# Mullis & Associates, Inc.

*Specialists in Regulatory Affairs & Clinical Studies for Medical Devices and Biotechnology*


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**Conveniently located to Athens and Atlanta**


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From Concept to Market


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**Mullis & Associates, Inc.** is a regulatory affairs and clinical studies consulting firm focusing on medical devices and biotechnology. The firm's senior management has 23+ years of corporate experience in both small and large US and European based companies. Mullis & Associates, Inc. can provide your company with management experience and technical expertise to successfully bring your new products through the FDA regulatory process.

Our regulatory affairs, quality and clinical studies expertise includes, but is not limited to, products in the areas of cardiology, urology, gastrointestinal, oncology, radiology, orthopedic and surgical devices. We have worked with varied technologies including pacemakers, leads, vascular and biliary stents, vascular grafts, ports, implantable cardioverter-defibrillators, infusion pumps, surgical irrigation devices, heart catheters, urological catheters and instruments, surgeon's gloves, antimicrobial coatings, bulking agents for urinary incontinence, hernia repair products, polymer and hydrophilic coatings, endoscopes, laser fibers, invitro diagnostics, drugs, drug delivery systems, OTC drugs, and cells and tissue for human implantation.

Our firm will work with your company from initial product concept to the point when the product is fully marketed. Whether you are a start-up company preparing an initial regulatory strategy for a first product or an established firm needing incremental resources for a critical project, **Mullis & Associates, Inc.** can provide creative and cost effective solutions. Our expertise is available to you.

**Services offered by Mullis & Associates, Inc.:**

**Regulatory Affairs**

- Develop regulatory strategy
- Create product specific regulatory plans
- Conduct presubmission reviews
- Prepare regulatory submissions: IDEs, 510(k)s,
- PMAs, INDs, NDAs and annual reports
- Plan and coordinate FDA meetings
- Assist with FDA establishment inspections
- Help solve FDA compliance issues
- Review cGMP procedures and Quality Systems
- Assist clients with CE marking products
- Provide customized training programs

**Clinical Affairs**

- Develop clinical strategy for new products
- Prepare tactical clinical plans for new products
- Prepare and file IDE and IND submissions
- Plan and coordinate FDA presubmission meetings
- Review clinical study plans
- Manage or coordinate clinical studies
- Develop investigator brochures for IRBs
- Assist with writing summaries of clinical studies
- Provide oversight for clinical study monitoring
- Preparing for and respond to Bioresearch
- Monitoring audits

**Management**

- Identify and manage contract research organizations (CROs)
- Provide RA, QA & CA management support
- Evaluate client's RA & CA resources

**Project Reviews and Due Diligence**

Review client's new product development plans
Assist clients with evaluating new products and technologies for acquisition
Participate in design reviews for new projects

Why should I choose **Mullis & Associates, Inc.**?

***Experience*** We have an outstanding track record for obtaining FDA market clearance for medical products and for resolving regulatory compliance issues.

***Empathy*** We understand the importance of "speed to market".

***Knowledge*** We have a working knowledge of the FDA regulations and how they impact your business.

***Availability*** We work with your schedule to be available when you need us.

***Confidentiality*** We maintain the highest level of confidentiality regarding your intellectual property and trade secrets.

***Commitment to Quality*** We are dedicated to providing quality work. Our goal is to meet your regulatory needs and the FDA requirements the first time.

***Ethics*** We are committed to exemplifying the highest level of ethical behavior with each client and customer.

To learn more about how **Mullis & Associates, Inc.** can help your company with its regulatory and clinical needs, please contact us at the address provided on the last panel of this brochure.