



SERAPHIM

LIFE SCIENCES CONSULTING LLC

LEGAL, ACCOUNTING & CONSULTING SUPPORT SERVICES

Seraphim was founded by attorneys and consultants who understand the unique service needs of legal and accounting firms dealing with life sciences matters. Our guiding principle is that the best advice requires domain expertise as well as the ability to effectively use and communicate that knowledge in legal and accounting environments.

Our experience covers the full scope of the life sciences industry, including:

<i>Biologics & Biotechnology</i>	<i>FDA & Global Regulatory Issues</i>
<i>Gene & Cell Therapy</i>	<i>Manufacturing & Outsourcing</i>
<i>Pharmaceuticals</i>	<i>Technology / Product Assessment & Valuation</i>
<i>Medical Devices & In Vitro Diagnostics</i>	<i>Intellectual Property Development & Licensing</i>
<i>Contract Research & Manufacturing</i>	<i>Business Development & Finance</i>
<i>Genomics, Proteomics, Bioinformatics</i>	<i>Marketing, Distribution & Reimbursement</i>
<i>Research Tools & Products</i>	
<i>Research, Discovery, Preclinical, Clinical & Post-Approval Testing</i>	

Services Our support spans the spectrum of legal and accounting needs including:

*Expert Witnesses Provision
Preparation & Support
Case Analysis & Preparation
Discovery & Investigations
Mediation & Arbitration
Transaction, Offering & Counseling Support*

We partner with law firms, accountants and consultants—extending their capabilities with our regulatory, industry and technical expertise. In all matters, our clients trust Seraphim's commitment to professionalism and discretion. Where needed, we can be powerful advocates, trusted advisors, educated arbitrators or impartial mediators.

*“Counsel woven into the fabric of
real life is wisdom.”*

...Walter Benjamin

Legal, Accounting & Consulting Support Services

EXPERT WITNESSES PROVISION, PREPARATION & SUPPORT: We excel at finding, qualifying and managing the best experts. We bring the legal and technical expertise needed to identify the right expert for each matter. We employ stringent conflict assessment and document management procedures.

CASE ANALYSIS & PREPARATION: We help clients evaluate and develop life sciences cases, from complaint and brief preparation to developing technical visuals and conducting specialized research.

DISCOVERY & INVESTIGATIONS: Life sciences disputes often involve difficult technical and regulatory issues. Our experience and technical insight can make the critical difference in crafting, implementing and evaluating discovery and investigations. We specialize in analysis of large volume of complex documents, focusing on discovery efforts, and assisting in internal investigations.

MEDIATION & ARBITRATION: Our team brings the technical insight, professional experience and objectivity needed to resolve disputes quickly, fairly and efficiently. We have experience in multiple roles and are able to bring parties together, and rationally determine responsibility and consequences.

TRANSACTION, OFFERING & COUNSELING SUPPORT: We provide comprehensive expertise in negotiating and crafting technical and regulatory provisions of contracts, licenses, as well as review and opinions for offering memorandum. We provide the know-how needed to counsel on complex regulatory matters, conduct asset and business valuation and fairness opinions.

Examples of Our Recent Work

- ❖ *Patent licensing and outsourcing dispute involving a top 10 biopharmaceutical company:* Within three days we located, qualified, and retained top experts with extensive and direct experience on the highly technical legal and operational issue in dispute.
- ❖ *Medical Device Related Commercial & Government Litigation:* Provided testifying expert brief development in FDA jurisdiction and requirements.
- ❖ *Medical Device Related Professional Malpractice Case:* Provided expert on FDA requirements, professional and billing standards, and extensive case development support.
- ❖ *International Biopharmaceutical Licensing Dispute:* Provided expert in licensing and FDA requirements and discovery support, and brief development.
- ❖ *Global Phase III / Commercial API Supply Agreements:* Provided expert assistance in developing regulatory and quality provisions, technical definitions and quality agreement implementation documents.

The Seraphim Team

The experts at Seraphim and in the Seraphim Network have proven track records in both strategy and implementation. We bring the rare ability to integrate understanding of complex technical issues, with explaining them to lay and non-specialist service professionals.

Gary E. Gamerman, MS, JD. President

Gary co-founded Seraphim and leads its Professional Support Services, and is a retained expert in several cases. His experience covers legal, regulatory, scientific, and executive roles. Prior to Seraphim, Gary was the Senior Vice President of Latros Bio/Pharma Inc., where he managed its IP licensing program, government contracting, business restructuring and financing, and complex litigation. Before Latros, he was a senior attorney in the FDA/Life Sciences practices of Heller Ehrman White & McAuliffe and Fenwick & West, where he counseled bio/pharmaceutical and medical device companies and investors on due diligence, FDA regulatory compliance, product development and marketing, outsourcing and technology licensing matters. Prior to practicing law, he was an FDA reviewer, responsible for review and oversight of biotechnology and diagnostic products. Gary is on the Corporate or Scientific Advisory Boards of several companies and the Editorial Boards of leading regulatory and industry journals. He also is the inventor on six pending patents in gene therapy, vaccines, bioinformatics, encryption and other technologies. He received a BA (Biochemistry) & MS (Applied Molecular Biology, *Summa cum laude*) from University of Maryland, and a JD from George Washington University (High Honors, Order of the Coif, Law Review).

THE SERAPHIM NETWORK—ALL THE ISSUES, WORLDWIDE

No one has all the answers. We bring the right expertise to every matter by drawing upon the skills of a wide range of highly trusted collaborating experts. 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.

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*
- ❖ *Regulatory Consulting & Compliance Services*
- ❖ *Outsourcing Management Services*
- ❖ *Due Diligence & Oversight Services*
- ❖ *Business Development Services*