



SERAPHIM

LIFE SCIENCES CONSULTING LLC

REGULATORY CONSULTING & COMPLIANCE SERVICES

Seraphim provides a new approach to life sciences consulting. Seraphim, founded by industry professionals, uses cross-discipline teams to quickly deliver comprehensive, results-oriented services that focus on specific decision points, meaningful benchmarks and actionable plans. We integrate technical knowledge with a genuine appreciation for the practical considerations of resource limitations and competitive demands. Our expertise covers the full scope of the global life sciences industry, including:

Biologics, Gene & Cell Therapy	FDA & Global Regulatory Issues
Pharmaceuticals	Preclinical & Clinical Development
Medical Devices & In Vitro Diagnostics	Manufacturing & Outsourcing
Contract Research & Manufacturing	Marketing, Distribution & Reimbursement
Research & Discovery	Product

We provide a complete spectrum of regulatory and technical services including:

- Product Development & Regulatory Strategies
- Regulatory Submissions & Meetings
- Pre-clinical & Clinical Testing
- Operations, QA & QC Support
- Compliance Audits & Training
- US Agent Services
- Crisis Intervention & Resolution
- On-site Professional Staffing

Comprehensively Simple We apply a few simple principles in our work: (i) Understand the big picture; (ii) Check the details; (iii) Verify critical assumptions; and (iv) Tie it all together. These principles were honed over years of industry experience. We tell you what you want to know directly, and we do it quickly and cost-effectively. We illuminate solutions, risks and value. If requested, we can direct or help implement execution of our recommendations.

In all matters, our clients trust Seraphim's professionalism, judgment and discretion. Where needed, we can be powerful advocates, trusted advisors, impartial mediators, and effective implementers.

*"Know or listen to those who know."
...Baltasar Gracian*

Regulatory Consulting & Compliance Services

PRODUCT DEVELOPMENT & REGULATORY STRATEGIES: Our tightly integrated regulatory, technical, operational and business experience drives product development and regulatory strategies of exceptional efficiency, clarity, speed and robustness. Because we can appreciate complex interactions, we anticipate and avoid development and regulatory pitfalls. Whether it is early stage long range planning or late stage go to market planning, Seraphim will lead you to on-time and on-budget goal achievement.

REGULATORY SUBMISSIONS & MEETINGS: We have complete experience in successfully planning, drafting, editing and defending the full range of technical and regulatory documents and meetings including:

Pre-IND, INDs/IDEs/CTXs, BLAs/NDAs/MAs, 510(k)s/PMAs, IVDD/MDD Dossiers
Pre-IND, IND, Advisory Committee Meetings
DMFs, Orphan Designations & Export Application
APHIS/CDC Import, LR/SAT & Specialty Applications
Product Labeling, Marketing & Sales Materials and Scientific Publications
Adverse Events, Complaint & Compliance Actions

PRE-CLINICAL & CLINICAL TESTING: Developing robust, time and cost-effective protocols is a Seraphim specialty. We use advanced planning, vendor selection and implementation methods to minimize the risk of study failure or compliance problems. Our Outsourcing Services group can quickly source and efficiently manage the CRO/CMO services needed for any program.

OPERATIONS, QA & QC SUPPORT: We can help you dramatically improve manufacturing, analytics, and QA/QC operations. We bring years of experience in those disciplines at both management and line level responsibility. We can help with a wide range of tasks including:

Method, SOP and Policy Development
Production Process Assessment & Improvement
Outsource Planning & Implementation
 US Resident Agent Services

COMPLIANCE AUDITS: We bring the technical insight, professional experience and objectivity needed to audit systems for global GMP, GLP, GCP and other requirements. We focus on rapidly identifying root causes and practical corrective actions. We conduct all types of audits: Internal Audits, Vendor Qualification & Management, Inspection & PAI Preparation, and Due Diligence. We can audit independently or as part of a company team. With Seraphim audits, you will be confident of your systems, data and operations.

TRAINING: Seraphim's standard and customized training programs focus on your needs. Our training

programs provide your staff with the knowledge and skills needed for program success. Our training curriculum spans technical, regulatory and other disciplines. We can couple in-house training with ongoing consulting to quickly address immediate needs, with real feedback and follow-up, while eliminating travel and time off-site.

CRISIS INTERVENTION & RESOLUTION: When crisis blooms, whether a crash deadline, project emergency or FDA compliance event, we jump into action calmly and objectively. Our experts know how to solve problems quickly and effectively, with consent decrees, FDA submission rejections and objections, and 483s/warning letters. We can show you how to achieve rapid closure to the toughest problems before they escalate to disasters.

ON-SITE PROFESSIONAL STAFFING: We understand finding the right people for critical positions can be challenging. Our experts can work on-site to immediately fill your staffing needs, including manufacturing, regulatory, clinical, project management personnel for short- or long-term assignments. We can help you find, assess and train new hires so you can build the right team.

The Seraphim Team

Our experts have proven track record in strategy and implementation. We bring the rare ability to integrate understanding of board level business objectives with technician level execution. Our experts have direct operating experience with every phase of product and company development. A list of consultants and their resumes are available upon request.

The Seraphim Network – All the Issues, Worldwide

No one has all the answers. We bring the right experience to every project by drawing upon the skills of a wide range of highly trusted collaborators. We stake our reputation on giving the best answer, every time by asking the right questions and knowing who can provide the right answers. Our consultants are skilled in every business and technical aspects of developing and commercializing biopharmaceuticals, drugs, medical devices and research tools and services.

Strategic Alliances

Seraphim has established value added alliances with qualified service providers that extend beyond our global reach, technical scope and resources in business, regulatory, technical and domains. Our clients can quickly access providers with established track records.

Interested in Learning More? In fast moving markets, there is no room for error or delay. Contact us today to learn how we apply deep experience and innovation to business development in client organizations. The following brochures are available upon request:

- ❖ Seraphim Services Overview
- ❖ Outsourcing Consulting & Management Services
- ❖ Business Development & Advisory Services
- ❖ Due Diligence Services
- ❖ Legal & Accounting Support Services