

WHY CHOOSE US?

Committed to Your Success. We want your business to succeed. We pay attention to the details, listen to your concerns, give you the advice and information that you need to know, and work with you to help you reach your goal(s).

Understand Regulated Industry. We have a thorough understanding of the industries that manufacture and market food, dietary supplements, drugs (Rx/OTC), medical devices, biologics, blood products, cosmetics, colors, animal drugs and feed - to help guide your firm throughout the life cycle of your FDA-regulated product.

Extensive FDA Experience. We have a breadth of FDA experience as a result of working in FDA policymaking and "in the trenches," reviewing data, and auditing manufacturing and laboratory settings.

Science-Based Perspective. Our scientific-based backgrounds, coupled with our in-depth knowledge of FDA's regulatory requirements, enable us to effectively analyze your regulatory concerns and provide you with practical solutions.

Global Regulatory Services. In addition to our US-based experts, we have associates in the US, Europe, UK, the Pacific Rim, Australia, and Latin America who can assist you in resolving your international regulatory concerns.

Convenient Washington DC Location. Our office is convenient to the FDA offices located in the greater Washington DC metropolitan area. We are just minutes away from the Dulles International Airport. If you have a tight schedule, you can meet with us at our office and discuss strategy; we can go to the FDA for a meeting; and you can take a flight home the same day.

To obtain the regulatory expertise that you need for business success, contact us:

Phone: 703/406-0906
Toll-Free: (U.S. & Canada) 888/483-0040
Fax: 703/406-9513
Email: phoenix@phoenixrising.com

Visit our website: www.phoenixrising.com

PhoenixSM

Your regulatory guide



www.phoenixrising.com

Whether your company is global or a start-up, we can provide the help you need.

We have regulatory expertise with all products regulated by FDA.

NEED HELP WITH...

- ✓ Obtaining Premarket Approval?
- ✓ Staying in Compliance?
- ✓ Resolving Regulatory Problems?

We are a highly respected firm based in the Washington DC area with decades of combined FDA and industry experience. Our management team is composed of ex-FDA-ers who have helped shape FDA policy, worked in the labs, reviewed petitions, and inspected clinical and manufacturing facilities. We understand what the FDA wants and can read between the lines regarding FDA policies. This insight helps you save time and money in getting your product to market and keeping your product in the marketplace.

The Phoenix founders and our large network of senior consultants are experts in FDA regulations. Our consultants in the UK, Europe, the Pacific Rim, Latin America, Australia and Canada understand the specific regional/country requirements.

Please call us at 703/406-0906 or visit our website, www.phoenixrising.com. Go to "Contact Us." Then complete and submit the Quick Response Form.

WANT TO OBTAIN PREMARKET APPROVAL?

Avoid wasted time and money with our expert help which includes:

- Advising on Nonclinical Proof of Safety
- Consulting on the Implementation of Efficacy Trials
- Reviewing Manufacturing Facilities and/or Consulting on Facility Design
- Preparing Submissions to FDA (e.g., INDs, NDAs, ANDAs, DMFs, 510(k)s, IDEs, PMAs, FAPs, GRNs, FCNs, CAPs, FMFs, NADAs, 75-day Notifications, Infant Formula Petitions - Including Time-Saving Electronic Submissions)
- Assisting with Meeting QA Requirements
- Performing GxP Audits

CONCERNED ABOUT STAYING IN COMPLIANCE?

Maintain your market presence for FDA-regulated products with our services. They include:

- Advising on GxP/QA Requirements
- Performing GxP Audits
- Reviewing Product Labeling

WANT TO RESOLVE REGULATORY PROBLEMS?

If FDA actions threaten your product revenue, we can help you with the following services:

- Developing and Managing Responses to List of Observations Contained in FDA 483s and to Warning Letters
- Assisting with Development and Implementation of Corrective Action Plans
- Resolving Data Integrity Problems

WE CAN HELP YOU STAY IN COMPLIANCE THROUGHOUT THE PRODUCT LIFE CYCLE:

R&D → Nonclinical → Clinical → Premarket Approval → Manufacturing → Marketing