BioLink LIFE SCIENCES, Inc.

250 QUADE DRIVE, CARY, NC 27513 • 919-678-9478 • Fax 919-678-9474 • E-mail: biolink_life@yahoo.com

OUR MISSION

Our mission is to provide high quality consulting services to the life sciences industries, with a particular focus on the needs of clients in the pharmaceutical, biotechnological, and medical device industries. We will meet or exceed our customers' requirements and expectations.

AREAS OF EXPERTISE

BioLink Life Sciences, *founded in 2001, provides consulting and contract R&D services directed to chemical modification of drugs, polypeptides, and proteins. We supply both well-known and custom-designed PEGylation reagents. We design/execute/manage projects and programs for product development, including synthesis/process development to meet GMP requirements, analytical methods development and validation in compliance with GLP, design and implementation of Quality programs, and process transfer from small to commercial scales. As part of our services, we review and analyze data, and then summarize it in specific formats for oral or written presentation internally or to the regulatory, scientific, business, or venture capital communities. We complete technology assessments in a spectrum of life science-related areas, and are registered to practice before the United States Patent and Trademark Office. In this last capacity, we also manage Intellectual Property for clients.*

BioLink *draws on a network of associates to provide the best expertise for its customers. Through these associates we provide services in areas such as:*

- *Process Engineering*
- *Warehousing*
- *ISO 9000 Certification*
- *Chemistry/Biochemistry*
- *Medical Device Manufacturing & Validation*
- *Intellectual Property Management.*
- *Sterilization Microbiology & Engineering*
- *Quality Assurance*
- *Quality Systems Auditing*
- *Analytical Methods Development*
- *Marketing Support*
- *Health Care Communications*

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SERVICES

- ✓ **Project Management:**
  - o Program or project coordination
  - o Vendor identification, audit and qualification
  - o Protocol design and writing
  - o Protocol execution
  - o Data analysis and report writing
  - o Data and report review
  - o Contract R & D management

- ✓ **Technology Assessment:**
  - o Technology review
  - o Comparison of internal technologies with the "State of the Art"
  - o Patent review and analysis
  - o Patent preparation, submission, and management

- ✓ **Drug Discovery & Development:**
  - o NO sources
  - o Oxidant scavengers

- ✓ **Contract R & D:**
  - o Development of client technology from concept to product
  - o Custom synthesis in support of client technology
  - o Analytical methods development & validation in support of client technology
  - o Custom database searches

- ✓ **Technical Writing:**
  - o Reports
  - o Program or project reviews
  - o Reviews customized for the business, regulatory, scientific, or venture capital communities
  - o Regulatory submissions: Technical reviews/CMC/IND/NDA/BLA/EMAA experience
  - o Proficient in meeting ICH E3 and E6 guidelines, requirements for specific journal styles

- ✓ **Regulatory Compliance:**
  - o SOPs
  - o GMP SOPs
  - o Training
  - o Audits

- ✓ **Intellectual Property Management:**
  - o Comparison of internal technologies with the "State of the Art"
  - o Patent review and analysis
  - o Patent preparation, submission, and management

- Coordination with external counsel

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ABOUT DEANNA NELSON, Ph.D.

*Deanna Nelson, Principal, **BioLink Life Sciences, Inc.**, has over 25 years of experience in the pharmaceutical industry, a Bachelor of Science Degree in Chemistry and Mathematics, and a Doctor of Philosophy Degree in Organic Chemistry, coupled with continuing education in areas critical to the industry. Deanna developed her expertise working in projects such as:*

- ***Drug development**: Deanna has experience in synthesis, analysis, formulation, manufacturing, sterilization, and packaging of small molecule drugs, primarily as IV products.*

- ***Therapeutic protein development**: As a core member of Baxter's Hemoglobin Therapeutics Division, Deanna led project teams charged with the development of synthesis and analysis of existing and innovative therapeutic hemoglobins. She also orchestrated manufacturing process development and technology transfer from bench-top scales through large laboratory preparations into pilot and manufacturing facilities in the U.S. and Europe. In doing so, she wrote raw material specifications, batch records, product specifications, test methods and related validation summaries, and GMP manufacturing documents.*

- ***Project management:** Deanna has developed and executed both short- and long-range plans that integrated efforts across project teams and were effective in meeting goals. She recruits and hires the right people and then delegates responsibilities in a way that empowers them to execute in parallel with other team members. She persistently conveys a sense of urgency and drives for results and success within project time lines.*

- ***Program management**: In addition to her experience in managing technical programs, she is an experienced Radiation Safety Officer who has demonstrated compliance under a broad-scope license for radioactive materials.*

- ***Technical writing & presentations**: Deanna has a record of publications and presentations that attests to her outstanding ability to complete research in an area, organize the data and material, and convey the information in an interesting, intelligible manner.*

- ***Technology assessment**: Deanna has participated in teams assessing the state of the art and break-through technologies in materials, drug delivery, new therapies, new diagnostics, new methods for pathogen inactivation, and the like.*

- ***Regulatory Compliance**: Deanna has written and implemented compliance programs that include elements such as SOPs, IQ/OQ/PQ, process validation, training, and change control.*

- ***Intellectual property management**: Deanna is a U.S. Patent Agent and is registered to practice before the United States Patent & Trademark Office.*