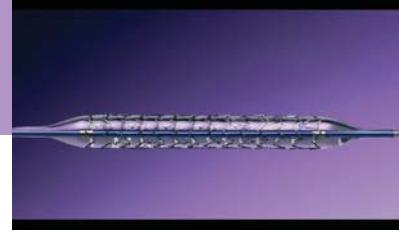


Beckloff Associates

Medical Devices Consulting Services



Support Throughout the Lifecycle of your Medical Device and In Vitro Diagnostic Products

Who is it for?

Virtual, small, and large medical device companies, and their corporate partners, that require consultation and supportive resources in the product development, approval, and post-approval phases of their medical device or in vitro diagnostic product(s).

What is provided?

Product Development Stage

- Medical Devices; IVDs; Laboratory-Developed Tests; Combination products
- Investigational Device Exemption (IDE) - Preparation and Maintenance of Applications
- Labeling Development/Compliance
- Identification of Predicate Devices; Demonstration of Substantial Equivalence; Clinical Study Design
- Product Development Planning - RFD, HDE; Manufacturing; Nonclinical; Clinical
- Regulatory Agency Meetings - Planning, Support and Conduct
- Compliance Assessments/Audits - GMP, QSR
- Medical Device Reporting - Adverse Events, Product Complaints

Approval Phase

- Application Preparation and Submission - 510(k); PMA; HDE; 513(g), CE Mark
- Identification, Screening, and Contracts with Notified Bodies

Post-Approval Phase

- Preparation and Submission - Application Supplements; Amendments; Annual Reports
- Post-Market Surveillance and Adverse Event Reporting
- Product Recalls, Corrections, Removals
- Compliance Remediation Support - Enforcement Action CAPA Responses

Contact Us:

To obtain more information, or to request a proposal for Medical Device Consulting Services, please contact Beckloff Associates at **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web page at <http://www.cardinalhealth.com/beckloff/services>

Beckloff Associates Medical Devices Consulting Services

Resourceful Solutions for Your Medical Device Development and Commercialization Needs



Expertise:

- Innovative Product Development Planning
- Regulatory Strategy Development
- Quality Management
- Risk Analysis and Assessment
- Compliance Assessments and Enforcement
- Application Preparation and Submission
- Post-Approval Support

Why Beckloff Associates?

- A track record of success spanning four decades;
- Experience with all classes of pharmaceutical products;
- A strategic global approach to regulatory planning and product development;
- Successful relationships with regulatory agencies worldwide;
- Continuity of service from the laboratory bench to the pharmacy shelf and beyond;
- A commitment to quality, efficiency, and our clients' needs;
- The leveraged resources of a Fortune 20 company.

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