

Biologics Consulting Group, Inc.

specializes in providing regulatory and product development advice to manufacturers of biopharmaceutical products. Our staff consists of experts in regulatory affairs, product manufacturing and testing, pharmacology-toxicology, statistics, clinical trial design and evaluation, and GCP Regulatory Compliance, each with extensive biopharmaceutical product experience. We are thus able to offer consulting services and regulatory support based on a full understanding of regulatory expectations and policies.

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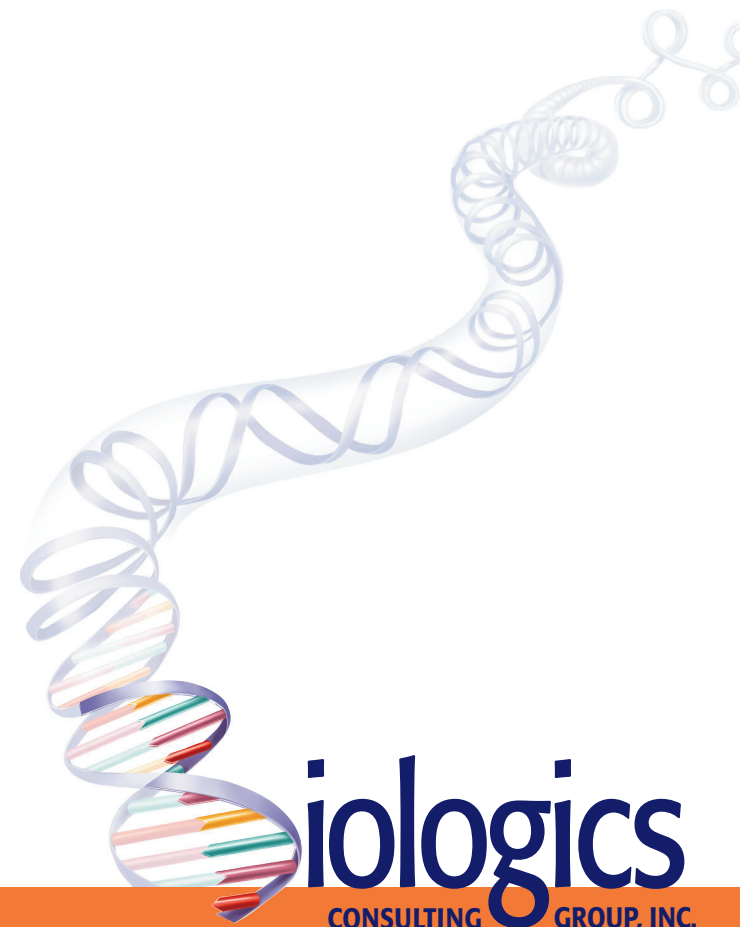
**Regulatory
Services for**

**Devices &
Combination
Products**



www.bcg-usa.com

www.bcg-china.com



Medical Device Services

Whether you need limited assistance with a manufacturing or testing protocol issue, or comprehensive management of product development, BCG has the expertise to provide you with the specific assistance you need. Because our consultants have extensive experience with FDA, including experience working at FDA, we are able to provide expert assistance with the regulatory and product development aspects of devices and combination products.

BCG Strengths

- Able to provide expert advice on FDA regulated devices and combination products
- Experience in preparation and/or review of device submissions including 510(k)s, IDEs, and PMAs
- Extensive experience with FDA requirements and regulations; in-depth knowledge and understanding of FDA expectations for device submissions
- Experience with device and combination product development issues, including preclinical data requirements, clinical trial design, device regulatory strategy development, device testing design, advertising and promotion, and post-approval studies
- Able to provide expert advice and auditing of cGMP manufacturing, facilities, processes and quality systems
- Experience developing quality systems for clinical trials including auditing clinical sites
- Experience in conducting clinical QA qualification and surveillance audits of clinical trial vendors including contract research organizations (CROs), clinical and non-clinical laboratories, institutional review boards (IRBs), and ECG core laboratories
- Extensive experience in conducting quality assurance assessments of medical device sponsors for compliance with GCP regulations including data management, clinical trial monitoring, and human subject protection
- Consultants have extensive experience in industry and government

Product Experience: Class II/III Devices

- Cell and Gene Therapy Devices, Regenerative Medicine and related devices
- In Vitro Diagnostics
- Combination Products: biologic/device, drug/device
- Cardiology devices
- Dental devices
- Cardiovascular Therapies
- Diagnostic devices and software
- Drug/Biologic delivery devices and systems

BCG Experience: Class II/III Devices

- Regulatory and scientific assessment of products and processes (gap analysis)
- Development of a Product Development Plan (PDP) for drug/device and biologic/device combination products
- Design/Review of Clinical Trials
- Design/Review of preclinical data requirements
- Development of Regulatory Strategy for devices and combination products
- GxP Audits; evaluation of vendors, facilities, clinical sites, processes and quality systems
- Preparation/Review of FDA meeting documents
- GxP training
- Design/Review of 510(k) sections/PMA sections
- Screening and oversight of contract testing organizations, contract manufacturing organizations, CRO, and clinical trial vendors
- Manufacturing process evaluation
- Regulatory submissions: IDE, 510(k), PMA, including pre-submission review and support
- Preparation/Review of Request for Designation
- Design/Review of device testing protocols
- Design/Review of post-approval studies
- Design/Review of biocompatibility and preclinical testing
- Design/Review of software validation
- Review of labeling, advertising and promotional materials
- U.S. Agent Services

BCG can assist you and your company with top-level strategic planning and evaluations related to new medical device product development. We can help resolve questions regarding regulatory pathways and achieving the most efficient path to market for new medical devices. We provide consulting services regarding FDA requirements for clinical trial design, preclinical (bench and animal) testing, post-approval studies, 510(k) and PMA requirements, and labeling and marketing claims. BCG can prepare or assist in the preparation of, and/or review regulatory submissions to FDA including Pre-IDE materials, Investigational Device Exemption applications (for approval to conduct a clinical trial), 510(k) Premarket Notifications, Premarket Approval applications to commercially market a new Class III medical device, and other submissions relating to device classification, regulatory status or regulatory pathways.

BCG has experience with combination products and can provide consulting expertise for drug/device, biologic/device, RFD (request for designation) and other related issues.

BCG can represent the client to the FDA including facilitating, planning, and organizing meetings between FDA and your company.

We also offer assistance with compliance regarding cGMP (current Good Manufacturing Practices) and QSR (Quality Systems Regulations) and can provide audits, mock FDA inspections and assistance in resolving quality and compliance issues.

We can also assist the client with understanding and compliance with respect to Good Clinical Practice (GCP) requirements. BCG works with your company to develop or improve quality systems for clinical trials and prepare for FDA inspections. Experienced former FDA Bioresearch Monitoring inspectors can train your staff on GCP essentials, from auditing vendors to mock FDA Inspections.

Brief History of BCG –

1993
Founded as
Kenimer Associates

1998
Reorganized as
BCG, LLC

1999
Opened
West Coast Office

2000
Opened
North Carolina Office

2005
Opened
Massachusetts Office

2006
Reorganized as
BCG, Inc.