



From Concept To Consumer

- Pharmaceutical Production & Testing
- Clinical Development
- FDA Regulatory Submissions
- Process, Design & Facility Construction
- Safety & Environment
- FDA Compliance & Validation
- FDA Legal Services



EXPERIENCE

Active Pharmaceutical Ingredients (API)
Biotechnology
Pharmaceuticals
Nutraceuticals
Medical Devices
Defense
Electronics
Steel & Metals
Power, Energy Generation



SERVICES

Clinical Trials
CAPAs & Product Investigations
Project and New Construction Financing
Legal Assistance
Management Team Support
Regulatory Submission Assistance
Mock Audits
Training
Design Engineering & Review
IT Systems Assistance & Consulting
Investigations
483 and Warning Letter Consulting
Development & Implementation of Core Quality Systems, such as Change Control, Documentation, Training, Metrology, etc.
Vendor Audits
Development and Consulting on product parameters and process specifications
Development and Implementation of Product Labeling and Packaging Programs
Annual Product Review Services and Data Trend Analysis

RESOURCES

Over five hundred consultants with a diversity of experiences and knowledge in industry practices and government mandates, providing proven results.

Offices across the United States, China and Europe.