



Arkin Consulting Group Services Provided

Arkin Consulting Group offers comprehensive FDA and ISO regulatory, quality and clinical consulting services including:

[Quality Assurance & Compliance](#)

[Strategic Consulting](#)

[Regulatory Submissions](#)

[Clinical Management](#)

[Validation Consulting](#)

Since 1994, Arkin Consulting Group (ACG) has been serving the U.S. and international medical device, pharmaceutical, biologics and veterinary product industries. We provide expertise in regulatory, quality assurance and clinical management. Working with the ACG means adding years of experience and expertise to your team and partnering with consultants who are practical, cost conscious and who take a “hands-on” interest. We are a firm, whose senior professionals get personally involved in every account. We take the time to listen and learn because we are committed to building long lasting relationships. Clients gain knowledge, confidence and skills from our expertise.

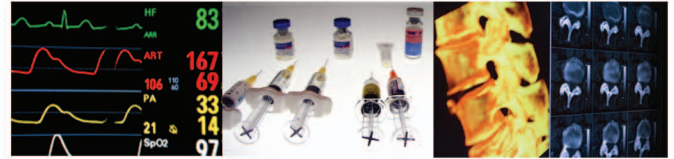
ACG has effectuated Quality Management Systems, regulatory submissions and clinical strategies for multi-national corporations in bringing new medical products to markets. We are often called upon to evaluate proposed regulatory compliance approaches, design controls, Quality Management Systems and clinical trials.

Our experience comes from working directly with manufacturers world-wide seeking to gain market entry and providing in-depth understanding of their regulatory environments and technologies. Launching products in the current regulated markets requires extensive efforts that can overwhelm company resources and potentially delay market entry without the appropriate regulatory strategy.

ACG also provides FDA-required U.S. Agent and Official Correspondent services for foreign medical product companies desiring to import into the U.S.

ACG's reputation of seasoned experience with industry and regulatory agencies distinguishes itself from other consulting firms. Our best advertising comes from current and former clients. Contact us to explore how we may bring value to your projects.

Clients gain confidence and skills from ACG because of our knowledge of and ability to combine science with business from a regulatory basis. We view ourselves not so much as the “experts,” but educators so clients can sustain the processes and expertise gained from our association on their own.



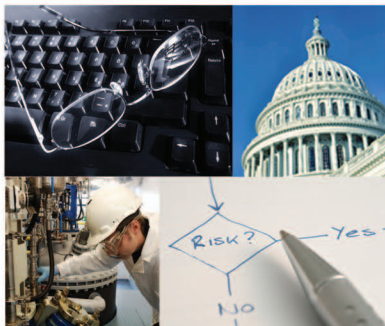
Strategic Regulatory Consulting

- PMA, 510(k), IDE, NDA, IND, HDE Submissions, Amendments, Reporting & Supplements
- Laser Product Radiation Reports
- Establishment Registrations
- Device Listings
- Experienced U.S. Agent
- Negotiations with Government Agencies
- International Dossiers, CE Mark
- US & International Strategic Reg. Planning
- FDA-483, Warning Letter Replies
- Injunction Strategies
- FDA / ISO Preparation & Attendance
- Internal Auditing
- Crisis Management
 - Recall Resolution
 - Warning Letters
 - MDR and Vigilance Reporting
 - Consent Decree Assistance



Validation Consulting & Verification

- Development of Master Plans
- Protocol Development
- Process Validations
 - Software (IQ, OQ, PQ)
 - Software Requirements Specifications
 - Software Test Planning & Protocols
 - System Testing
 - V&V Report Package
- Development of Master Plans
- Protocol Development
- Process Validations
- Software (IQ/OQ/PQ)
- Software Requirements Specifications
- Software Test Planning and Protocols
- System Testing
- SOP Development
- Validation Report Package



Quality Assurance & Compliance

- Audits (GMP/QSR, GxP, ISO, etc.)
- MDR, Complaint Systems
- Traceability
- Part 806 Response & Resolution
- Recall Response & Resolution
- FDA Warning Letter
- QSIT, HACCP
- Risk Management
- Root Cause Analysis
- Quality Systems Dev. & Audits
- ISO 13485:2003
- CMDR, CMDCAS
- Design Control Development & Audits
- CE-Mark
- Packaging, Sterilization & Labeling
- GMP/QSR Development
- Software Testing
- Labeling & Advertising Review

Clinical Planning, Management & Monitoring

- Planning/Clinical Development
- Advisory Board Charters and Hosting
 - Author Case Report Form Guidelines
 - Author Clinical Monitoring Plans
 - Biostatistical Analysis & Reporting
 - Case Report Forms Development
 - Clinical CGP Development (ICH/GHTF)
 - Clinical Project Management
 - Clinical Research Unit Design
 - Clinical Site Monitoring
 - Clinical Strategies
 - Clinical Study Size Training
 - Data Safety Monitoring Board Setup
 - Elec. Med. Records in Research Process
 - Investigator Site Setup
 - Pre-FDA/Regulatory Inspection Readiness
 - Site Monitoring (as a CRA)
 - SOP Development for Sponsors/Sites
- Product Analysis/Testing
- Business Development
 - Product Testing
 - Product Packaging
 - Third-Party Testing Certifications
- Clinical Studies for Devices, Pharma & Biologics
- Specializing in Phase I Clinical Studies
 - Training for Clinical Study Participants
 - Sponsors, PI/CI, Associates/Assistants, Techs, Lab, Personnel, etc.

ACG Product Experience

- Connection Needle Systems
- Blood Containers & Tubing
- Blood/Plasma
- Cancer Therapies
- Cardiac Monitors
- Contact Lenses & Solutions
- Diagnostic Assisting Software & Equip.
- Diagnostic Examination Systems for EKG
- Dialysis Devices
- ECG Devices
- Immunohematology Devices
- Intravenous Catheters
- In-Vitro Diagnostics
- Liver Assist Devices
- Monitoring & Diagnostic Devices
- Neuro-Muscular Stimulation Devices
- PACS Devices & Systems
- Pharmaceutical Compounding Devices
- Rehabilitation & Orthopedic Products
- Shockwave Therapy Devices
- Sterile Tubing Sets
- Textiles
- Drug Delivery Systems
 - Drug Release Implants
 - Implantable Drug Infusion Pumps
 - Isotope Seeds
 - Safety Syringes
 - Wound Healing Agents & Bandages
- Surgical Devices
 - Biopsy Needles
 - Bipolar Electrodes
 - Cannula/Trocar Systems
 - Cardiovascular, Neurovascular, Peritoneal Catheters
 - Freehand Neuro & Orthopedic Surgical Instruments
 - Keratomes, Knives & Blades
 - Lasers
 - Pre-Surgical Planning & Operative Software
 - PTCA Balloon Catheters
 - Robotic Microscopes and Instruments
 - Stereotactic Systems
 - Surgical Instruments (manual/auto.)
 - Ultrasonic type devices
 - Viscoelastics
- Surgical Implants
 - Cardiovascular and Peripheral Stents
 - Cerebral Aneurysm Clip
 - Corneal Inlays
 - CSF Flow Control Valve/Shunt Systems
 - Dental Implants
 - Glaucoma Valves
 - Intraocular Lenses
 - Spinal and Orthopedic Implants