mdi Consultants, Inc.

The Global Regulatory Experts

FDA Compliance Services

Medical Device Industry

mdi Consultants, Inc. has helped medical device companies across the world achieve FDA compliance.

Partial List of Clients

Becton Dickinson
Biogen
Everest & Jennings
Fukuda Denshi
Panasonic
Pentax
Philips Ultrasound
Playtex Products, Inc.
Roche Diagnostics
Sci-Med
Siemens

OUR PERFORMANCE GUARANTEE

If you follow our process and recommendations, we guarantee an approved 510(k).

OUR FDA COMPLIANCE SERVICES

We provide a broad range of FDA compliance services to the Medical Device Industry. Since our team is composed of former FDA officials and industry quality managers, we understand the complete regulatory and QA process for getting and keeping a product in the marketplace. Below is a list of our FDA compliance services, across the product lifecycle:

PRODUCT LIFECYCLE

Idea Generation | **Product Development** | **Launch and Lifecycle Management** | **End of Life**

- **FDA strategic planning**
- **Clinical Trial Management**
- **510(k)/PMA/DMF Submission**
- **FDA Quality System Strategy**
- **Quality System Implementation**
- **cGMP Audits**
- **Training**
- **Validation**
- **HACCP**
- **FDA Liaison – FDA communications, FDA audits**
- **Crisis Intervention – Warning Letters, Product Recalls, MDRs**
- **U.S. Agent**

+1 (516) 482 9001 **www.mdiconsultants.com** **info@mdiconsultants.com**

WHAT OUR CLIENTS HAVE SAID ABOUT US

"Your regulatory strategies for a 510(k) application versus an IDE/PMA saved the company from unwanted time delays and crippling financial setbacks. We…are fortunate to have an organization like yours to support our efforts…Please feel free to forward any potential new clients to my attention for professional or personal references."

John Giungo, VP, Design and Development, Photogenesis

"[mdi] working with the FDA reviewers was able to save us $1,000's in retesting dollars and even further delays. I would have no hesitation to recommend mdi to others in my field."

Drew Queen, Regulatory Affairs Specialist, Fukuda Denshi

"I am happy to inform you that your hard work and knowledge of the FDA rules and regulations have been…successful in helping Rozinn Electronics…This means so much to the reputation of our organization…In the future, you can be sure that anyone who needs help in regulatory affairs will be referred to MDI by Rozinn Electronics. The competence and professionalism of your company is unsurpassed in the industry."

Mark Rosoff, President, Rozinn Electronics

"24 days for clearance of 3 products, not too bad!! This is a new record in Microlife. Thank you for your outstanding work."

Gerhard Frick, Director of Regulatory Affairs, Microlife

"When colleagues want help with Regulatory issues, I tell that I had success because I had a great consulting group fighting for me and that they should give mdi a call!"

Lauren Ziegler, Senior Manager, Technical Services, Respironics Healthscan, Inc.

"Your professional handling of the FDA official and overseeing how our management responded to FDA's inquiries was an integral part in the process of the inspection. Your presence made the inspection…smoother, assured Foshan in passing the inspection and resulted in continuing compliance with the US FDA GMP and regulations preventing any interruption in our being able to ship products to the US."

Bai Xianzhong, Director, Guangong Huatong Medical Equipment Development

WHO WE ARE

mdi Consultants, Inc. is the leading quality assurance, regulatory compliance and clinical consulting firm that assists healthcare companies with market entry into the United States and Europe. mdi has been in business since 1978 and provides FDA compliance, ISO compliance, Crisis Intervention and CE Mark services to the medical device, pharmaceutical and food industries. We have an international staff of former industry executives, FDA officials and quality managers that provide expert knowledge to our clients. mdi has served over 500 companies worldwide on their important quality and regulatory issues.

---

mdi

mdi Consultants, Inc.

Main Office: 55 Northern Blvd ● Great Neck, N.Y. 11021

Phone: 1 516 482 9001 ● Fax: 516 482 0186
E mail: info@mdiconsultants.com
Website: www.mdiconsultants.com

Other Representative Locations:
California, China, Germany