

STATEMENT OF QUALIFICATIONS

Business & Technology Consulting



“Your Partner for Innovation”

Table of Contents

Statement of Qualifications	1
Business & Technology Services Offered	2
Business and Technology Projects	3
Sample of Clients	6
Business and Technology Consulting Team.....	8
Code of Ethics for Consultants	13

Welcome to SPI USA, your global partner in business and technology consulting

SPI USA, Inc. is a consulting and training company with a diverse range of experience and expertise.

This Statement of Qualifications represents a brief summary of SPI USA's Business & Technology Consulting credentials.

We invite you to visit our website for more information about SPI USA, Inc.: www.usaspi.com.

Please contact one of the following SPI USA offices for further information or to request a proposal of service:

SPI USA, Inc

1050 17th Street, NW, Suite 600
Washington, DC 20036 | USA
Telephone: +1 202.587.2990
Fax: +1 949.253.5703
Email: spiusa-washington@usaspi.com

SPI USA – Irvine

2102 Business Center Dr., Suite 220E
Irvine, CA 92612 | USA
Telephone: +1 949.253.5702
Fax: +1 949.253.5703
Email: spiusa-irvine@usaspi.com

Statement of Qualifications

SPI USA is a US-based consulting firm specializing in a variety of business and technology-consulting services, including specialized training in various areas of our competence. In addition, SPI USA works in the developing world to improve local infrastructure, technology, and industry through thorough analysis.

SPI USA has established itself as a reliable and effective provider of tailored consulting and training services. The firm applies its diverse business experience and technical expertise towards the specific needs of each client.

An SPI USA Senior Consultant manages each specific service with support from in-house consultants and affiliated experts. SPI USA experts are selected from a personal network of proven independent consultants and well-established professors at renowned academic institutions.

SPI USA also possesses a strong global perspective. SPI consultants have extensive international experience, which provides clients the opportunity to reach markets and develop partnerships worldwide. SPI USA's international activities are supported through five affiliated offices located in Europe and the Republic of China.

SPI USA's extensive network and in-house capabilities provide clients the necessary competitive edge to remain successful in highly dynamic industries.

Business & Technology Services Offered

- ✓ High technology market assessments and market entry strategy development for the United States, European Union and The People's Republic of China markets.
- ✓ Consumer product market assessments and market entry strategy development for the United States, European Union and The People's Republic of China markets.
- ✓ International partnering opportunities in support of market expansions, R&D needs, and technology acquisitions.
- ✓ R&D and Innovation strategic planning support for companies in dynamic and fast track industries.
- ✓ Technology and manufacturing feasibility studies.
- ✓ Business Incubator development and implementation strategies in support of public and private entities.
- ✓ National and regional Science & Technology policy assessments and framework strategy development in support of public entities.
- ✓ R&D project management support to public entities such as the European Commission (DG-Enterprise, DG-Research).
- ✓ National and international public program assessments.

Business and Technology Projects

- **Commercialization of Ceramic Products in the United States** – Identified and analyzed the necessary requirements to reinforce a European manufacturer's presence in relevant U.S. market segments. This involved establishing an overview of the U.S. market and developing a strategy that leveraged the U.S. market and specific buyer channels in support of the client's export objectives. (Client - Ceramic Manufacturer)
- **Priority Market Regions in the United States** – Analyzed the U.S. market and identified regions with high concentrations of potential customers and low concentrations of competitors in order to determine the key regional markets to establish sales representatives. (High Technology Product Manufacturer)
- **R&D and Innovation Company Strategic Plan** – Developed a strategy that identified and detailed the R&D and Innovation projects necessary to meet a pharmaceutical company's business strategy. Human and financial resource requirements were determined. Possible financing opportunities through public agencies were identified and assistance provided in submission of requests. (Pharmaceutical Manufacturer)
- **R&D and Innovation Project Financing Strategic Plan** – Identified potential opportunities for public funding through national and international programs designed to support R&D and Innovation projects. The strategy included an ongoing process to assess relevant programs and potential partners on an annual basis. (Software Developer)
- **Leonardite Vendor Survey and Supplier Assessment** – Surveyed suppliers across the United States of America and Canada for product quality, price, service, and other criteria. Assessed each supplier based upon the client's requirements. (Fertilizer Manufacturer)
- **Market Development and Client Approach** – Identified the pertinent individuals within a large international firm, contacted them on behalf of the client, developed a rapport, established and supported meetings between the client and the international firm. (Software Developer)
- **Technology Innovation Center Expansion Feasibility Study** – Assessed the market opportunity and investment requirements to expand an existing technology incubator's capabilities to include wet lab facilities. (University)
- **Small-Scale CGMP Manufacturing Facility Study** – Assessed the market opportunity for establishing a small-scale CGMP biopharmaceutical manufacturing facility in the northern U.S. (Pharmaceutical Manufacturer)
- **Macau Business Incubator Feasibility Study** – Conducted a feasibility study to establish a business incubator in Macau. The most relevant economic sectors were identified and a business incubator strategy was developed with the aim of improving the economic development of the region. (Private Investment Firm)

- **Patent Portfolio Assessment** – Conducted an assessment of a high technology company’s patent portfolio. The assessment included an analysis of the global market opportunity for resulting products. (Private Investment Firm)
- **Bridging Innovation Between the U.S. and Portugal** - Conducted a review of American and Portuguese innovation in several technology sectors. Partnering opportunities were identified and action plans developed in support of the opportunities. (Not-For-Profit Organization)
- **Partnering Opportunities in the U.S. and European Biotechnology Sectors** – Developed an overview of the trends and opportunities in the field of Biotechnology worldwide with a focus on the U.S. and Europe. Organized a mission to the U.S. and Europe to develop contacts within relevant Biotechnology companies and organizations. (Chinese Biotechnology Consortium)
- **Egyptian Food Processing Technology Centre Strategy and Industry Support** – Conducted a Technology Centre Feasibility Study for the Egyptian Food Processing Sector. Assessed the processing capabilities of 15 Egyptian food processors and provided recommendations on process and equipment upgrades to improve the processors’ competitiveness in the international market. (Egyptian Government)
- **The Development of a Mozambique Science & Technology Framework Strategy** – Provided assistance to the Mozambican S&T Ministry with regard to creating potential policies and programs designed to leverage the positive attributes of the current Mozambican S&T sector towards long-term sector growth and stability. (World Bank)
- **The Impact of the e-Economy on Entrepreneurship and Start-up Development in the ICT Sector** – Conducted a study on the impact of the e-Economy on entrepreneurship and start-up development in the Information and Communication Technology sector of the European Union. This included identifying and recommending policies that have had the highest positive impact. (European Commission, DG-Enterprise)
- **Evaluation of the European Program Socrates, Area of Engineering 1995-1999** – Conducted an analysis of the impact of the Socrates Program, a European Union initiative, in the field of studies in engineering and technology. The assessment involved an extensive survey across several European countries. (European Commission, DG-Education)
- **Albania: Agribusiness Sector Definitional Mission** – Assessed the Albanian Agribusiness sector and identified infrastructure projects that would improve the sectors export market potential. Developed a Scope of Work to conduct a feasibility study on the modernization and upgrading of the Durrës port bulk feed terminal. This recommendation was well received by the Albanian government and had significant potential for U.S. grain exporters (United States Trade and Development Agency)

- **Strengthening Market Access Opportunities for SMEs in the Caribbean Agri-Food Industry** – Analyzed the competitiveness and export capacity of SMEs in the agri-food sector of the Caribbean Community (CARICOM). Member States: Antigua and Barbuda, Barbados, Dominica, Guyana, Haiti, Jamaica, St. Lucia, St. Vincent, and Trinidad and Tobago. Increased SMEs’ knowledge and compliance with food safety requirements, standards, and trade rules in order to improve their access to regional and international specialty food markets. (Inter American Development Bank).

- **India: Cold Chain Improvement Definitional Mission** – Assessed the Cold Chain infrastructure and capability within India’s agribusiness and biotechnology sectors. Developed Scopes of Work for cold chain technical assistance programs. The Scopes of Work detailed a workshop series designed to further develop and integrate India’s cold chain. The workshop series was complimented by a U.S. mission that focused on applied cold chain practices in the U.S. (United States Trade and Development Agency)

Sample of Clients

- Abbott Laboratories
- AgroMisr
- ATRAL-CIPAN Group
- Bio Reliance
- Biotecnol
- Boston Life Sciences
- Charles River Labs
- Colorado State University
- Dare Group Ltd.
- Egyptian Private Sector Development Programme
- El-Mohandes National Food Products
- El Nasr
- El Tanbouly
- Elim Biopharmaceutics
- European Commission Directorate of Education & Culture
- European Commission Directorate of Enterprise
- European Commission Directorate of Research
- European Commission Directorate of Information Society
- Farm Frites
- Febrfarm
- Frezite, Ferramentas de Corte
- FLAD – Fundação Luso-Americana
- Grupo Visabeira
- Hagerstown Community College
- Hellsinki University of Technology
- Hong Kong Productivity Council
- Human Genome Sciences
- Instituto Pedro Nunes
- Inter-American Development Bank
- JMS Singapore
- Maamoun Group
- Northeast Biomanufacturing Institute
- Orouba Agrifoods Processing Company
- ParaRede ICT
- Paragon BioServices Inc.
- PME Capital
- PREMAS
- Sekem Group
- Tomorrow Options
- Tradecorp

**STATEMENT OF QUALIFICATIONS
BUSINESS & TECHNOLOGY CONSULTING**

- United States National Institutes of Health (NIH)
- United States Trade and Development Agency (USTDA)
- University of Maryland Baltimore County (UMBC)
- The Wadi Food Processing Company
- The World Bank

Business and Technology Consulting Team

Mark Spinoglio – mspinoglio@usaspi.com

Mr. Mark Spinoglio is a Senior Consultant with SPI USA – Irvine. Mr. Spinoglio manages project teams located in the United States, Europe and Asia on international assignments that assist companies in creating growth through product development, leveraging R&D, market expansions and business-to-business partnerships.

As a consultant with SPI in Europe for a number of years, Mr. Spinoglio managed strategy development projects for the European Commission, which allowed him to establish a strong network of Science & Technology experts within Europe and other regions of the world. Mr. Spinoglio also developed a range of strategies for public entities designed to attract and support S&T based companies on a regional scale such as incubators and technology centers.

Mr. Spinoglio held several management positions with The Clorox Manufacturing Company at the manufacturing plant and corporate levels. He coordinated the production at 8 facilities nationwide, 65 million cases annually, which involved managing the support of various company departments and national suppliers. While with The Clorox Manufacturing Company, Mr. Spinoglio developed a product launch strategy for the company's largest product conversion. This involved working closely with the company sales and marketing groups, 8 manufacturing facilities and several national suppliers.

Mr. Spinoglio holds a Master of Science degree from the University of California - Davis, College of Engineering. While associated with the University, Mr. Spinoglio conducted research in the area of postharvest product cooling methods. He carried out engineering activities for the Cooperative Extension that included designing on-farm cold storage facilities incorporating forced air precooling and consulting farmers and processors on product packaging and cooling techniques.

Edward M. Sybert – esybert@usaspi.com

Mr. Edward M. Sybert is a Senior Consultant for SPI USA, Inc. Mr. Sybert was recruited by the University of Maryland in 1984 to develop and direct a Biotechnology Program, aimed at assisting the growth of the biotechnology industry in the state. While at Maryland, he served as director of the Technology Advancement Program, a business incubation program for technology start-ups.

With over thirty years experience in biotechnology and engineering, Mr. Sybert possesses invaluable experience in all aspects of bioprocessing and protein production. In addition to his University experience, Ed has consulted on a number of bio facility design projects, providing guidance on CGMP regulatory compliance, facility layout and equipment selection. He has held several management positions at companies such as Per Immune, Inc., where he was Director of CGMP manufacturing facilities and Bio Science Contract Production Corp. where he was Vice President of Operations. Other positions he has held are Vice President, Process and Product Development, IGI

Biotechnology, Inc., Manager of the Fermentation Production Plant at Fr. Detrick, MD and Microbiologist, Bioproducts Research Department, W. R. Grace & Co.

Douglas Thompson – douglasthompson@spi.pt

Mr. Douglas Thompson is an Economic Consultant for SPI in Portugal. During his extensive career, Douglas has provided consulting to several clients within the private and public sectors. In this capacity, Douglas has provided extensive mathematical, econometric and statistical analysis, as well as financial modeling – he has also conducted several seminars and customized training courses for client staff.

Mr. Thompson has a vast experience in interacting with international agencies, such as the European Commission, the World Bank and the European Bank of Reconstruction and Development, among others. Besides, Douglas also has a comprehensive experience in relating with other foreign Governments/Institutions, such as the Government of Azerbaijan, Guyana, Thailand and Poland, for instance.

Ashish Agarwal

Mr. Ashish Agarwal is the founder-CEO of ONCO Life Sciences Pvt. Ltd., established in 2005 and based in Pune, India. He is a first Generation Entrepreneur, a Gold medalist in pharmacy with a degree in Management. He commands more than a decade of diversified experience in Pharmaceutical, Diagnostic and Healthcare Industry with the first step into the industry set in 1990. In his capacity he has experience across all departments of a healthcare corporation including New Product development, Production, Corporate Affairs, Sales, Marketing, Commercial, Logistics and International liaison and affairs.

Tom Burkett, Ph.D

Dr. Burkett is an associate professor and director of the Biotechnology and Biomanufacturing program at The Community College of Baltimore County located in Catonsville, MD. In addition, Dr. Burkett is a regional director for the Northeast Biomanufacturing Center and Collaborative (NBC²); a National Science Foundation funded Advanced Technology Education Center.

Colman Casey, Ph.D

Dr. Casey is currently employed by the University College Cork and responsible for setting up a training partnership between universities, technical institutes and the National Training Authority in Ireland (Fás) to service the needs of the pharmaceutical industry. He spent seven years as General Manager of an FDA/EMEA regulated multinational biopharmaceutical manufacturing company with over 900 employees. He managed almost \$200 million of capital investment projects covering additional capacity and associated infrastructure and CGMP upgrades.

Alison Demarest

Alison Demarest has more than 20 years of experience in biotechnology and FDA-regulated industries under GMP and GLP, in both consulting and operating companies. She is a principal of Meridian BioGroup LLC, a compliance and validation service provider to the Maryland biotech community. Prior to Meridian BioGroup LLC, Ms. Demarest was director of quality and regulatory for BioReliance, an Invitrogen company and one of the largest contract biosafety/toxicology testing firms in the world. She is a member of the PDA TRI Education Advisory Committee and a contributor to the ISPE Professional Certification Commission exam.

Barry Friedman, Ph.D

Barry A. Friedman, Ph.D., is a Senior Consultant in the Biotechnology and Aseptic Processing Arena. Dr. Friedman was most recently associated for seven years with Cambrex Bio Science Baltimore, a contract manufacturer of GMP bulk biopharmaceuticals located in Baltimore, MD, as the Director, Quality Control. Prior to 2000, Dr. Friedman was the Laboratory Director for Chesapeake Biological Laboratories, a contract Aseptic Fill 'n Finish manufacturer located in Baltimore, MD.

Dr. Friedman has over 30 years of industrial managerial experience in various aspects of biopharmaceuticals and medical devices to include quality control, sterility assurance and fermentation technology. In addition to the associations listed above, other associations have included W.R. Grace, Sigma Chemical Co., Sherwood Medical, Becton Dickinson, American Cyanamid and Union Carbide.

Nuno Goncalves

Nuno Gonçalves is a Junior Business Development Consultant for Sociedade Portuguesa de Inovação (SPI USA), currently located at the company's Washington, D.C. office. Mr. Gonçalves helped initiate the office, having been its first permanent staff, and is currently responsible for project proposal work involving development banks, aiming at increasing SPI's business in the field, as well as office management. He works on a daily basis with other SPI offices worldwide and the identification of potential opportunities and clients are also among his responsibilities.

Prior to moving to Washington, Mr. Gonçalves was located at SPI USA's Irvine office, in California, and he was involved in international consulting projects, mainly in developing countries, and usually financed by development banks and donor organizations. His duties included executive research, strategic assessments and development of work methodologies, elaboration and edition of technical reports, and design and production of training materials.

During his stay in SPI USA's Irvine office, Mr. Gonçalves' was also responsible for the management and marketing of SPI USA's Open Enrollment Seminars on Biotechnology. In this capacity, he oversaw the seminars' organization and logistics, interacted with partners, lecturers and attendees, managed marketing activities and developed cost/revenue analysis for each event. Before joining SPI, Mr. Gonçalves was an intern at the world renowned Institut Français du Pétrole (IFP), in Lyon,

France, where he developed computerized models of heavy crude residue hydrocracking reactors. He worked in close collaboration with experimental researchers and senior scientists at IFP. Mr. Gonçalves has a Master's degree in Chemical Engineering from the Technical University of Lisbon, Higher Institute of Technology.

Jon Gryskiewicz

Jon Gryskiewicz is a Junior Consultant for Sociedade Portuguesa de Inovação (SPI USA). Mr. Gryskiewicz has developed expertise in a range of activities, including project proposal creation and regional networking. Prior to SPI, he worked as a research assistant for Georgetown University and the J. William and Harriet Fulbright Center where he developed strong research, analytical, editing, and writing skills in a number of fields, including world history, international treaties, and global peace.

Mr. Gryskiewicz is currently responsible for SPI USA's activities in the Washington, DC area. He aims to increase SPI USA's business with international development banks, delivers top quality business consulting services, and works to develop nations around the globe. Jon has advanced French language skills.

Mr. Gryskiewicz has a Bachelors degree in Government and History with a minor in English from Georgetown University. He graduated *magna cum laude* with an honors thesis in intelligence history. His research work was recently published.

Collins Jones, Ph.D

Dr. Collins Jones is the coordinator for the Biotechnology Program at Montgomery College. In this capacity he works closely with a number of leading Biotechnology companies in Montgomery County including BioReliance, Human Genome Sciences and QIAGEN Sciences to develop and implement a curriculum that is current and industry relevant. The curriculum provides laboratory-based instruction in proteomics, genomics, immunology, tissue culture, high throughput methods, and biomanufacturing including bioprocessing. In addition to his duties at Montgomery College, Dr. Jones serves as adjunct professor and advisor to the Biotechnology Masters Degree program offered by the Johns Hopkins University and is a consultant and facilitator for Team Business USA. He is also a co-founder of TechnoVisions, a company dedicated to creating multimedia resources for the Biotechnology community.

Alex McClung

Mr. Alex McClung has more than nineteen years of experience in Manufacturing, Quality and Regulatory Affairs management. He has worked with companies of all sizes from start-ups to Fortune 500. Mr. McClung has led more than 20 US and international regulatory inspections, including FDA audits, that have opened multiple overseas markets and secured or defended domestic franchises worth over \$4 billion/year. He has directed and collaborated in the production and commercialization of several drugs such as Neupogen®, Neulasta®, Epogen®, Procrit® and

AraNesp®. Alex McClung has developed several regulatory documents for medical device and biotech product approvals, and executed corporate regulatory strategies to achieve unique de novo product classifications to protect patent positions and create substantial barriers for competing products. He has led multi-layered organizations of up to 300 people and managed inter-departmental budgets of over \$35 million.

Semih Oktay, Ph.D

Dr. Semih Oktay is the President and founder of CardioMed Device Consultants. Prior to founding CardioMed, he was Vice President of Regulatory Affairs and Engineering at MicroMed Laboratories, Inc (Petaluma, CA). In this capacity, Dr. Oktay provided engineering and regulatory consulting services to the medical device and related industries, and managed MicroMed's east-coast office.

Paula Shadle, Ph.D

Dr. Paula Shadle is founder of Shadle Consulting, which offers consulting services for biotechnology and biopharmaceutical firms in quality, process development, and strategic planning to build quality systems. Prior to founding Shadle Consulting, Dr. Shadle worked in technical and quality control/assurance positions of increasing responsibility at Chiron Corporation, Scios Inc., GlaxoSmithKline PLC, and Bayer Corporation. At GSK she was director of downstream process development and biopharmaceutical quality operations, and oversaw QA, QC, analytical methods, and validation. Dr. Shadle was director of quality control of marketed products at Bayer Corporation.

Ben Woodard

Mr. Woodard is the Director of the University of Maryland, Bioprocess Scale-up Facility. He is an experienced laboratory manager and department director with over twelve years of fermentation, cell culture and production purification experience. Before obtaining his present director position at the University of Maryland, he was the Manager of the Bioprocess Scale-up Facility. Mr. Woodard is an established instructor and has managed many of the University of Maryland's key outreach programs.

Code of Ethics for Consultants

ARTICLE I: Consultants, while always maintaining high standards of personal and professional conduct, shall:

- a. Accept responsibility for their actions.
- b. Undertake projects and accept responsibility only if qualified by training or experience, or after full disclosure to their employers or clients of pertinent qualifications.
- c. Maintain their professional skills at the highest degree and recognize the importance of continued personal development and education.
- d. Advance the integrity and prestige of the profession by practicing in a dignified manner.
- e. Support this code and encourage colleagues and co-workers to act in accordance with this code.
- f. Support the professional society by actively participating and encouraging colleagues and co-workers to participate.
- g. Obey the laws of the country in which the work is being performed.

ARTICLE II: Consultants shall, in their work:

- a. Provide the necessary project leadership to promote maximum productivity while striving to minimize costs.
- b. Apply state-of-the-art project management tools and techniques to ensure schedules are met and the project is appropriately planned and coordinated.
- c. Treat fairly all project team members, colleagues and co-workers, regardless of race, religion, sex, age, or national origin.
- d. Protect project team members from physical and mental harm.
- e. Provide suitable working conditions and opportunities for project team members.
- f. Seek, accept and offer honest criticism of work, and properly credit the contribution of others.
- g. Assist project team members, colleagues and co-workers in their professional development.

ARTICLE III: Consultants shall, in their relations with employees and clients:

- a. Act as faithful agents or trustees for their employers or clients in professional or business matters.
- b. Keep information on the business affairs or technical processes of an employer or client in confidence while employed, and later, until such information is properly released.

**STATEMENT OF QUALIFICATIONS
BUSINESS & TECHNOLOGY CONSULTING**

- c. Inform their employers, clients, professional societies or public agencies of which they are members or to which they may make any presentations, of any circumstances that could lead to a conflict of interest.
- d. Neither give nor accept, directly or indirectly, any gift, payment or service of more than nominal value to or from those having business relationships with their employers or clients.
- e. Be honest and realistic in reporting project cost, schedule and performance.

ARTICLE IV: Consultants shall, in fulfilling their responsibilities to the community:

- a. Protect the safety, health, and welfare of the public and speak out against abuses in those areas affecting the public interest.
- b. Seek to extend public knowledge and appreciation of the project management profession and its achievements.

From: "Ethics for Project Managers". Proceedings of the 1982 PMI Seminar/Symposium on Project Management.