

## Curriculum Vitae

**Scott R. Burger**

January 1, 2007

### Personal Information

Date of Birth: April 14, 1962

Citizenship: USA

Place of Birth: Utica, NY

### Present Position

Principal  
Advanced Cell & Gene Therapy, LLC  
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### Education and Training

1983            B.S., cum laude, distinctive honors in Biology, Tulane University, New Orleans, LA  
1988            M.D., University of Pennsylvania School of Medicine, Philadelphia, PA  
7/89-6/94      Laboratory Medicine Residency, Washington University Medical Center, St. Louis, MO  
7/93-6/94      Transfusion Medicine Fellowship, Washington University Medical Center, St. Louis, MO

### Professional Experience

5/02-Present    Principal, Advanced Cell & Gene Therapy, LLC, Chapel Hill, NC  
                    Adjunct Associate Professor, Department of Pathology and Laboratory Medicine  
                    School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC

5/01-5/02        Vice President, Research and Development  
                    Merix Bioscience, Inc., Durham, NC

12/00-5/01      Medical Director, Minnesota Molecular and Cellular Therapeutics Facility  
                    University of Minnesota Academic Health Center, Minneapolis, MN

7/94-12/00      Director, Cell Therapy Clinical Laboratory; Assistant Medical Director, Blood Bank  
                    Fairview-University Medical Center, Minneapolis, MN

7/94-5/01        Physician Assistant Professor, Department of Laboratory Medicine and Pathology  
                    Associate Member, Graduate Faculty in Clinical Laboratory Science (1997-2001)  
                    University of Minnesota Medical School, Minneapolis, MN  
                    Assistant Medical Director, North Central American Red Cross, St. Paul, MN

## Honors and Awards

- 1982      Beta Beta Beta Honorary Biological Society
- 1983      Distinctive honors in Biology, Tulane University
- 1983      Omicron Delta Kappa Honorary Scholarship and Leadership Society
- 1983      U.S. Navy Health Professions Scholarship
- 1984      Medical student essay competition, honorable mention, Alpha Omega Alpha  
Honorary Medical Student Society
- 1989      International Travel Award, Society for Complex Carbohydrates
- 1989      Young Investigator Award With Distinction, Academy of Clinical Laboratory  
Physicians and Scientists
- 1991      Young Investigator Award, Academy of Clinical Laboratory Physicians and  
Scientists
- 1993-94    Chief Resident, Department of Laboratory Medicine, Barnes Hospital, Washington  
University Medical Center
- 1999      Scholar Award, National Blood Foundation
- 2000      Best Abstract Award, International Society for Hematotherapy and Graft  
Engineering

## Grants and Contracts

- 1983      Aerosolization of *Serratia marcescens*: possible selective function for prodigiosin.  
Undergraduate Research Award, American Heart Association. Principal  
investigator: Scott R. Burger.
- 1990-93    NHLBI Institutional Training Grant, 5 T32 HL07038-16. Department of Pathology,  
Washington University School of Medicine, St. Louis, MO.
- 9/93-8/96    Establishment and operation of a cell processing center. Baxter Healthcare  
Corporation Cell Processing contract award, \$335,000. Principal investigator: Jeffrey  
McCullough, MD. Co-investigators: Scott R. Burger, MD, David Stroncek, MD.
- 11/95-10/96    Development of a quality assurance program for stem cell collection, processing, and  
storage. Baxter Healthcare Corporation Cell Processing contract award, \$65,850.  
Principal investigator: Jeffrey McCullough, MD. Co-investigators: Scott R. Burger,  
MD, Mary Clay, MT(ASCP).

## Grants and Contracts, continued

- 10/95-9/96 Progenitor and somatic cell processing/preservation project. Baxter Healthcare Corporation Cell Processing contract award, \$102,326. Principal investigator: Jeffrey McCullough, M.D. Co-investigators: Scott R. Burger, M.D., Allison Hubel, Ph.D.
- 7/97-6/99 Adhesive interactions in hematopoietic cell homing. National Blood Foundation grant, \$30,000. Principal investigator: Scott R. Burger, M.D.
- 1998 Stem cell gene therapy for chronic myelogenous leukemia. University of Minnesota Academic Health Center Faculty Development grant, \$299,006. Principal investigator: Catherine Verfaillie, M.D. Co-investigators: Scott R. Burger, M.D., Philip McGlave, M.D., Scott McIvor, Ph.D., Cheryl Zimmerman, M.D.
- 1999-2001 Establishment of a center for molecular and cellular therapy. University of Minnesota Interdisciplinary Research and Postbaccalaureate Education grant, \$100,000. Participants: Molecular and cellular therapy committee members.
- 4/00-4/01 *In vitro* validation of ViaStem™, a DMSO-free cryoprotectant for hematopoietic cells. Protide Pharmaceuticals contract award, \$40,000. Principal investigator: Scott R. Burger, M.D.
- 5/00-8/00 Clinical development, scale-up, validation, and small-scale GMP systems development for production of a peptide-based A2 anti-tumor vaccine. Pharmacia contract award, \$150,000. Principal investigator: Scott R. Burger, M.D.
- 6/01-6/02 ViaStem™ as a cryopreservative for autologous peripheral blood progenitor cells, a phase I clinical trial in patients undergoing autologous transplant for Hodgkin's disease, NHL, or breast cancer. Protide Pharmaceuticals contract award, \$125,060. Principal investigator: Linda Burns, M.D. Co-investigators: Daniel Weisdorf, M.D., Scott R. Burger, M.D.

## Patents

- 9/21/99 Infusible-grade short-term cell storage solution for mononuclear cells. Patent #5,955,257. Scott R. Burger, Allison Hubel, Jeffrey McCullough.
- 8/21/01 Infusible-grade short-term cell storage medium for mononuclear cells. Patent #6,277,557. Scott R. Burger, Allison Hubel, Jeffrey McCullough.

## Medical Licensure and Board Certification

- 1990 Diplomate, National Board of Medical Examiners, #341174
- 11/19/97 Diplomate in Clinical Pathology, American Board of Pathology, #97-650
- 9/94-02 State of Minnesota Medical License #37314

## **Editorial Boards, Committees**

American Association of Blood Banks (AABB)

Somatic Cell Therapy Standards Program Unit (8/02-12/04)

International Society for Cellular Therapy (ISCT)

Gene Therapy Committee (6/95-5/04), Legal and Regulatory Affairs Committee (5/03-present)

Advisory Board (5/00-5/02), Executive Committee (5/01-present)

Editorial Board, Cytotherapy (5/02-5/05)

Editorial Board, Telegraft (1/99-present; Editor, 5/01-8/05)

U.S. Pharmacopeia (USP)

Cell and Gene Therapy Expert Committee (4/05-present)

Williamsburg BioProcessing Foundation

Editorial Board, BioProcessing, (4/02-6/04)

## **Scientific Advisory Boards (excludes non-disclosable board participation)**

BioE, Inc., White Bear Lake, Minnesota

Scientific Advisory Board, (9/02-12/04)

Schering AG, Berlin

Spheramine Scientific Advisory Board, (7/03-7/06)

Johnson & Johnson Stem Cell Internal Venture, Radnor, Pennsylvania

Scientific Advisory Board, (4/04-present)

Opexa Therapeutics, The Woodlands, Texas

Clinical and Scientific Advisory Boards, (4/05-present)

## **Grant and Manuscript Reviews**

American Society of Hematology

National Heart, Lung, and Blood Institute, NIH - Extramural Review Panel

National Marrow Donor Program - Review Panel

BioProcessing

Bone Marrow Transplantation

Cytotherapy

Transfusion

## **Professional Societies and Organizations**

American Association of Blood Banks  
American Society of Hematology  
International Society for Cellular Therapy

## **Military Service**

1/22/88 U.S. Navy, honorable discharge

## **Teaching and Invited Presentations**

- 1989-94 Therapeutic Drug Monitoring, Approach to the Bleeding Patient, Blood Component Therapy and Transfusion Reactions. Laboratory Medicine lecture series, Washington University School of Medicine, St. Louis, MO.
- 4/91 Evaluation of Hemostasis. Resident's Didactic Conference, Department of Medicine, Jewish Hospital of St. Louis, St. Louis, MO.
- 1/94 Overview of Laboratory Medicine. Occupational Therapy Program, Washington University Medical Center, St. Louis, MO.
- 1995-2000 Introduction to Transfusion Medicine, Evaluation of Hemostasis. Pathology Course LaMP-5101, University of Minnesota Medical School, Minneapolis, MN.
- 3/96 Hematopoietic Cell Processing For Transplantation. Resident's Didactic Conference, Department of Laboratory Medicine and Pathology, University of Minnesota Medical School, Minneapolis, MN.
- 1996-2000 Clinical Transfusion Medicine. Pathology courses LaMP 5-172, 5-177, University of Minnesota School of Allied Health, Minneapolis, MN.
- 2/97 Blood Component Therapy. Resident's Didactic Conference, Department of Laboratory Medicine and Pathology, University of Minnesota Medical School, Minneapolis, MN.
- 5/97 Adhesive Interactions in Hematopoietic Cell Homing. Resident's Didactic Conference, Department of Laboratory Medicine and Pathology, University of Minnesota Medical School, Minneapolis, MN.
- 5/97 Cell Processing For Hematopoietic Transplantation. Upper Midwest Flow Cytometry Users Group Meeting, St. Paul, MN.
- 7/97 Cell Therapy In Hematopoietic Transplantation. National Testing Laboratory, American Red Cross, Eagan, MN.

**Teaching and Invited Presentations, continued**

- 10/97 Blood Component Collection By Apheresis. American Association of Blood Banks annual meeting, educational session.
- 2/98 Current Good Manufacturing Practices For Cellular Engineering. BioTransplant Corporation, Charlestown, MA.
- 3/98 Graft Engineering For Transplantation. Arkansas Cancer Research Center, University of Arkansas Medical School. Little Rock, AR.
- 4/98 Cord Blood Banking. American Red Cross Spring Conference, St. Paul, MN.
- 5/98 Laboratory Support For Bone Marrow and Blood Stem Cell Transplants. Minnesota Collaborative Laboratory Professionals spring meeting, Minneapolis, MN.
- 6/98 Design of an Academic cGMP Cell Engineering Facility. International Society for Hematotherapy and Graft Engineering annual meeting, Baltimore, MD.
- 7/98 Cell Engineering For Hematopoietic Transplantation. Department of Pathology and Laboratory Medicine, University of Rochester School of Medicine and Dentistry, Rochester, MN.
- 1/99 Essentials of Hematopoietic Progenitor Cell Cryopreservation, Storage, Shipping, and Infusion. American Association of Blood Banks/International Society for Hematotherapy and Graft Engineering Audioconference.
- 1/99 Adhesive Interactions in Blood and Marrow Transplantation. Grand Rounds, Department of Laboratory Medicine and Pathology, University of Minnesota Medical School, Minneapolis, MN.
- 3/99 Hematopoietic Progenitor Cell Processing Laboratory Standards. Inspector's Workshop, Foundation for the Accreditation of Hematopoietic Cell Therapy, Keystone, CO.
- 4/99 Cell Engineering For Transplantation. Clinical Laboratory Conference, Veteran's Administration Medical Center, Minneapolis, MN.
- 4/99 Quality Assurance, Standards, and Regulation of Hematopoietic Progenitor Cells. American Association of Blood Banks/International Society for Hematotherapy and Graft Engineering Audioconference.
- 4/99 Environmental Monitoring For Cell Engineering Laboratories. International Society for Hematotherapy and Graft Engineering GMP Workshop, Tempe, AZ.
- 6/99 cGMP Cellular Engineering For Transplantation. Mayo Clinic-Luther Forum on Hematopoietic Stem Cells, Rochester, MN.

**Teaching and Invited Presentations, continued**

- 6/99 T-Lymphocyte Suicide Gene Transduction and Expansion. International Society for Hematotherapy and Graft Engineering annual meeting, Oslo, Norway.
- 9/99 cGMP Cellular Engineering For Clinical Therapies. Cell and Tissue BioProcessing Conference, Alexandria, VA.
- 10/99 Clinical Applications of Cell Engineering. Pediatric Oncology/BMT Nursing Symposium, University of Minnesota Medical School, Minneapolis, MN.
- 11/99 Cellular Engineering For Transplantation. National Marrow Donor Program, Minneapolis, MN.
- 3/00 Advanced Cell Engineering For Clinical Therapy. Upper Midwest Flow Cytometry Users Group Meeting, Minneapolis, MN.
- 4/00 Advances in Cellular Therapy. American Association of Blood Banks/International Society for Hematotherapy and Graft Engineering Audioconference.
- 5/00 Advanced Cellular Engineering For Transplantation. Minnesota Collaborative Laboratory Professionals spring meeting, Minneapolis, MN.
- 9/00 Development, Scale-Up, and Validation of Advanced Cellular Therapies. Cell and Tissue BioProcessing Conference, Framingham, MA.
- 11/00 Lot Release Testing In GMP Cellular Engineering. American Association of Blood Banks annual meeting, Washington, DC.
- 12/00 Equipment and Software Validation and Monitoring. International Society for Hematotherapy and Graft Engineering GMP 2000 Workshop, San Francisco, CA.
- 1/01 Quality For Advanced Cellular Therapies. BioWhittaker Quality Day 2001, Walkersville, MD.
- 4/01 Advanced Cellular Therapies. National Marrow Donor Program Spring Meeting, Minneapolis, MN.
- 4/01 Advanced Cellular Therapies. Georgetown University Medical Center, Current Topics in Histocompatibility and Transplantation audioconference.
- 5/01 Translational Development of Novel Cell Therapies. Somatic Cell Therapy meeting and workshop, Captiva Island, FL.
- 5/01 Overview of Good Clinical Practices. Somatic Cell Therapy meeting and workshop, Captiva Island, FL.
- 5/01 Academic GMP Facilities. Somatic Cell Therapy meeting and workshop, Captiva Island, FL.

**Teaching and Invited Presentations, continued**

- 7/01 Immune Effector Cell Therapies: Donor Lymphocyte Infusions and Tumor Cell Vaccines. American Association of Blood Banks/International Society for Hematotherapy and Graft Engineering audioconference.
- 11/01 Development of Novel Dendritic Cell Vaccines. Cell and Tissue BioProcessing 2001 Conference, Williamsburg, VA.
- 12/01 Overview of Validation. International Society for Hematotherapy and Graft Engineering GMP 2001 workshop, Orlando, FL.
- 12/01 Translational Development of Cellular Therapies Workshop. International Society for Hematotherapy and Graft Engineering GMP 2001 workshop, Orlando, FL.
- 5/02 Gene Transfer Into Dendritic Cells - Gene Therapy Workshop. International Society for Cellular Therapy 2002 annual meeting, Barcelona, Spain.
- 7/02 Novel Cell and Gene Therapies: Translational Development and GMP Production For Clinical Trials. Bone Marrow Transplant Program Seminar, Duke University Medical Center, Durham, NC.
- 9/02 Translational Development and GMP Production of Novel Cell and Gene Therapies. Kyoto University Hospital, Kyoto, Japan.
- 9/02 Translational Development and GMP Production of Advanced Cell and Gene Therapies. Translational research symposium, Japanese Society of Hematology-Japanese Society of Clinical Hematology 2002 joint meeting, Yokohama, Japan.
- 9/02 GMP Production and Testing of Cellular Therapies. Cellular Graft Engineering Society 2002 annual meeting, Myrtle Beach, SC
- 9/02 Novel Cell, Gene, and Tissue Therapies: Issues In Development and GMP Production. Cell and Tissue BioProcessing 2002 conference, Santa Barbara, CA.
- 10/02 Cell Therapy GMP Production Facilities. Facilities for Mammalian Cell Products 2002 conference, Seattle, WA.
- 10/02 Development, Production, and Regulation of Cell Therapy Products. Dendreon Corporation, Seattle, WA.
- 11/02 Advanced Cellular Therapies - Translational Development and GMP Production. Scientific symposium, International Society for Pharmaceutical Engineering 2002 annual meeting, Lake Buena Vista, FL.
- 3/03 Development and GTP/GMP Production of Novel Cell and Gene Therapies. Mayo Clinic, Rochester, MN.

**Teaching and Invited Presentations, continued**

- 3/03 Stem Cell Processing and GTP Regulations: Impact on Transplant Centers. National Marrow Donor Program, Minneapolis, MN.
- 3/03 Novel Cell and Gene Therapies - Development and GTP/GMP Production. Grand Rounds, Department of Pathology and Laboratory Medicine. University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC.
- 3/03 GMP/GTP Cell Engineering for Hematopoietic Cell Therapies. Georgetown University Medical Center, Current Topics in Histocompatibility and Transplantation audioconference.
- 3/03 Overview of Cell and Gene Therapies - Clinical Applications and GMP/GTP Production. Emerging Biotechnologies Seminar, Bioprocessing & Process Development Group, North Carolina Biotechnology Center. Research Triangle Park, NC.
- 5/03 Validation of Computerized Systems. International Society for Cellular Therapy GTP 2003 workshop, Phoenix, AZ.
- 5/03 Issues in Implementing Gene Therapy Clinical Studies - Gene Therapy Educational Session. International Society for Cellular Therapy 2003 annual meeting, Phoenix, AZ.
- 6/03 Advances in Cellular Immunotherapy. Georgetown University Medical Center, Current Topics in Histocompatibility and Transplantation audioconference.
- 7/03 Viable Cells: Critical Raw Material for Cell and Gene Therapy. Raw Materials and Contract Services for Mammalian Cell Products 2003, Newport Beach, CA.
- 9/03 Issues in Commercialization of Cell and Gene Therapies. Cell and Tissue BioProcessing 2003 conference, Memphis, TN.
- 10/03 Process Validation for Cell Therapy Products. Biological Products Validation Seminar, North Carolina Biotechnology Center. Research Triangle Park, NC.
- 12/03 cGMPs in Cell Therapy Product Manufacturing. Scientific Applications of cGMP for *Ex-Vivo* Cellular Therapies, CellGenix seminar, San Diego, CA.
- 1/04 Purity and Potency of Cell Therapy Products: Novel Therapies, Unique Issues. Characterization and Comparability for Complex Biological Products 2004, Coronado, CA.
- 2/04 Cell and Gene Therapies: Translational Research and Clinical Production. University of Pennsylvania School of Medicine, Philadelphia, PA
- 4/04 Advanced Cellular Therapies - Development, GMP Manufacturing, and Product Characterization. Cytonet workshop, Heidelberg, Germany.

**Teaching and Invited Presentations, continued**

- 5/04 Cell and Gene Therapy Process Development. Educational Session, International Society for Cellular Therapy 2004 annual meeting, Dublin, Ireland.
- 6/04 Enabling Commercialization of Clinical Cell and Gene Therapies: Challenges and Strategies. Regenerate 2004, Seattle, WA.
- 6/04 Cell Therapy Clinical Trials in Australia. Clinical Trials Australia Symposium, San Francisco, CA.
- 6/04 Cell and Gene Therapy: Challenges and Strategies for an Emerging Industry. BioProcessing Asia-Pacific 2004, Sydney, Australia.
- 12/04 Manufacturing Process: Strategies for Cell Therapy Products. DIA/EMEA Joint Meeting on Gene Therapy and Cell Therapy Products, London, UK.
- 1/05 Commercialization of Cell and Gene Therapy Products: When and How? Phacilitate Cell and Gene Therapy Forum, Washington, DC.
- 2/05 Strategies for Manufacturing Cell Therapy Products. Johnson & Johnson Cell Therapy and Regenerative Medicine Task Force, New Brunswick, NJ
- 5/05 Developing Cell Therapy Product Manufacturing: Avoiding the Pitfalls. Special Session - Development and Commercialization of Cell and Gene Therapy Products for Startup Companies. International Society for Cellular Therapy 2005 annual meeting, Vancouver, BC.
- 5/05 Steps Toward Compliance - Laboratory Practices and Regulatory Affairs Workshop, International Society for Cellular Therapy 2005 annual meeting, Vancouver, BC.
- 6/05 Manufacturing Cell Therapy Products – Challenges and Opportunities. GE Healthcare Cell Technologies Science Programme, Uppsala, Sweden.
- 6/05 Regulatory Pathway for Cell Therapy Products. Stem Cells for Treatment of Neurological Diseases, BIO 2005 annual meeting, Philadelphia, PA.
- 8/05 Manufacturing Cell and Gene Therapy Products: Overcoming the Obstacles. Cambridge Healthtech Institute Stem Cell Research conference, Cambridge, MA.
- 1/06 Options for Manufacturing Cell Therapy Products. Speaker and session chair, Phacilitate Cell & Gene Therapy Forum 2006, Baltimore, MD.
- 2/06 Manufacturing Cell and Gene Therapy Products. Biomanufacturing Workshop, Institute of Bioengineering and Bioscience, Center for the Engineering of Living Tissues, Georgia Institute of Technology/Emory University, Atlanta, GA.
- 5/06 Cell Therapy Product Characterization. Technical Session, International Society for Cellular Therapy 2006 annual meeting, Berlin, Germany.

### Teaching and Invited Presentations, continued

- 9/06 Cell Therapy Products: Translational Development and Manufacturing. Harvard Center for Human Cell Therapy, Boston, MA.
- 9/06 Regulations and Standards for Cell Therapy - International Perspective. Somatic Cell Therapy annual meeting, Bethesda, MD.
- 9/06 Translational Development: From Bench, to Clinic, to Commercial Manufacture. IBC Life Sciences Gene Therapy conference, London, UK.
- 1/07 Overcoming Comparability and Scale-up Challenges in Cell Therapy and Tissue Engineered Product Commercialization. Phacilitate Cell & Gene Therapy Forum 2007, Baltimore, MD.

### Publications

1. Burger SR, and DC Blanchard. 1983. The persistence of air bubbles at a seawater surface. *J. Geophys. Res.* 88:7724-26.
2. Burger SR. 1985. Two related works: Osler's Aequanimitas and Bernard's An Introduction to the Study of Experimental Medicine. *Pharos* 48:6-8.
3. Burger SR, and JW Bennett. 1985. Droplet enrichment factors of pigmented and non-pigmented *Serratia marcescens*: possible selective function for prodigiosin. *Appl. Environ. Microbiol.* 50:487-90.
4. Williams TM, L Eisenberg, JE Burlein, CA Norris, S Pancer, D Yao, SR Burger, M Kamoun, and JA Kant. 1988. Two regions within the human IL-2 gene promoter are important for inducible IL-2 expression. *J. Immunol.* 141:662-66.
5. Spitalnik PF, JM Danley, SR Burger, and SL Spitalnik. 1989. The glycosphingolipid composition of the human hepatoma cell line, Hep-G2. *Arch. Biochem. Biophys.* 273:578-91.
6. Burger SR, AT Remaley, RJ Muschel, M Kelsten, W Wunner, and SL Spitalnik. 1991. Stable expression of the rabies glycoprotein gene in mammalian cells – a model to study the regulation of protein glycosylation. *J. Gen. Virol.* 72:359-67.
7. Remaley AT, M Ugorski, N Wu, L Litzsky, SR Burger, JS Moore, M Fukuda, and SL Spitalnik. 1991. Expression of human glycoporphin A in wild-type and glycosylation-deficient Chinese hamster ovary cells. *J. Biol. Chem.* 266:24176-83.
8. Burger SR, MM Zutter, S Sturgill-Koszycki, and SA Santoro. 1992. Induced cell surface expression of functional alpha<sub>2</sub>-beta<sub>1</sub> integrin during megakaryocytic differentiation of K562 leukemic cells. *Exp. Cell Res.* 202:28-35.
9. Burger SR, BT Thomas, and JE Grishaber. 1994. Integration of concurrent collection of plasma into a plateletpheresis program. *J. Clin. Apheresis* 9:126-29.

**Publications, continued**

10. Spitzer G, DR Adkins, and SR Burger. 1994. Peripheral blood stem cells: Possibilities and limitations. In Hematopoietic Stem Cells: Biology and Therapeutic Applications, (D. Levitt and R. Mertelsmann, eds.). Marcel Dekker, Inc., New York, pp. 391-401.
11. Stroncek DF, SK Fautsch, SR Burger, JE Wagner, and J McCullough. 1995. Mislabeling of elutriation media: a demonstration of the need to improve the quality control of reagents produced for cell processing. *Transfusion* 35:952-54.
12. Whitley CB, RS McIvor, EL Aronovich, SA Berry, BR Blazar, SR Burger, JH Kersey, RA King, AJ Faras, RE Latchaw, JJ McCullough, D Pan, NKC Ramsay, and DF Stroncek. 1996. Retroviral-mediated transfer of the iduronate-2-sulfatase gene into lymphocytes for treatment of mild Hunter syndrome (mucopolysaccharidosis type II): human gene therapy protocol. *Human Gene Therapy* 7:537-49.
13. Burger SR, BT Thomas, and JE Grishaber. 1996. Concurrent collection of plasma. In Donor Recruitment: Strategies for Success (C Mihalko and L Botos, eds.). AABB Press, Bethesda.
14. Burger SR, SK Fautsch, DF Stroncek, and J McCullough. 1996. Concentration of citrate anticoagulant in peripheral blood stem cell collections. *Transfusion* 36:798-801.
15. Verfaillie CM, R Bhatia, W Miller, F Mortari, V Roy, S Burger, J McCullough, K Stiegelbauer, G Dewald, S Heimfeld, JS Miller, PB McClave. 1996. *BCR/ABL* negative primitive progenitors suitable for transplantation can be selected from most early chronic phase but not accelerated-phase chronic myelogenous leukemia patients. *Blood* 87:4770-9.
16. Shankar R, C Whitley, D Pan, S Burger, J McCullough, D Stroncek. 1997. Retroviral transduction of peripheral blood leukocytes in a hollow fiber bioreactor. *Transfusion* 37:685-90.
17. Burger SR, AH Hubel, J McCullough. 1999. Development of an infusible-grade solution for non-cryopreserved hematopoietic cell storage. *Cytotherapy* 1:123-133.
18. Stroncek DF, A Hubel, RA Shankar, SR Burger, D Pan, J McCullough, CB Whitley. 1999. Retroviral transduction and expansion of peripheral blood lymphocytes for the treatment of mucopolysaccharidosis II, Hunter syndrome. *Transfusion* 39:343-50.
19. Burger SR, DM Kadidlo, J McCullough. 1999. Improved progenitor assay standardization using peripheral blood progenitor cells from a donor treated with granulocyte-colony-stimulating factor. *Transfusion* 39:451-56.
20. Burger SR. 2000. Design and operation of a cGMP cell engineering laboratory. *Cytotherapy* 2:111-22.
21. Mascotti K, J McCullough, SR Burger. 2000. Hematopoietic progenitor cell viability measurement: trypan blue *versus* acridine orange/propidium iodide. *Transfusion* 40:693-96.

**Publications, continued**

22. Burger SR. 2001. Umbilical cord blood stem cells. In Handbook of Transfusion Medicine, (C.D. Hillyer, K.L. Hillyer, F.J. Strobl, L.C. Jeffries, and, L.E. Silberstein, eds.). Academic Press, San Diego.
23. Simpson MA, J Reiland, SR Burger, LT Furcht, AP Spicer, Jr., TR Oegema, JB McCarthy. 2001. Hyaluronan synthase elevation in metastatic prostate carcinoma cells correlates with hyaluronan surface retention, a prerequisite for rapid adhesion to bone marrow endothelial cells. *J. Biol. Chem.* 276:17949-57.
24. Orchard PJ, BR Blazar, S Burger, B Levine, L Basso, DMK Nelson, K Gordon, RS McIvor, JE Wagner, JS Miller. 2002. Clinical scale selection of anti-CD3/CD28 activated T cells following transduction with a retroviral vector expressing herpes simplex virus thymidine kinase and truncated nerve growth factor receptor. *Human Gene Therapy* 13:979-88.
25. Schmid JL, J McCullough, SR Burger, A Hubel. 2002. Non-cryopreserved bone marrow storage in STM-Sav, an infusible-grade cell storage solution. *Cell Preservation Technology* 1:45-51.
26. McKenna DH, Rupp C, Wagner J, McGlennen R, Hirsch B, Dolan M, Burger S, Hanson M, Jaszcz W, Nguyen PL. 2002. Increased lymphoblast-like cells following umbilical cord blood stem cell transplantation do not predict recurrent acute leukemia. *Leukemia* 16:2171-2.
27. Koenigbauer UF, SR Burger, J McCullough. 2002. Non-frozen preservation of umbilical cord blood. *Transfusion* 42:1383-84.
28. Burger SR. 2002. Advanced cell and gene therapies: translational development and GMP production. *BioProcessing* 1:19-23 (invited review).
29. Burger SR. 2003. GTP/GMP cell engineering for cell and gene therapies. *BioProcessing* 2:66-69 (invited review).
30. Burger SR. 2003. Current regulatory issues in cell and tissue therapy. *Cytotherapy* 5:289-298 (invited review).
31. Burger SR. 2003. Therapeutic cancer vaccines. *BioProcessing* 2(4):16 (invited editorial).
32. Burger SR, DM Kadidlo, N Bostrom, PJ Orchard. 2003. Cellular engineering of HSV-tk-transduced, expanded T-lymphocytes for GVHD management. *Acta Haematologica* 110:121-131 (invited review).
33. Burns LJ, Weisdorf DJ, DeFor TE, Vesole DH, Repka TL, Blazar BR, Burger SR, Panoskaltis-Mortari A, Keever-Taylor CA, Zhang MJ, Miller JS. 2003. IL-2-based immunotherapy after autologous transplantation for lymphoma and breast cancer induces immune activation and cytokine release: a phase I/II trial. *Bone Marrow Transplant* 32:177-86.

### **Publications, continued**

34. Burger SR. 2004. Cell and gene therapy - challenges and strategies for an emerging industry. *Cell & Gene Therapy* 1:9-14 (invited review).
35. Prince HM, Wall DP, Stokes KH, Wood R, Burger SR, Coghlan P, Boyce N. 2004. Cell processing for clinical trials and commercial manufacture. *Cell & Gene Therapy* 1:15-21.
36. Burger SR. 2006. Manufacturing cell-based therapies - overcoming the obstacles. *European Biopharmaceutical Review* (invited review, in press).

### **Abstracts**

1. Harpstead SD, MR Urbano, J Vincent, SR Burger, EM Hrabak, FB Dazzo. 1978. Bacteriophages which degrade the capsular polysaccharide of *Rhizobium trifolii*. American Society for Microbiology, Michigan branch, annual meeting.
2. Burger SR, JW Bennett. 1983. Possible selective function for prodigiosin, a secondary metabolite of *Serratia marcescens*. American Society for Microbiology, Annual Meeting Abstracts, p. 277.
3. Spitalnik SL, JM Danley, SR Burger, PF Spitalnik. 1988. Secretion of blood group P active glycolipids by the Hep-G2 human hepatoma cell line. *Glycoconjugate J.* 5:306.
4. Burger SR, RJ Muschel, W Wunner, SL Spitalnik. 1989. Stable expression of the rabies glycoprotein gene in mammalian cells: a model to study the regulation of protein glycosylation. Academy of Clinical Laboratory Physicians and Scientists, Stony Brook, NY.
5. Burger SR, RJ Muschel, M Kelsten, W Wunner, SL Spitalnik. 1989. Stable expression of the rabies glycoprotein gene in mammalian cells - a model to study the regulation of protein glycosylation. Gordon Conference on Glycoproteins and Glycolipids, Ventura, CA.
6. Burger SR, AT Remaley, RJ Muschel, M Kelsten, W Wunner, SL Spitalnik. 1989. Stable expression of the rabies glycoprotein gene in mammalian cells - a model to study the regulation of protein glycosylation. Proceedings of the Tenth International Symposium on Glycoconjugates, Jerusalem, Israel. Abstract 127.
7. Burger SR, SA Santoro. 1991. Changes in integrin expression accompanying induced differentiation of K562 cells. Academy of Clinical Laboratory Physicians and Scientists, Little Rock, AR.
8. Burger SR, BT Thomas, JE Grishaber. 1994. Concurrent collection of plasma. American Association of Blood Banks annual meeting. *Transfusion* 34:81S.
9. Burger SR, SK Fautsch, J McCullough. 1995. Factors affecting mononuclear cell recovery in an automated cell separation system. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 4:220.

**Abstracts, continued**

10. Burger SR, SK Fautsch, DF Stroncek, J McCullough. 1995. Concentration of citrate anticoagulant in peripheral blood stem cell collections. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 4:225.
11. Verfaillie CM, R Bhatia, JS Miller, J McCullough, SR Burger, PB McGlave. 1995. Clinical scale selection and *ex vivo* expansion of *BCR/ABL*-negative CD34<sup>+</sup>/HLA-DR<sup>-</sup> cells from CML marrow suitable for transplantation. American Society of Hematology annual meeting. *Blood* 86:294a.
12. Burger SR, DF Stroncek, SK Fautsch, JE Wagner, J McCullough. 1995. Mislabeling of elutriation media results in cell loss during processing. American Society of Hematology annual meeting. *Blood* 86:981a.
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