MARY C. LONG, PH.D., NRCC

EDUCATION

Ph.D., Pharmacology and Toxicology
University of Alabama at Birmingham, 2006
Dissertation topic: Adenosine kinase from *Mycobacterium tuberculosis*
Advisor: Dr. William B. Parker, Ph.D.

Bachelor of Science in Chemistry
Minor in mathematics
University of Alabama at Birmingham, 1997

CERTIFICATIONS

National Registry of Certified Chemists board certified Toxicological Chemist, registrant #3851, 2014-2016.

Licensed clinical laboratory director for high complexity laboratories by the state of Georgia, Expires Dec 2014, license #11003RE.

State of Nevada Registered Lab Director for high complexity laboratories, license #34386RLD-0, 2014-2016.

CURRENT EMPLOYMENT

US Medical Scientific, LLC, May 2014 - Current
Chief Scientific Officer

US Medical Scientific is developing toxicology confirmation laboratories in several states. These laboratories are using state of the art LC/MS/MS techniques to quantitatively determine levels of scheduled pain management and behavioral medications. US Medical Scientific is committed to providing doctors with therapeutic tools that will aid them in effective treatment of their patients.

Criterion Chemistries, LLC, June 2014 — Current
President/CEO

Criterion Chemistries is a new business venture that specializes in preparing custom laboratory standards for use as calibrators or quality control standards for a variety of analytical tests. Criterion works with the client to develop standards in client-specified matrix and concentrations. Further, the standards that we produce

are tested for precision and accuracy prior to distribution to our clients so that they know that their calibration curves and QCs will pass the first time, every time.

MS Solutions, LLC, April 2013-Current
President and CEO

At MS Solutions, I have acted in the role as a consultant and contract Laboratory Director for physician's practices that wanted to provide in-house testing solutions in order to improve patient services. Consultation services included evaluating existing in-house testing infrastructure for quality and compliance with COLA and CL1A testing standards. Evaluations included reviewing employee qualifications and competency testing, existing policy and procedure manuals, testing practices, and all quality assurance records. Recommendations are made to testing providers in order to insure that all testing policies and procedures are in place for compliance with state and federal testing standards. I am currently retained by five laboratories in the capacity of Laboratory Director.

Quintiles, July 2013-April 25,2014

Responsible for development of LC/MS/MS assays for the quantitation of small molecules in biological matrices. Provide supporting documentation such as assay validation reports and standard operating procedures, and train clinical staff to implement assays for clinical trials. Assays must meet or exceed FDA and CLSI standards for assay development. Assays recently developed are for hormone testing and drugs of abuse testing.

Supervisor: Joseph George, Ph.D., Associate Director of the Assay Development Laboratory

US AccuScreen, llc, June, 2010 - April, 2013 Titles held:
Technical Director, Laboratory Director, General Supervisor,

Developed a full-service urine toxicology laboratory from the ground-up. Responsibilities included developing, validating, and implementing assays for the quantitation of pain management medications and drugs of abuse from human urine using ultra performance liquid chromatography coupled with tandem mass spectrometry (UPLC/MC/MS). I was also responsible for guiding the laboratory through CLIA and State inspections as well as overseeing the laboratory's participation in Forensic Urine Drug Conformation proficiency testing through the College of American Pathologists (CAP).

Assay development includes validating assays according to federal guidelines, writing assay validation reports, and standard operating procedures for LC-MS-MS assays developed in-house. I have developed the quality control and quality

assurance program for the laboratory. I am also responsible for maintaining workflow, training new technicians, seeing to the accurate and timely reporting of laboratory results, interpreting results, communicating with clients, ordering supplies, and facilities management.

CEO: Laboratory Director: Michael Lupi, DO
COO: Catherine C. Veal

Adjunct Assistant Professor of Biology. College of Coastal Georgia
July 1, 2012 - Current

Duties included teaching rotation students from the MLT program about skills that are necessary for a toxicology laboratory. During their rotation, students were exposed to all aspects of laboratory operations, beginning with specimen receipt and accessioning and moving through the various phases of laboratory testing, including specimen validity testing, adulterant testing, the EIA screen using the Carolina BioLis, and finally quantitative LC/MS/MS analysis using the Waters Acquity UPLC couples with a TQD (tandem mass spec detector). Rotations include didactic training in laboratory operations, with a tour of the facility. At each stage of the rotation, the student will get a more concise tutorial about the importance of their specific station, be trained on the tasks involved in the testing process, and be permitted to shadow our testing personnel. Rotation students also particippated in directly-supervised testing for specimen validity testing, adulterant testing, and EIA screen.
Dean, School of Mathematics and natural Sciences:
Keith E. Belcher, Ph.D., MLS^{CM} (ASCP) SM

RESEARCH EXPERIENCE

Research Associate, University of Alabama at Birmingham August, 2008
- June, 2010

Responsibilities included development of novel assays for the detection and quantitation of antimicrobial drugs using HPLC-MS-MS, expanding the laboratory's capabilities to include intracellular metabolites, determination of protein-free drug levels, grant writing, and training graduate students.
Laboratory Director: Edward P. Acosta, Pharm. D.
Professor, Department of Pharmacology and Toxicology

Postdoctoral Research, University of Alabama at Birmingham July, 2006
— August, 2008

Developed HPLC/MS/MS assays for the quantitation of antiretroviral drugs in human plasma. Assays were typically utilized in a dose-finding study for the FDA indication for antiretroviral drugs in pediatric populations. Other studies included determination of the transplacental transfer rate of azithromycin levels in pregnant rhesus monkeys for the purpose of treating intrauterine *Ureaplasma urealyticum*

infection. My role includes advising on study design, development of HPLC/MS/MS assays for the quantitation of azithromycin in plasma and amniotic fluids, data analysis, and analyzing pharmacokinetic data. I also trained on WinNonLin and NONMEM software for the determination of pharmacokinetic and pharmacodynamic parameters. As part of my training in clinical pharmacology, I was also included in the planning phase for bioequivalence studies. Responsibilities also included writing and proofreading manuscripts, troubleshooting HPLC and mass spectrometer problems, and overseeing the training of a laboratory intern and graduate students.
Advisor: Edward P. Acosta, Pharm. D.
Professor, Department of Pharmacology and Toxicology

Doctoral Research, Southern Research Institute August, 2000 - July, 2006.

Dissertation research consisted of the purification, characterization, cloning, and crystallization of adenosine kinase from *Mycobacterium tuberculosis.* Purification of the protein led to the identification of the gene coding for adenosine kinase (Rv2202c, renamed *adoK* based on this work). Cloning of *adoK* permitted verification of the function of the protein. Characterization of the enzyme included determination of Michaelis-Menton parameters for natural and alternative substrates as well as physical characterization of the enzyme. I formulated a working model of the active site of this enzyme using a comprehensive structure-activity relationship by assessing 165 purine nucleoside analogs as substrates and inhibitors. Further, I assessed a series of structurally diverse purine analogs for antimycobacterial activity using a colorimetric microdilution broth assay for the determination of their minimum inhibitory concentration. Based on this work, I proposed modifications that could be made to adenosine that may produce novel compounds for assessment as substrates for adenosine kinase and MIC analysis.
William B. Parker, Ph.D.
Director, Department of Biochemistry and Molecular Biology
Division of Drug Discovery
Southern Research Institute, Birmingham, Alabama

Research Technician, University of Alabama at Birmingham July, 1997- August, 2000

Developed antiviral efficacy assays for human herpesviruses 6, 7, and 8 (HHV-6, 7, and 8) using immunofluorescence staining and flow cytometry. Isolated lymphocytes from human umbilical cord blood and maintained multiple lymphocytic cell lines. Performed cytotoxicity and antiviral efficacy testing on compounds submitted for analysis against HHV-6, 7, or 8. Detected the presence of cytomegalovirus (CMV) by PCR analysis in eye tissue excised from SCID-Hu animal models of CMV infection.
Earl Kern, Ph.D.

Department of Pediatric Virology

Research Technician, University of Alabama at Birmingham June, 1996 - July, 1997

Senior Research, January, 1996 - May, 1996 (same laboratory)

Performed research required for American Chemical Society-certified Bachelor of Science in Chemistry. Purified gram-quantities of crystallization-quality protein and performed enzymatic activity assays. Physical biochemistry techniques include differential scanning calorimetry, titration calorimetry, and BioCore technology for the determination of thermodynamic parameters and binding kinetics of small molecule-protein interactions.

Christie G. Brouillette, Ph.D.
Associate Director
Center for Biophysical Sciences and Engineering

TEACHING EXPERIENCE

Guest Lecturer for PHR 735, Nucleotide Metabolism and Chemotherapy.
Department of Pharmacology and Toxicology, University of Alabama at Birmingham. 2008.

An in-depth graduate-level course focusing on the synthesis, metabolism, and interconversion of nucleic acids, as well as the pharmacology of nucleoside analogs, comparative biology of these pathways, and pathology of enzymatic deficiencies. My lecture topics include: configuration and conformation of nucleosides and nucleotides, catabolism of purine nucleotides, and the metabolism and biochemical effects of pharmaceutical purines and pyrimidines.

Medical Pharmacology, School of Medicine, University of Alabama at Birmingham. 2009.

I participated in teaching the Medical Pharmacology course to second-year medical students. This course consisted of a series of lectures taught by different lecturers, depending on topic. The topics that I covered were: antiviral drugs, antibiotics, and immunosuppressants.

Proctor for Medical Pharmacology case studies, School of Medicine, University of Alabama at Birmingham. 2003-2009.

My role is to facilitate discussion of pharmacologic case studies that are taught in conjunction with the medical pharmacology courses taken by first and second year medical students.

Teaching Assistant, Chemistry Department, University of Alabama at Birmingham. 1994-96.

Instructed undergraduate inorganic and organic chemistry laboratory sections. I oversaw experiments, lectured on main topics, prepared and graded quizzes, instructed on maintenance of lab notebooks, demonstrated techniques, and assisted students in everyday laboratory routines.

PUBLICATIONS

Acosta, E.P., Grigsby, P.L., Larson, K.B., James, A.M., **Long, M.C.,** Duffy, L.B., Waites, K.B., and Novy, M.J. 2013. Transplacental Transfer of Azithromycin and its Application For Eradicating Intraamniotic Ureaplasma Infection in a Primate Model. *J. Infect. Dis.* Epub ahead of print Nov 25, 2013.

Grigsby, P.L., Novy, M.J., Sadowsky, D.W., Morgan, T.K., **Long, M.C.,** Acosta, E.P., Duffy, L.B., and Waites, K.B. 2012. Maternal azithromycin therapy for Ureaplasma Intraamniotic infection delays preterm delivery and reduces fetal lung injury in a primate model. *American Journal of Obstetrics & Gynecology. ;* **207: 475el-14.**

Ofotokun, I., Lennox, J.L., Eaton, M.E., Ritchie, J.C., Easley, K.A., Masalovich, S.E., **Long, M.C.,** Acosta, E.P. **2011.** Immune activation mediated change in alpha-1-acid-glycoprotein: Impact on total and free Lopinavir plasma exposure. *Journal of Clinical Pharmacology.* Jan 5th.

Long, M.C., King, J.R., and Acosta, E.P. 2009. Pharmacologic aspects of new antiretroviral drugs. Invited review for *Current HIV/AIDS Reports.* **6(1): 43-50.**

Long, M.C., King, J.R., and Acosta, E.P. 2008. Pharmacologic aspects of new antiretroviral drugs. Invited review for *Current Infectious Disease Reports.* **10(6): 522-9.**

Long, **M.C.,** Bennetto-Hood, C.J., and Acosta, E.P. 2008. A rapid, sensitive HPLC-MS-MS method for the determination of Raltegravir in human plasma. *Journal of Chromatography B.* 867(2): 165-71.

Long, **M.C.** and Parker, W.B. 2008. Structure-activity relationship for adenosine kinase from *Mycobacterium tuberculosis.* II. Modifications to the ribofuranosyl moiety. *Biochemical Pharmacology.* 75(8): 1588-600.

Moore, J.D., Acosta, E.P., Johnson, V.A., Bassett, R., Eron, J.J., Fischl, M.A., Long, M.C., Kuritzkes, D.R., and Sommadossi, J.P. 2007. Intracellular nucleoside triphosphate concentrations in HIV-infected patients on dual nucleoside reverse transcriptase inhibitor therapy. *Antiviral therapy.* 12(6):981- **86.**

Bennetto-Hood, C., King, J.R., **Long, M.C.,** and Acosta, E.P. 2007. Development of a sensitive and specific liquid chromatography/mass spectrometry method for the determination of tenofovir in human plasma. *Rapid Communications in Mass Spectrometry.* 21; 2087-94.

Acosta, E. Wiznia, A., Nachman, S., Teppler, H., **Long, M.,** Homony, B. Handelsman, E., Worrell, C., Fenton, T., and Sheeran, E. 2008. Raltegravir pharmacokinetics in adolescents: Preliminary results from IMPAACT protocol 1066. The HIV Pharmacology Workshop, New Orleans, Louisiana, April 7-9, 2008.

Long, M.C., Escuyer, V.E., and Parker, W.B. 2005. Characterization of adenosine kinase from *Mycobacterium tuberculosis* and development of nucleoside analog antitubercular agents. Presented at the first meeting of the Southeastern Mycobacterium Consortium.

Long, M.C. and Parker, W.B. 2004. A structure-activity relationship for *Mycobacterium tuberculosis* adenosine kinase. Presented at the 44th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC).

Long, M.C., Escuyer, V.E., and Parker, W.B. 2003. Purification and characterization of adenosine kinase from *Mycobacterium tuberculosis.* Gordon Conference for Purines, Pyrimidines, and Related Substances.

Long, M.C. and Parker W.B. 2002. Purification and characterization of adenosine kinase from Mycobacterium tuberculosis. The 4th World Congress on Tuberculosis.

Long M.C., Williams, S.W., Bidanset, D.J. and Kern, E.R. 2000. A flow cytometric assay system for the determination of antiviral efficacy against lymphotropic herpesviruses. The 13th International Conference on Antiviral Research.

AWARDS AND HONORS

2007 Postdoctoral Scholar Award from the UAB Postdoctoral Association

1996 American Chemical Society Certificate of Accomplishment awarded for undergraduate research.

ADDITIONAL TRAINING

2012 AACC Principles of Clinical Toxicology Certification Program.

2011 COLA Laboratory Director Roles and Responsibilities training course.

2008 Training course for the API 5000 triple quadrupole mass spectrometer offered by Applied Biosystems, 4 days.

2007 Introductory Nonmem workshop offered by the ICON and Globomax corporation, 3 days.

2007 Advanced population pharmacokinetic analysis workshop offered by Dick Brundage, Department of Experimental and Clinical Pharmacology, University of Minnesota, 3 days.

2006 Quattro Micro training course from Waters Corporation for operating the triple-quadrupole mass spectrometer, 1 week.