Susan E. Alters, Ph.D.

Email : salters@stanfordalumni.org
Phone/FAX: 650 856-2364
URL: altersbioscience.com

Summary of Qualifications

- Broad and extensive experience in the biopharmaceutical industry. Expertise spans all phases of drug development from basic research through IND.
- Experience with a range of therapeutics including proteins, small molecules, viral and non-viral vectors, antibodies, cell-based vaccines and nanoparticles.
- Proven expertise in multiple therapeutic areas including oncology, autoimmunity, inflammation, transplantation and asthma/allergy.
- Experience in major technology areas including targeted therapeutics, immunotherapy, drug delivery, biomarker identification and gene therapy.
- Excellent collaborative skills as evidenced by initiation and management of collaborations with contract labs, government agencies and thought leaders in academia and industry.
- Business perspective in drug development from both the client and provider side.
- Proven analytical, writing and presentation skills as evidenced by completed study reports, publications, patents and presentations to external experts in the field.
- Management experience including scientists with diverse educational backgrounds, project teams composed of cross-functional contributors and external collaborators.

Professional Experience

Consultant, Pre-clinical Development: 6/03 – present

Provided expertise to biopharmaceutical companies to establish and implement strategy for their pre-clinical R&D program. Responsibilities include identifying company needs, designing mechanistic, efficacy and pharmacology study protocols, choosing and overseeing appropriate contract and academic collaborators and integrating study results into ongoing development plans. Additional responsibilities include evaluating new product and in-licensing opportunities and serving as company spokesperson at scientific meetings and business presentations.

- Selected optimal *in vivo* tumor models and designed series of studies to demonstrate significant efficacy of oncology compound both as a single agent and in combination therapy.
- Designed and implemented studies to document *in vitro* activity, toxicity and mechanism of action of oncology therapeutic as single agent and in combination with standard cytotoxic drugs.
- Worked closely with pharmacology group to implement pharmacokinetic and biodistribution study in tumor model using both irradiated compound and LC/MS technology.
- Collaborated with process science group to trouble shoot pre-clinical toxicology issue.
- Worked with team to write pre-clinical development section of Investigator Brochure, IND, Annual Report and other corporate documents.
- Provided objective pre-clinical evaluation of new corporate ventures including in-licensing opportunities and research feasibility proposals. Assisted with implementation of proposals.
- Represented company at scientific meetings, presented findings and initiated collaborations.
- Prepared study results for internal and external reports, publications and presentations.

Targesome Inc. Palo Alto CA: 9/02 – 6/03

Director, Drug Discovery Research: Developed and led pre-clinical R&D program to assess efficacy, safety and mechanism of action of lead compound.

- Designed, implemented and wrote study reports for pre-clinical efficacy studies in solid and blood borne tumor models.
- Initiated and managed pre-clinical efficacy collaborations with external colleagues in academia, industry, government and at contract labs.
- Evaluated new product opportunities including appropriate target and targeting agent selection, technology platform and biological models.
- Provided technical expertise to business development for new R&D ventures.
- Provided *in vitro* and *in vivo* pre-clinical support for chemistry and process development groups resulting in selection of next generation candidates.

SurroMed Inc. Mountain View CA: 1/98 – 8/02

Manager, Cell and Molecular Biology (7/00- 8/02): Responsible for target antigen identification and validation, immunoassay development, study design, data analysis and report generation for all clinical studies.

- Identified disease specific target antigens, designed immunoassay panels and implemented clinical studies for biomarker discovery.
- Managed the asthma/allergy project team that included contributors from clinical affairs, biology, chemistry, bioinformatics, engineering, clinical operations and external scientific experts.
- Developed immunoassays and protocols for identifying and validating biomarkers in disease specific compartments including sputum, bronchial lavage, synovial fluid, serum and blood.
- Analyzed all data and prepared final study reports, abstracts and presentations from five biomarker discovery studies.

Senior Scientist, Cell and Molecular Biology (1/98 – 7/00): Primary responsibility for researching biomarker target antigens and developing panels of cell type and disease specific assays for use in clinical studies.

- Developed a panel of >150 cell-based and immunoassays to monitor disease specific target antigens in mouse and human blood samples.
- Recruited and served as scientific liaison to academic and industrial colleagues.

Applied Immune Sciences/RPR GenCell, Santa Clara, CA: 5/92 - 1/98

Group Leader, Immunology and Gene Therapy Group (5/94 – 1/98): Led group charged with researching and developing new lead therapeutics for oncology.

- Generated pre-clinical efficacy data in a variety of tumor models to support two IND submissions for antigen specific immunotherapy of cancer.
- Used viral and non-viral vectors to gene modify T cells, tumor cells and dendritic cells for use as tumor vaccines.
- Developed in vitro assays as surrogates to measure effectiveness of tumor antigen specific vaccines.
- Served as clinical studies project manager coordinating efforts of multidisciplinary team in taking project from research concept through phase I clinical trial.

Manager, Animal Sciences Dept (7/94 – 1/98): Managed group of animal facility personnel charged with performing all animal studies for R&D department.

- Researched and assisted in implementation of new animal models of cancer, autoimmune disease and transplantation.
- Served as scientific advisor to Institutional Animal Care and Use Committee (IACUC).

Senior Scientist, Autoimmunity, (5/92 - 5/94): Started autoimmunity department and initiated projects in multiple sclerosis, diabetes, and myasthenia gravis.

- Identified and characterized disease relevant target antigens in pre-clinical models of multiple sclerosis, myasthenia gravis and insulin dependent diabetes mellitus.
- Established the SCID-Hu Pancreas mouse model to investigate pathogenic subsets of T cells in patients with type I diabetes.
- Developed a cell selection device to assist in islet cell isolations for transplantation into diabetic mouse recipients.

Postdoctoral Fellow, Dr. C.G. Fathman, Department of Medicine/Immunology, Stanford University Medical Center, Stanford, CA: 9/89 - 5/92

Identified T cell anergy as the mechanism responsible for anti-CD4 mediated islet transplantation tolerance in murine and rat streptozotocin induced diabetes models and explored the role of IL2 in tolerance induction. Supervised two medical students in their research projects.

Postdoctoral Fellow, Dr. V.T. Oi, Department of Molecular Immunology, Becton Dickinson, Mountain View, CA; 5/89 - 9/89

Expanded thesis studies using the panel of chimeric anti–CD4antibodies in treatment of experimental allergic encephalomyelitis in mice.

Graduate Student, Dr. V.T. Oi, Department of Molecular Immunology, Becton Dickinson Monoclonal Center, Mt. View, CA. and Dr. L. Steinman, Department of Neurology/Immunology, Stanford University Medical Center, Stanford, CA: 1/85 - 5/89

Implemented molecular biology and cellular immunology techniques to generate a panel of chimeric anti–CD4 antibodies. Characterized the *in vitro* and *in vivo* efficacy of these antibodies in murine experimental allergic encephalomyelitis, a model for multiple sclerosis. Supervised an undergraduate student in her research project.

Education

Ph.D. Cancer Biology, Stanford University, Stanford, CA.

B.S. Molecular Genetics with high distinction in research, University of Rochester, NY.

Professional Society Memberships

American Association of Cancer Research
American Association of Immunologists
Clinical Immunology Society
Federation of American Societies of Experimental Biology
American Association for the Advancement of Science
Association for Women in Science

Patents, Presentations and Publications

Patents

Pending/Targesome: Two patent applications that relate to development of targeted anti-angiogenesis therapy for cancer.

US Patent # 6,753,135: "Biological Markers for Evaluating Therapeutic Treatment of Inflammatory and Autoimmune Disorders". (Assigned to SurroMed.)

Recent Abstracts and Presentations

Susan E. Alters, Alvin Wong, Alshad Lalani, and W.D. Henner, “The targeted cytotoxic prodrug, AQ4N, has significant activity in the breast adenocarcinoma model, MDA-MD-231.” Presented at the AACR annual meeting, April, 2006.

Susan E. Alters, Alvin Wong, Alshad Lalani, and W.D. Henner, “The cytotoxic prodrug, AQ4N, demonstrates tumor targeting and accumulation resulting in anti-tumor activity in the BxPC3 pancreatic xenograft model.” Presented at the AACR annual meeting, April, 2006.

Bart A Nijmeijer, Marianke LJ Van Schie, **Susan E Alters**, Alvin Wong, Jeffrey L Cleland, Roelof Willemze and J.H. Frederik Falkenburg, “The prodrug AQ4N displays potent anti-tumor activity in a xenotransplantation model of primary human acute lymphoblastic leukemia.” Presented at the American Society for Hematology annual meeting, December, 2005.

Susan E. Alters, Jeffrey L. Cleland, Alvin Wong and W. David Henner, “The tissue targeted prodrug, AQ4N, is activated to AQ4 in murine tissues and has anti-tumor efficacy in HCT116 colon and Panc-1 pancreatic carcinoma xenograft models.” Presented at the AACR/EORTC/NCI meeting, November, 2005.

Jeffrey L. Cleland, **Susan E. Alters** and Alvin Wong, “The tissue targeted cytotoxic prodrug, AQ4N, is an effective single agent therapy in solid tumor and leukemia models.” Presented at the Controlled Release Society meeting, July, 2005.

Susan E. Alters, Alvin Wong, and Jeffrey L. Cleland, “The targeted cytotoxic prodrug, AQ4N, has anti-tumor efficacy in L1210, P388 murine leukemia and Namalwa human lymphoma models.” Presented at the AACR annual meeting, April, 2005.

Jeffrey L. Cleland, Alvin Wong, and **Susan E. Alters**, “The targeted cytotoxic prodrug, AQ4N, has comparable activity to standard of care agents in colon and pancreatic cancer models.” Presented at the AACR annual meeting, April, 2005**.**

Jeffrey L. Cleland, Alvin Wong, and **Susan E. Alters,** “The targeted cytotoxic prodrug, AQ4N, persists in the spleen, large intestine, and subcutaneous tumors.” Presented at the AACR annual meeting, April, 2005**.**

Susan E. Alters, Alvin Wong, and Jeffrey L. Cleland, “A novel N-oxide drug, AQ4N, demonstrates in vitro cytotoxicity on solid tumor and hematopoietic tumor cell lines” Presented at the Experimental Biology annual meeting, April, 2005.

Jeffrey L. Cleland, Alvin Wong, **Susan E. Alters**, John G. Curd, Robert L. Capizzi, and William D. Henner, “A Novel N-Oxide Drug, AQ4N, Has In Vitro Activity in Lymphoma and Leukemia Cell Lines and Selectively Targets Lymphocytes and Lymphatic Tissues In Vivo.” Presented at the American Society for Hematology annual meeting, Dec, 2004.

Publications

Alshad S. Lalani, **Susan E. Alters**, Alvin Wong, Mark R. Albertella, Jeffrey L. Cleland, and W.D. Henner, 2007 “Selective Tumor Targeting by the Hypoxia Activated Prodrug, AQ4N, blocks Tumor Growth and Metastasis in Preclinical Models of Pancreatic Cancer.” Clin Cancer Res. 13: 2216.

Charles A. Wartchow, **Susan E. Alters**, Lingyun Li, Tina Doede, Susan J. Knox and Jeffrey L. Cleland, 2004” Enhancement of the efficacy of an antagonist of an extracellular receptor by attachment to the surface of a biocompatible carrier.” Pharm Res. 21:1880.

Aaron B. Kantor, **Susan E. Alters**, Karen Cheal and Louis Dietz, 2004 “Immune Systems Biology: Immunoprofiling of Cells and Molecules.” BioTechniques, 36: 520.

Susan E. Alters, Pedro Avila, Harini Govindarajan, Jun Deng, Homer Boushey and Aaron B. Kantor, 2002 “Phenotypic Profiling of Blood and Airway Secretions in Asthmatic and Healthy Subjects.” J. Allergy Clin. Immunol. 109, S340

Susan E. Alters, Andrea Perrone, Karen Cheal and Aaron B. Kantor, 2001 “Identification of biomarkers in allergy and asthma: effects of glucocorticosteroids on cell surface and soluble factors.” J. Allergy Clin. Immunol. 107, S164.

Ramila Philip, **Susan E. Alters,** Elisa Brunette, Jean Ashton, Jose R. Gadea, Jane Lebkowski and Mohan Philip, 2000 “Dendritic cells loaded with MART-1 peptide or infected with adenoviral construct are functionally equivalent in the induction of tumor specific CTL responses in patients with melanoma.” J. Immunotherapy 1:168.

Susan E. Alters, Jose R. Gadea, Jane Lebkowski and Ramila Philip, 1999 "IL13 Can Substitute for IL4 in the Generation of Dendritic Cells for Induction of CTL and Gene Therapy", J. Immunotherapy 22:229.

Ramila Philip, Elisa Brunette, Jean Ashton, **Susan Alters,** Jose R. Gadea, Gerard O'Donoghue, Martin Sorich, Josephine Yau, Jane Lebkowski and Mohan Philip, 1998 "Transgene Expression in Dendritic Cells to Induce Antigen CTL in Healthy Donors", Canc. Gene Therapy 5:236.

Susan E. Alters, Jose R. Gadea, Gerard O'Donoghue, Martin Sorich, Sohel Talib and Ramila Philip, 1998 "Dendritic Cell Induced Generation of CEA Peptide Specific CTL: Correlation of TcR Repertoire with CTL Function and Phenotype", J. Immunotherapy 21:17.

Susan E. Alters, Jose R. Gadea and Ramila Philip, 1997, "Immunotherapy of Cancer: Generation of CEA Specific CTL Using CEA Peptide Pulsed Dendritic Cells", Adv. Exp. Med. Biol. 417:519.

Ananda W. Goldrath, Karen E. Chen, Leann Barber and **Susan E. Alters,** 1995, "Differences in Adhesion Markers, Activation Markers and TcR in Islet Infiltrating vs. Peripheral Lymphocytes in the NOD Mouse", J. Autoimmunity 8:209.

Ananada W. Goldrath, Karen E. Chen, Lamont G. Weide, Parvis M. Pour, Jane S. Lebkowski and **Susan E. Alters,** 1995. "Retention of Endocrine Function in the SCID-Hu Pancreas Mouse: A Model for the Development of Human Fetal Islet Tissue", Transplantation 59:1496.

Susan E. Alters, Howard K. Song and C. Garrison Fathman, 1993. "Evidence That Clonal Anergy Is Induced In Thymic Migrant Cells After Anti-CD4 Mediated Transplantation Tolerance." Transplantation 56:633.

Howard K. Song, **Susan E. Alters** and C. Garrison Fathman, 1993. "Evidence that Anti-CD8 Abrogates Anti-CD4 Mediated Clonal Anergy but Allows Allograft Survival in Mice." Transplantation 55:133.

Lawrence Steinman, William Lindsey, **Susan Alters** and Suzanne Hodgkinson, 1993 "Anti-CD4 Therapy: From Treatment of Experimental Allergic Encephalomyelitis to Clinical Trials in Multiple Sclerosis", Immunol. Ser. 59:253.

Judy Shizuru, **Susan E. Alters** and C. Garrison Fathman, 1992. "Anti-CD4 Monoclonal Antibodies in Therapy: Creation of Nonclassical Tolerance in the Adult", Immunol. Rev. 129:105.

Susan E. Alters, Davida Grossman and C. Fathman, 1992. "Anti-CD4 Mediated Transplantation Tolerance: Mechanisms and Memory." A Critical Analysis of Monoclonal Antibody Therapy in Transplantation, W. J. Burlingham ed, p.79-99.

Susan E. Alters, Judy Shizuru, Jill Ackerman, Davida Grossman, Karl Seydel and C. G. Fathman, 1991. "Anti-CD4 Mediates Clonal Anergy During Transplantation Tolerance Induction", Journal of Experimental Medicine 173:491.

Karl Seydel, Judith Shizuru, Davida Grossman, Anna Wu, **Susan Alters** and C.G. Fathman, 1991. "Anti-CD8 Abrogates the Effect of Anti-CD4 Mediated Islet Allograft Survival in a Rat Model", Diabetes 40:1430.

Susan E. Alters, Koichiro Sakai, Lawrence Steinman and Vernon T. Oi, 1990. "Mechanisms of Anti-CD4 Mediated Depletion and Immunotherapy: A Study Using a Set of Chimeric Anti-CD4 Antibodies", Journal of Immunology 14:4587.

Susan E. Alters, "Comparison of Rat and Rat-Mouse Chimeric Anti-Murine CD4 Antibodies for Use in Immunotherapy." Doctoral thesis, Stanford University, 1989.

Susan E. Alters, Lawrence Steinman and Vernon T. Oi, 1989. "Comparison of Rat and Rat-Mouse Chimeric Anti-Murine CD4 Antibodies In Vitro: Chimeric Antibodies Lyse Low Density CD4+ Cells", Journal of Immunology, 142:2018.