

# We provide better solutions

BioLink is a contract research organization that provides a broad spectrum of services from Research & Development to Reformulated Drugs.

We offer a full range of product development, services including custom synthesis, process development, analytical method development and validation, stability studies, GMP release of API and drug products, CMC services, and reference standard synthesis & characterization. State-of-the-art instruments, cutting-edge technologies and experienced scientific staff ensure high quality and efficient services to support drugs, biologicals, devices, and nutraceuticals.

## Custom Synthesis (Milligrams to Kilograms)

- Synthetic route design
- New Chemical Entities
- Drug metabolites and degradants
- Analogs & congeners of lead compounds
- Reference standards

## Specialty Synthesis

- Process research & scale-up
- Stable-isotope labeled compounds
- PEG derivatives

## Isolation and Purification

- Preparative chromatography, including preparative HPLC
- Flash chromatography
- Liquid/liquid and solid phase extraction
- Recrystallization

## Structural Elucidation & Physico-chemical Characterization

- NMR ( $^1\text{H}$ ,  $^{13}\text{C}$ ,  $^{32}\text{P}$ ,  $^{19}\text{F}$ ), FT-IR, UV-Vis, MS, and LC-MS
- Assay and Purity (HPLC, GC, IC)

## Analytical methods development, validation & testing per FCC, ICH and FDA guidelines for:

- Nutraceuticals
- Drug substances and excipients
- Oral, topical and liquid dosage forms
- Proteins and peptides
- Medical devices

## Specialized Testing

- Melamine content in raw materials, ingredients, foods and formulas

## Consultation Activities

- DMF and CMC review
- Product development and formulation development



**Dr. Jie Li, Synthesis/Process Chemistry**  
jieli@biolinkonline.com

**Mr. Walter Holberg, Analysis**  
wholberg@biolinkonline.com

**Dr. Deanna J. Nelson, President**  
dnelson@biolinkonline.com

Phone: 1.919.678.9478

Fax: 1.919.678.9474

[www.biolinkonline.com](http://www.biolinkonline.com)

