

CV for Bing Li

**Associate Director, Quality Assurance
China Preclinical Management Services
Email: bli@chinapreclin.com**

PROFESSIONAL PROFILE

1 year as a full time GLP auditor and monitor.

11 years experience in pharmaceutical and radiopharmaceutical analysis, chemical analysis, quality control, chromatographic techniques (GC, HPLC, and TLC), spectroscopic methods (UV/VIS, IR, and IMS), qualitative and quantitative analysis, bacteria endotoxin test and sterility test. Preparation of radiopharmaceuticals, wet chemistry, analytical method development and validation, instrumentation, sample preparation, instrument calibration, operation and maintenance, data collection and analysis, results and procedure documentation, source book maintenance, lab maintenance. Worked and trained in GLP and GMP environments.

2 years experience in enzyme assay, protein purification, DNA sequencing, DNA libraries screening, sub-cloning and transformation, Northern and Southern blotting, PCR technique, gel electrophoresis, preparation of lambda lysates and isolation of lambda DNA, restriction mapping, radioactive labeling, ELISA, cell culture and encapsulation, microbiology.

1 year experience in molecular modeling of peptides, saccharide and glycopeptide, conformational analysis, Macmimic, WIZARD, GA, UNIX.

EDUCATION

Ph.D Candidate, Master of Science (Biochemistry)

Department of Chemistry, Ohio University, Ohio, USA, 9/93-3/97

Thesis: Investigation of the Enhanced WIZARD for Modeling the Peptide Backbone, the Saccharide Side Chain and the Glycopeptide Fragment of the Major Repetitive Glycopeptide of the Proline and Hydroxyproline-Rich Glycoprotein.

Relevant courses: Advanced Analytical Chemistry, Advanced Topics on Polysaccharide, Biochemistry, Protein Chemistry, Enzymology, Molecular & Cellular Biology, Molecular & Cellular Biology Lab, Molecular Genetics, Gene Manipulation.

Bachelor of Science (Chemistry)

Department of Chemistry, Nankai University, Tianjin, China, 9/85-9/89

Thesis: Synthesis and Characterization of Ferrite.

Relevant courses: Analytical Chemistry and Lab, Instrumental Analytical Chemistry and Lab, Organic Chemistry and Lab, Inorganic Chemistry and Lab, Physical Chemistry and Lab, Structural Chemistry and Lab, Chemical Engineering and Lab, Computer Language, etc.

RESEARCH AND PROFESSIONAL EXPERIENCE

10/2008 - Associate Director, Quality Assurance, CPMS, Needham Massachusetts, USA & Beijing, PRC.

After training in conducting GLP audits and study monitoring at CPMS, I now oversee and monitor all the CPMS monitoring and auditing activities in PRC.

10/2000 - 4/2007 Analytical Chemist, Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, Connecticut, USA

Provide analytical support by developing, validating and implementing methods for clinical drug products and new compounds being developed. Support PDL and Pharmaceutics for cleaning validation. Assay the incoming ID samples, stability samples and cleaning validation samples. Maintain lab instruments, especially HPLC, IMS, and UV etc. Perform formulation and formulation assay to support GLP and non-GLP toxicokinetic studies and pharmacokinetic studies for nonclinical research, very familiar with GLP regulations. Provide qualitative and quantitative analyses to support chemical process research and scale-up activities. Perform in-process testing (reaction monitoring) and final product assay (including chropurity, assay, KF and LOD etc). Perform chemical and physical analysis on drug substances and products for release, incoming ID and stability samples. Prepare appropriate laboratory data documentation and reports to support regulatory filings. Develop and validate HPLC methods for a variety of compounds under GLP and GMP guidelines.

1/00 - 6/00 QC Manager - KC Pharmaceuticals, Pomona, California, USA

Manage all activities and operations of the QC Chemistry Lab. Ensure efficient department workflow to meet company goals within established timeline under highly regulatory environment. Evaluates the capability of the lab and tests demands necessary for release of products, and determine which test can be handled by the lab and be cost effective. Evaluates, establishes, writes and implements tests procedures (SOP) that are valid and meet the standards both regulatory and pharmacopeial. Performs internal audit of the operation of the lab in terms of the tests procedures being employed, validation of procedures and equipment, record keeping, traceability of data to determine compliance with cGMPs. Performs actual chemistry testing, including HPLC and TOC, when needed. Hires, trains and reviews Chemistry Department personnel. Prepares and manages expenses, salaries and overhead budget for the chemistry department.

6/98 - 12/99 Analytical Chemist - United Medical Reference Laboratory, Baldwin Park, California, USA

Prepare samples and perform drug analysis on HPLC, perform general laboratory assays as assigned, evaluate data, generate reports and document procedures, develop and validate analytical methods on HPLC in accordance with GLP, maintain lab.

1/98 - 5/98 Analytical Chemist - Pyramid Laboratories, Inc., Costa Mesa, California, USA

Prepare samples and perform pharmaceutical analyses on the GC, HPLC and other analytical instruments, perform general laboratory assays and analyses according to the applicable guidelines, i.e. FDA etc., develop and validate analytical methods in accordance with GLP/GMP, document and develop Sops.

5/97 - 12/97 Research Associate - University of California, Irvine, California, USA

Perform quality control tests for synthesized pharmaceuticals using HPLC, GC, TLC, etc. Document SOP for pharmaceutical production in compliance with FDA regulations, develop and validate analytical methods in accordance with GMP/GLP, synthesize pharmaceuticals for PET research, maintain source book, maintain lab.

9/96 - 4/97 Analytical Chemist -Midwest Isotope Diagnostic Imaging, Ltd., Cincinnati, Ohio, USA

Carry out quality control tests for synthesized radiopharmaceuticals, including chemical and radiochemical analysis using HPLC, GC and TLC, bacterial endotoxin test and sterility test, develop and validate analytical methods in accordance with GLP/GMP, update and document SOP for radiopharmaceutical production in compliance with FDA regulations, maintain source book and maintain lab, synthesize radiopharmaceuticals for clinical SPECT.

9/93 - 8/96 Research/Teaching Assistant - Ohio University, Athens, Ohio,

Develop method to assay carnosine synthetase using Amino Acid Analyzer, conduct research on purification and cDNA cloning of carnosine synthetase, DNA sequencing of tomato arabinogalactan protein (AGP) genes, molecular modeling of the major repetitive glycopeptide of the proline and hydroxyproline rich glycoprotein (PHRGP), instruct general chemistry lab.

9/89 - 8/93 Research Associate - Hepato-Biliary Disease Research Institute, Tianjin, China

Develop analytical methods for the active components of various kinds of Chinese medicine and cholic acid, study the controlled-release system of testosterone, participate research on artificial liver.