA approach
- Breakthrough Device Designation
- CLIA Waivers for IVD devices

Regulatory Submissions

- **US submissions**
  - FDA meeting representation
  - Q-subs, IDE, different types of 510(k), PMA, PMA Supplements
- **EU/UK submission**:
  - Technical File/Dossier creation
  - EUDAMED Registration
- **International Regulatory**:
  - STED or equivalent submission package creation
  - New Product Registration
  - GMP Certification & License Renewals

Other Regulatory Activities

- Address RFIs/AI requests from Regulatory bodies
- Response to FDA Form 483 & Warning Letters
- Assess compliance gaps and conduct impact analysis against new legislation & regulations
- Transition to RIMS (Regulatory Information Management System)

Medical Writing / Technical Writing

- Literature Search - generation of clinical evidence
  - Clinical Evaluation Plan & Report for EU-MDR
  - Scientific Validity Report for EU-IVDR
- IVDR Performance Evaluation Plan & Report
- Risk Management Plan & Report
- Usability: Formative & Summative Reports
- Clinical Study Protocol & Report
- Post-Market Reports: PMCF, PMPF, PSUR, SSP, SSCP

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