

## Curriculum Vitae



**Lei Zhang, M.D., Ph.D.**  
**lzhang@bcg-usa.com**  
Head, China Office  
Biologics Consulting Group, Inc.

### **EDUCATION**

Ph.D. *Cellular Biology and Immunology*, Dept. Of Cellular Biology, University of Georgia, Athens, Georgia (1997)

M.S. *Immunology*, Dept. Of Immunology of Malaria, First Army Medical College, Guangzhou, People's Republic of China (1987)

M.D. Medical College of South China University, People's Republic of China. (1984)

### **EXPERIENCE**

**Biologics Consulting Group, Inc., Head, China Office**  
Beijing China (Apr. 2007 – present)

**FDA/CDER/Office of Oncology Drug Product, Reviewer**  
Rockville, MD (Oct. 2005 - Mar 2007)

**FDA/CBER/Division of Monoclonal Antibodies, Reviewer**  
Rockville, MD (Oct. 2000 – Oct. 2005)

**Center for Disease Control (NIOSH), Visiting Associate**  
(Jan. 1998 – Sep. 2000)

**University of Georgia, Dept. Of Cellular Biology, Graduate Research Assistant**  
(Jan. 1993 - Dec. 1997)

**General Hospital of Guangzhou, Resident Doctor in Dept. Of Medicine**  
Guangzhou, People's Republic of China (Sep. 1987 - Sep. 1992)

## **HONORS, AWARDS, AND FELLOWSHIPS**

- FDA Group Recognition Award for exceptional performance in reviewing and approval of the first new class of agent (Tysabri) for the treatment of multiple sclerosis. 2005
- Award for Excellence in research on T cell activation by Division of Monoclonal Antibodies. 2004

## **REGULATORY RESPONSIBILITIES**

### **Submission Review**

The BINDs that I have reviewed are generally antibody-based therapeutic proteins for treatment of varieties of diseases including tumors, autoimmune diseases. I have good understanding of regulatory issues as well as scientific and technical issues related to development and manufacturing of therapeutic protein. Because of proprietary issues related to BIND, I can not give specific details on my review activities.

### **Inspection**

Pre-approval inspection and cGMP inspection on US biotechnology pharmaceuticals.

### **REGULATORY TRAINING (PARTIAL LIST)**

1. Reviewer Training Program: Introduction to the Regulatory Process, CBER, FDA
2. CDER's Review Training Program.
3. CMC Strategy Workshop offered by CDER.
4. Symposium on Quality Control and Manufacturing and Inspection of Biomolecules. CDER, FDA
5. Workshop on Analytical Method Validation and Qualification. CDER, FDA
6. OBP Training Program for Reviewer (Consisted series of courses), CDER, FDA
7. Clinical Trials: Design, Conduct and Analysis, CBER, FDA
8. IND Regulations, CDER, FDA
9. Drug Law, CDER, FDA
10. Technical Writing for Reviewers, CDER, FDA
11. Well Characterized Biologicals: Managing Pre- and Post- Approval Manufacturing Changes, Special Symposium: Evaluating Immunogenicity of Recombinant Proteins, CDER, FDA
12. PDA/FDA Viral Clearance Forum.
13. Reviewing INDs and BLA.
14. Series of FDA training on issues of clinical trials.
15. Series of FDA training on Pharmacology and Toxicology
16. Series of FDA inspection trainings.
17. Series of cGMP and GLP trainings.

## PUBLICATIONS

Lei Zhang, Elaine F. Lizzio, Trina Chen, and Steven Kozlowski. Peptide immunization excludes antigen specific T cells from splenic lymphoid compartments. *European Journal of Immunology* 35:776-85. 2006

Lei Zhang, Elaine Lizzio, Elena Gubina, Steven Kozlowski. Organ specific cytokine polarization induced by adoptive transfer of transgenic T cells. *Journal of Immunology* 2002, 169:5514-21.

Hill DM, Kasliwal T, Schwarz E, Hebert AM, Chen T, Gubina E, Zhang L, Kozlowski S. A dominant negative mutant beta 2-microglobulin blocks the extracellular folding of a major histocompatibility complex class I heavy chain. *J Biol Chem.* 2003 Feb 21;278(8):5630-8.

Elena Gubina, Trina Chen, Lei Zhang, Elaine Lizzio and Steven Kozlowski. CD43 polarization in unprimed T cell is associated with raft coalescence and requires an intact cholesterol synthesis pathway. *Blood* 2002 99:2518-25

Rick Tarleton, Grusby M and Lei Zhang (2000). Increased susceptibility of STAT4 Deficient and enhanced resistance in STAT6 deficient mice to infection with *Trypanosoma Cruzi*. *Journal of Immunology* 165 (3):1520-5.

Lei Zhang and Sally Tinkle (2000). Chemical activation of innate and specific immunity in contact dermatitis. *Journal of Investigative Dermatology.* 115(2):168-76.

Lei Zhang and Rick L. Tarleton. (1999) Parasite persistence correlated with disease severity and localization in chronic Chagas' disease. *Journal of Infectious Diseases* 180:480-6.

Rick L. Tarleton and Lei Zhang (1999). Chagas' Disease Etiology: Autoimmunity or parasite persistence? *Parasitology Today* 15:94-99.

Rick L. Tarleton, Lei Zhang and M.O. Downs (1997) Autoimmune rejection of neonatal heart transplants in experimental Chagas' disease is a parasite-specific response to infected host tissue. *Proceedings of the National Academy of Science of the USA* 94:3932-3937.

Lei Zhang and Rick L. Tarleton (1996) Characterization of cytokine production in murine *Trypanosoma cruzi* infection by in situ immunocytochemistry: Lack of association between susceptibility and T helper type 2 cytokine production. *European Journal of Immunology* 26:102-109.

Lei Zhang and Rick L. Tarleton (1996) Persistent production of inflammatory and anti-inflammatory cytokines and associated MHC and adhesion molecule expression at the site of infection and disease in experimental *Trypanosoma cruzi* infections. *Experimental Parasitology* 84:203-213.

Lei Zhang. M.D., Ph.D.



Rick L. Tarleton, Jianren Sun, Lei Zhang and Mirian Postan (1994) Depletion of T-cell subpopulations results in exacerbation of myocarditis and parasitism in experimental Chagas' disease. *Infection and Immunity* 62:1820-1829.

Lei Zhang, Ouyang Minghui, Chao Sui and Yingjie Li (1988) Study on affinity of monoclonal antibodies against Plasmodium Inui. *Journal of Medical College of PLA*.

**INVITED PRESENTATIONS:**

NIH Immunology Retreat 10/29/02: Peptide immunization excludes antigen specific T cells from splenic lymphoid compartments.