



BioLink

Life Sciences, Inc.



The BioLink Team

The BioLink Life Sciences' Team is defined and characterized by the breadth & depth of our scientific knowledge and significant experience. The team has developed small molecules and biologicals in both large and small companies. In addition, we all have significant experience in providing high quality contract laboratory services to the industry. We are committed to working with you to achieve the results that you expect and require for your development program.

High Quality Science and Service

BioLink Life Sciences provides high quality contract laboratory services to small and mid-size companies engaged in drug development. We believe that our services will be of particular benefit to small start-up pharmaceutical companies that may not possess the capability to carry out the required development studies to enter their active pharmaceutical ingredient (API) into clinical studies. At the BioLink facility located in Cary, NC, we have the resources to complete the necessary development work required for the CMC section of an IND.

Bottom Line On Top – Work Smarter

- We do it right the first time. Quality, timeliness, value and responsiveness to customer needs are built into our programs.
- We are committed to scientific excellence.
- Our goal is to develop a long-term relationship with your company and work with you to create customized scientific plans to meet the needs of your program. The status of work will be communicated regularly across levels and functions between BioLink and you so that no surprises occur.

Services/Capabilities include:

- **Synthesis**
- **cGMP Compliant Analytical Method Development and Validation** for all dosage forms of drugs, supplements and nutraceuticals, devices, and combinations. We provide quality control, stability testing, and other technical support needed in the development of pharmaceutical products including a wide range of dosage forms (tablets, capsules, liquids, topicals).
- **Compatibility testing** associated with solid oral dosage forms and sterile injectable and parenteral product primary packaging (bags/ sets, ports, etc.)
- **Preformulation and formulation development,**
- **Compendial testing** per current USP/NF, EP, BP, JP, ACS, AOAC Monographs
- **Reference standard characterization**
- **Residual solvents testing**

Quality Assurance/Compliance

- Independent Quality Assurance unit
- Comprehensive written SOPs
- Instrument calibration & maintenance
- Exception management (LIR, Deviation, CAPA Systems)
- Material controls

Chemistry Testing

- Raw Materials, in-process and finished product testing
- Compendial testing using USP, BP, JP, EP, A13, AOAC Monographs
- Reference standard characterizations
- Test method qualification and validation
- Method validation/development/transfer

Highest Quality Science & Service

Work Smart with BioLink's Team

Our team of highly experienced pharmaceutical scientists and analytical chemists possesses a broad range of product development experience with different classes of large and small molecules. Our team has the scientific knowledge, capability and experience to drive your projects forward and to ensure deadlines are met.

- Pharmaceutical, biopharmaceutical and service provider industry experience
- Expertise in synthesis, analytical chemistry, pre-formulation, formulation, and product development
- Senior team has over 100 years combined experience

We have an experienced management team and scientific staff, who have received their training and expertise from leading companies including Baxter, Motorola, Mylan, Rainin, and Cardinal Health. We leverage our experience to prepare customized scientific strategies to complete high quality development work, prevent excessive development costs and product delays that can result from inadequate planning. We work closely with our clients through multi-level communications so they can be assured that important deadlines will be met. Our long-term involvement in a wide range of pharmaceutical product development programs gives us a valuable perspective that can help you avoid overkill and/or shortcuts that inevitably cost development programs time and money.

Services/Capabilities continued:

Analytical Development

- Method development & validation
- Preformulation support
- Analytical support of product development
- Method optimization & transfer
- Characterization of reference standard
- Forced degradation studies

Formulation Development

- Hard-shell capsules
- Liquids (solutions, suspensions, emulsions)
- Topicals (creams, ointments, gels, Lotions)

Pharmaceutical Consulting

Our highly experienced staff can offer expert consultation in the areas of CGMP, regulatory affairs, quality control, quality assurance and validation to the pharmaceutical and biopharmaceutical industries



Benefits of Working with BioLink

Our objective is to become your preferred provider of high quality contract laboratory services.

BioLink Life Sciences, Inc.

250 Quade Drive, Cary, NC 27513
919.678.9478 • www.biolinkonline.com