YOUR PARTNER IN REGULATORY AFFAIRS

BBA offers comprehensive regulatory services to assist you in achieving global success in the product approval process and post approval regulatory compliance. We will partner with you to understand your business objectives and market plans to define an efficient and effective regulatory strategy. We can develop complex regulatory strategies for you or work with your team to produce a regulatory submission that enhances your chance for product clearance with a minimum review cycle.

We take a holistic approach to guiding your program forward by providing these core regulatory affairs capabilities:

STRATEGY

- Strategic planning and regulatory guidance
- Interactions with the FDA

SUBMISSION SUPPORT

- Interpretation of standards and guidelines
- Development of bench testing protocols
- Development of biocompatibility testing strategies
- Interactions with testing houses
- Validation testing guidance and interface
- Development of animal study designs/protocols
- Interface with GLP animal testing facilities
- Design Risk Analysis

REGULATORY SUBMISSIONS

- Pre-market notifications – 510(k), De Novo
- PMA applications
- Advisory committee preparations
- 513 (g) Request for Designations
- IDE and IND
- Briefing Packages for FDA meetings (e.g.,PreSub and PreIND)
- Humanitarian Device Exemptions (HUD/HDE)
- International Dossiers
- EU Technical file, Design Dossier and CE Mark documents
- Global registrations and applications

POST-APPROVAL COMPLIANCE

- Recall strategies
- Warning letter mitigation and resolution
- Medical Device reporting and complaint handling
- Post-market surveillance reporting

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