

## Curriculum Vitae

**Scott R. Burger**

February 1, 2017

### Personal Information

Date of Birth: April 14, 1962  
Place of Birth: Utica, New York

Citizenship: USA

### Present Position

Principal  
Advanced Cell & Gene Therapy, LLC  
105 Highgrove Drive  
Chapel Hill, North Carolina 27516-8376

(919) 969-1103 - Telephone  
celltherapy@ac-gt.com  
[www.ac-gt.com](http://www.ac-gt.com)

### 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 (5/03-08), Commercialization Committee (8/06-4/16), Product and Process Development Subcommittee (8/10-present), Global Regulatory Perspectives Workshop Organizing Committee (1/08-present; co-chair, 10/07-5/12)

Advisory Board (5/00-5/02), Executive Committee (5/01-8/05)

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

Editorial Board, Telegraft (1/99-8/06; editor, 5/01-8/05)

U.S. Pharmacopeia (USP)

Biologics & Biotechnology: Cell, Gene, and Tissue Therapies Expert Committee (4/05-5/10)

Williamsburg BioProcessing Foundation

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

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

BioCision, San Rafael, California

Scientific Advisory Board (11/13-present)

Longevity Therapeutics, Chicago, Illinois

Scientific Advisory Board (12/11-present)

HemaCare Corporation, Los Angeles, California

Chairman, Scientific Advisory Board (4/11-4/16)

Regenerative Medicine Foundation, Winston-Salem, North Carolina

Scientific Advisory Council (7/10-present)

BioLife Solutions, Seattle, Washington

Scientific Advisory Board (9/07-present)

Opexa Therapeutics, The Woodlands, Texas

Clinical and Scientific Advisory Boards (4/05-4/08)

Johnson & Johnson Stem Cell Internal Venture, Radnor, Pennsylvania

Scientific Advisory Board (4/04-4/08)

Schering AG, Berlin, Germany

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

BioE, Inc., White Bear Lake, Minnesota

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

**Reviewer - Journals, Grants, Abstracts**

BioProcessing

Bone Marrow Transplantation

Cytotherapy

Nature Reviews Drug Discovery

Transfusion

American Society of Hematology (ASH)

California Institute for Regenerative Medicine (CIRM)

Defense Medical Research and Development Program (DMRDP)

International Society for Cellular Therapy (ISCT)

National Heart, Lung, and Blood Institute-NIH

National Marrow Donor Program (NMDP)

**Professional Societies and Organizations**

American Society of Hematology (ASH)

International Society for Cellular Therapy (ISCT)

Society for the Immunotherapy of Cancer (SITC)

**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.

**Teaching and Invited Presentations**

- 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.
- 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.

**Teaching and Invited Presentations**

- 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.
- 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.

**Teaching and Invited Presentations**

- 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.
- 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 (ISCT) 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.



**Teaching and Invited Presentations**

- 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.
- 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 (ISCT) GTP 2003 workshop, Phoenix, AZ.
- 5/03      Issues in Implementing Gene Therapy Clinical Studies - Gene Therapy Educational Session. International Society for Cellular Therapy (ISCT) 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

**Teaching and Invited Presentations**

- 4/04 Advanced Cellular Therapies - Development, GMP Manufacturing, and Product Characterization. Cytonet workshop, Heidelberg, Germany.
- 5/04 Cell and Gene Therapy Process Development. Educational Session, International Society for Cellular Therapy (ISCT) 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 (ISCT) 2005 annual meeting, Vancouver, BC.
- 5/05 Steps Toward Compliance - Laboratory Practices and Regulatory Affairs Workshop, International Society for Cellular Therapy (ISCT) 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.

**Teaching and Invited Presentations**

- 5/06 Cell Therapy Product Characterization. Technical Session, International Society for Cellular Therapy (ISCT) 2006 annual meeting, Berlin, Germany.
- 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.
- 6/07 Developing Stem Cell-Based Therapies - Characterization and Manufacturing. DIA 2007 annual meeting, Atlanta, GA.
- 6/07 Technology Transfer. Early Stages of Product Commercialization workshop, International Society for Cellular Therapy (ISCT) 2007 annual meeting, Sydney, Australia.
- 6/07 New Approaches to Product Characterization. Technical Session, International Society for Cellular Therapy (ISCT) 2007 annual meeting, Sydney, Australia.
- 10/07 Compliance with GTPs/GMPs for Clinical Cell-Based Therapies. Bureau of Food and Drug Analysis, Taipei, Taiwan.
- 10/07 Compliance with GTPs/GMPs in Manufacturing Cell and Gene Therapy Products (I). Design, Operation and Management of GTP/GMP Cell Engineering Facilities (II). 2007 International Symposium on Regulation of Human Cell and Tissue-Based Products, Bureau of Food and Drug Analysis, Taipei, Taiwan.
- 10/07 Advanced Cell & Gene Therapy - Enabling Development and Commercialization of Cell and Gene Therapy Products. New Trends in Cell and Gene Therapy. Industrial Technology Research Institute, Hsinchu, Taiwan.
- 10/07 Contract Manufacturing of Cell Therapy Products - Pros, Cons, and Strategies for Success. Industry Symposium, 3<sup>rd</sup> World Congress on Regenerative Medicine, Leipzig, Germany.
- 1/08 Promising Cell, Gene, and Tissue Therapy Products - North America. Phacilitate Cell & Gene Therapy Forum 2008, Washington, DC.
- 1/08 Managing Change and Assuring Comparability Throughout Clinical Development. Phacilitate Cell & Gene Therapy Forum 2008, Washington, DC.

**Teaching and Invited Presentations**

- 5/08 Global Regulatory Perspectives Workshop, organizing committee co-chair, moderator. International Society for Cellular Therapy (ISCT) 2008 annual meeting, Miami, FL.
- 1/09 Due Diligence for Cell and Gene Therapy. Phacilitate Cell & Gene Therapy Forum 2009, Washington, DC.
- 4/09 Principles of Batch Processing; Regulations and Requirements for Process Records. The Batch Process Record (BPR) in Cellular Therapy Production. International Society for Cellular Therapy (ISCT) webinar.
- 5/09 Raw Materials: Sourcing and Qualification Testing. International Society for Cellular Therapy (ISCT) 2009 annual meeting, San Diego, CA.
- 5/09 Global Regulatory Perspectives Workshop, organizing committee co-chair, moderator. International Society for Cellular Therapy (ISCT) 2009 annual meeting, San Diego, CA.
- 9/09 Stability Testing and Optimization: Considerations for Cell Therapy Products. International Society for Cellular Therapy (ISCT) webinar.
- 10/09 Manufacturing Cell Therapy Products. CGMP for Phase 1 INDs. NHLBI Production Assistance for Cellular Therapies (PACT) webinar.
- 10/09 GMP/GTP Manufacturing Process Development: Enabling Cell Therapy Clinical Trials and Commercialization. Wake Forest Institute for Regenerative Medicine, Winston-Salem, NC.
- 11/09 Cell/Gene/Tissue-based Therapies: Manufacturing and Characterization. Cell Systems Science Group, National Institute of Standards and Technology, Gaithersburg, MD.
- 1/10 Cell and Gene Therapy Commercialization: Cost Control, Risk Management. Phacilitate Cell & Gene Therapy Forum 2010, Washington, DC.
- 4/10 Integrative Commercialization Strategies plenary panel. Translational Regenerative Medicine Forum, Winston-Salem, NC.
- 4/10 The Great Debate: Ethics of Stem Cell Research (moderator). Clinical Development of Stem Cell Therapies: Scientific, Regulatory, and Ethical Considerations, Drug Information Association (DIA), Bethesda, MD.
- 4/10 Characterization: Enabling Manufacturing Process Development. Characterization and Its Critical Role in Manufacturing, California Institute of Regenerative Medicine (CIRM)/Regenerative Medicine Consortium (RMC) webinar.
- 5/10 Global Regulatory Perspectives Workshop, organizing committee co-chair, moderator. International Society for Cellular Therapy (ISCT) 2010 annual meeting, Philadelphia, PA.

**Teaching and Invited Presentations**

- 5/10 Manufacturing Patient-Specific Cell Therapy Products. International Society for Cellular Therapy (ISCT) 2010 annual meeting, Philadelphia, PA.
- 6/10 US Regulatory Requirements for Gene Therapy INDs and BLAs. DIA 2010 annual meeting, Washington, DC.
- 7/10 Progress and Challenges in Development of MSC-Based Therapies. Mayo Clinic-Luther Forum on Hematopoietic Stem Cells, Rochester, MN.
- 8/10 Regulation of Cellular Immunotherapy Products - Common Obstacles and Strategies for Success. CHI Immunotherapeutics & Vaccine Summit, Cambridge, MA.
- 8/10 *Ex Vivo* Expanded Cell Therapy Products - Manufacturing and Regulatory Issues. CHI Bioprocessing Summit, Boston, MA.
- 10/10 Pharma's Growing Investment in Regenerative Medicine: Effective Strategic Partnerships. World Stem Cell Summit, Detroit, MI.
- 10/10 Current Regulation of HCT-PS and Tissue Banks in US and Europe (I). Developments in Cellular Therapy in the US and Europe (II). Manufacturing Cell Therapy Products - Phase II to Commercialization (III). Cell Therapy Product Development: Case Study (IV). 2010 Taipei International Symposium on Human Cell and Tissue-based Products and Tissue Banks, Taipei, Taiwan.
- 10/10 Global Regulatory Trends (session co-chairman), Asia-Pacific Regional ISCT Meeting, Miyazaki, Japan.
- 11/10 Cell Therapy Products: An Evolving Global Regulatory Environment. Invitrogen Cell Therapy Industry Summit, Carlsbad, CA.
- 12/10 Manufacturing Cell Therapy Products: Models, Methods and Optimization. Informa Cell Therapy Manufacturing Conference, London, UK.
- 12/10 Characterising ATMPs: Developing Potency Assays and Performing Comparability Studies. Informa Cell Therapy Workshop, London, UK.
- 12/10 Regulation of Cell and Tissue Therapy Products: Europe and Asia. TERMIS North America 2010 annual meeting, Orlando, FL.
- 1/11 Potency Testing for Cell Therapy and Tissue-Engineered Products. Alliance for Regenerative Medicine - Potency Testing Workshop, Washington, DC.
- 1/11 Global Regulatory Update (speaker and session chairman). Phacilitate Cell & Gene Therapy Forum 2011, Washington, DC.
- 1/11 Coordinating Manufacturing Process Development With Progress in Clinical Trials. Phacilitate Cell & Gene Therapy Forum, Washington, DC.
- 3/11 Potency Testing. International Society for Cellular Therapy (ISCT) webinar.

**Teaching and Invited Presentations**

- 4/11 Scientific Discovery (session moderator). Translational Regenerative Medicine Forum, Washington, DC.
- 4/11 The Cell Therapy Industry: Status and Challenges. EMD Millipore, Billerica, MA.
- 5/11 US FDA Expectations for Potency Testing of Cell Therapy Products (speaker). Cell Characterization, Potency, and Comparability Studies (session chairman). International Society for Cellular Therapy (ISCT) 2011 annual meeting, Rotterdam, Netherlands.
- 5/11 Regulatory Requirements for Safety Testing of Cell Therapy Products. International Society for Cellular Therapy (ISCT) 2011 annual meeting, Rotterdam, Netherlands.
- 5/11 Global Regulatory Perspectives Workshop, organizing committee co-chair, moderator. International Society for Cellular Therapy (ISCT) 2011 annual meeting, Rotterdam, Netherlands.
- 6/11 Cancer Vaccines and Cellular Immunotherapy Products: Navigating the Regulatory Pathway. Workshop, Hanson Wade 2011 World Cancer Vaccine Summit, Boston, MA.
- 10/11 Standardization: Clinical and Regulatory Aspects. World Stem Cell Summit 2011, Pasadena, CA.
- 10/11 Clinical Translation of Cell Therapy Products. World Stem Cell Summit 2011, Pasadena, CA.
- 10/11 Financing Cell Therapy Development: Partnerships and Alliances. World Stem Cell Summit 2011, Pasadena, CA.
- 10/11 Developing the Product Characterization Profile. IBC Cell Therapy Bioprocessing meeting, Reston, VA.
- 10/11 Global Regulatory Issues in Cell Therapy (speaker and session chair). Asian Cellular Therapy Organization (ACTO) 2011 annual meeting, Miyazaki, Japan.
- 10/11 Tissue Engineered Products: Navigating Global Regulatory Pathways. Workshop, Hanson Wade Translational Strategies for Tissue Engineering conference, Boston, MA.
- 11/11 Potency Testing. International Society for Cellular Therapy (ISCT) webinar.
- 11/11 The Art of Scientific Advice. Workshop, Informa Cell Therapy Manufacturing Europe, Brussels, Belgium.
- 12/11 Due Diligence for Cell Therapy Products. Informa Cell Therapy Manufacturing Europe, Brussels, Belgium.

**Teaching and Invited Presentations**

- 12/11 Characterizing ATMPs: Developing Potency Assays and Performing Comparability Studies. Workshop, Informa Cell Therapy Manufacturing Europe, Brussels, Belgium.
- 1/12 Building the Characterization Package Throughout Product Development. Phacilitate Cell & Gene Therapy Forum 2012, Washington, DC.
- 2/12 Sourcing Human Blood-Derived Raw Material: Optimization, Qualification and Control. IBC Biopharmaceutical Raw Materials conference, San Diego, CA.
- 3/12 The Role of Clinical Trial INDs in Supporting the BLA. American Association of Blood Banks webinar.
- 6/12 Global Regulatory Perspectives Workshop, organizing committee co-chair, moderator. International Society for Cellular Therapy (ISCT) 2012 annual meeting, Seattle, WA.
- 6/12 Sourcing Biologic Materials and Managing Supply Chains: Quality Considerations (session chair). International Society for Cellular Therapy (ISCT) 2012 annual meeting, Seattle, WA.
- 6/12 Manufacturing and Characterization of Cellular Immunotherapy Products: Overcoming the Challenges. Cancer Vaccines & Active Immunotherapeutics Summit, Boston, MA.
- 9/12 Global Regulatory Perspectives (session chair). IBC Cell Therapy Bioprocessing 2012, Arlington, VA.
- 10/12 “Know Thy Product”: On the Acquisition of Knowledge. Regenerative Medicine Foundation 2012 Conference, Charlotte, NC.
- 11/12 Cell Therapy Regulatory Guidance: Global Update and Trends. FDA Cell Therapies Liaison Meeting, Bethesda, MD.
- 12/12 Roadblocks to Translation - Effective Characterization and Potency Testing (speaker and session chair). World Stem Cell Summit 2012, West Palm Beach, FL.
- 12/12 Global Regulatory Developments (speaker and session chair). World Stem Cell Summit 2012, West Palm Beach, FL.
- 1/13 Phacilitate-ISCT Global Regulatory Perspectives satellite workshop (session chair). Phacilitate Cell & Gene Therapy Forum 2013, Washington, DC.
- 1/13 Potency Testing for Combination Products (speaker and session chair). Phacilitate Cell & Gene Therapy Forum 2013, Washington, DC.
- 6/13 Potency Assay Development for Cell Therapy Products. FDA Cell Therapy Working Group, Office of Cellular, Tissue and Gene Therapies, Rockville, MD.
- 7/13 US Regulatory Perspective. Society for Cryobiology/ISCT Joint Session, Bethesda, MD.

- 11/13 Manufacturing and Regulatory Considerations for Cell and Gene Therapy Products. TERMIS-Americas, Atlanta, GA.
- 6/14 Cell Therapy. USP Global Education and Training Webinar.
- 11/14 CMC Considerations for Gene Therapy. NPS Pharma workshop, Bedminster, NJ.
- 12/14 Demonstrating Comparability: Mitigating Risk of Process Changes in Preclinical and Clinical Development. Informa Cell Therapy Manufacturing Conference, Brussels, Belgium.
- 12/14 Framing the Question - The Art of Seeking Scientific Advice. Scientific Advice Workshop, Informa Cell Therapy Manufacturing Conference, Brussels, Belgium.
- 5/15 Global regulatory developments. ISCT Global Regulatory Perspectives Workshop, Las Vegas, NV.
- 10/15 External Support for Cell and Gene Therapy Product Commercialization: Contract Services and Suppliers. IBC Cell Therapy Bioprocessing & Commercialization, Alexandria, VA.
- 10/15 Cell Therapy Product Development and Commercialization: Overcoming the Obstacles. Biogen seminar, Boston, MA.
- 2/16 Raw Materials for Cell Therapy Products: Regulatory and Manufacturing Considerations. Genetic Engineering & Biotechnology News (GEN) webinar.
- 8/16 Demonstrating Comparability in Gene Therapy Technology Transfer. CHI Bioprocessing Summit, Boston, MA.
- 8/16 Comparability: Mitigating Risk of Manufacturing Process Changes. CHI Bioprocessing Summit, Boston MA.
- 8/16 Commercial-Scale Gene Therapy: Manufacturing Issues. CHI Bioprocessing Summit Boston, MA.
- 10/16 Process Development and Validation for GMP Manufacturing of ATMPs. Taiwan FDA-TPDA ATMP GMP Workshop, Taipei, Taiwan.
- 10/16 GMP Facility Design for ATMP Manufacturing. Taiwan FDA-TPDA ATMP GMP Workshop, Taipei, Taiwan.
- 10/16 Regenerative Medicine Product Development and Regulatory Strategy. NCTERMIS 2016, Chapel Hill, NC.
- 12/16 Commercializing CAR T-Cell Products. GLG webinar.
- 1/17 Demonstrating Comparability in Manufacturing Cell and Gene Therapy Products. Phacilitate Cell & Gene Therapy World 2017, Miami FL.



## Publications

1. Burger SR, and DC Blanchard. The persistence of air bubbles at a seawater surface. *J. Geophys. Res.* 1983;88:7724-26.
2. Burger SR. Two related works: Osler's *Aequanimitas* and Bernard's *An Introduction to the Study of Experimental Medicine*. *Pharos* 1985;48:6-8.
3. Burger SR, and JW Bennett. Droplet enrichment factors of pigmented and non-pigmented *Serratia marcescens*: possible selective function for prodigiosin. *Appl. Environ. Microbiol.* 1985;50:487-90.
4. Williams TM, L Eisenberg, JE Burlein, CA Norris, S Pancer, D Yao, SR Burger, M Kamoun, and JA Kant. Two regions within the human IL-2 gene promoter are important for inducible IL-2 expression. *J. Immunol.* 1988;141:662-66.
5. Spitalnik PF, JM Danley, SR Burger, and SL Spitalnik. The glycosphingolipid composition of the human hepatoma cell line, Hep-G2. *Arch. Biochem. Biophys.* 1989;273:578-91.
6. Burger SR, AT Remaley, RJ Muschel, M Kelsten, W Wunner, and SL Spitalnik. Stable expression of the rabies glycoprotein gene in mammalian cells – a model to study the regulation of protein glycosylation. *J. Gen. Virol.* 1991;72:359-67.
7. Remaley AT, M Ugorski, N Wu, L Litzsky, SR Burger, JS Moore, M Fukuda, and SL Spitalnik. Expression of human glycophorin A in wild-type and glycosylation-deficient Chinese hamster ovary cells. *J. Biol. Chem.* 1991;266:24176-83.
8. Burger SR, MM Zutter, S Sturgill-Koszycki, and SA Santoro. Induced cell surface expression of functional  $\alpha_2\beta_1$  integrin during megakaryocytic differentiation of K562 leukemic cells. *Exp. Cell Res.* 1992;202:28-35.
9. Burger SR, BT Thomas, and JE Grishaber. Integration of concurrent collection of plasma into a plateletpheresis program. *J. Clin. Apheresis* 1994;9:126-29.
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. Mislabeling of elutriation media: a demonstration of the need to improve the quality control of reagents produced for cell processing. *Transfusion* 1995;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. 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* 1996;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.

**Publications, continued**

14. Burger SR, SK Fautsch, DF Stroncek, and J McCullough. Concentration of citrate anticoagulant in peripheral blood stem cell collections. *Transfusion* 1996;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 McGlave. *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* 1996;87:4770-9.
16. Shankar R, C Whitley, D Pan, S Burger, J McCullough, D Stroncek. Retroviral transduction of peripheral blood leukocytes in a hollow fiber bioreactor. *Transfusion* 1997;37:685-90.
17. Burger SR, AH Hubel, J McCullough. Development of an infusible-grade solution for non-cryopreserved hematopoietic cell storage. *Cytotherapy* 1999;1:123-133.
18. Stroncek DF, A Hubel, RA Shankar, SR Burger, D Pan, J McCullough, CB Whitley. Retroviral transduction and expansion of peripheral blood lymphocytes for the treatment of mucopolysaccharidosis II, Hunter syndrome. *Transfusion* 1999;39:343-50.
19. Burger SR, DM Kadidlo, J McCullough. Improved progenitor assay standardization using peripheral blood progenitor cells from a donor treated with granulocyte-colony-stimulating factor. *Transfusion* 1999;39:451-56.
20. Burger SR. Design and operation of a cGMP cell engineering laboratory. *Cytotherapy* 2000;2:111-22.
21. Mascotti K, J McCullough, SR Burger. Hematopoietic progenitor cell viability measurement: trypan blue *versus* acridine orange/propidium iodide. *Transfusion* 2000;40:693-96.
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. 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.* 2001;276:17949-57.
24. Orchard PJ, BR Blazar, S Burger, B Levine, L Basso, DMK Nelson, K Gordon, RS McIvor, JE Wagner, JS Miller. 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* 2002;13:979-88.
25. Schmid JL, J McCullough, SR Burger, A Hubel. Non-cryopreserved bone marrow storage in STM-Sav, an infusible-grade cell storage solution. *Cell Preservation Technology* 2002;1:45-51.

**Publications, continued**

26. McKenna DH, Rupp C, Wagner J, McGlennen R, Hirsch B, Dolan M, Burger S, Hanson M, Jaszcz W, Nguyen PL. Increased lymphoblast-like cells following umbilical cord blood stem cell transplantation do not predict recurrent acute leukemia. *Leukemia* 2002;16:2171-2.
27. Koenigbauer UF, SR Burger, J McCullough. Non-frozen preservation of umbilical cord blood. *Transfusion* 2002;42:1383-84.
28. Burger SR. Advanced cell and gene therapies: translational development and GMP production. *BioProcessing* 2002;1:19-23 (invited review).
29. Burger SR. GTP/GMP cell engineering for cell and gene therapies. *BioProcessing* 2003;2:66-69 (invited review).
30. Burger SR. Current regulatory issues in cell and tissue therapy. *Cytotherapy* 2003;5:289-298 (invited review).
31. Burger SR. Therapeutic cancer vaccines. *BioProcessing* 2003;2(4):16 (invited editorial).
32. Burger SR, DM Kadidlo, N Bostrom, PJ Orchard. Cellular engineering of HSV-tk-transduced, expanded T-lymphocytes for GVHD management. *Acta Haematologica* 2003;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. 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* 2003;32:177-86.
34. Burger SR. Cell and gene therapy - challenges and strategies for an emerging industry. *Cell & Gene Therapy* 2004;1:9-14 (invited review).
35. Prince HM, Wall DP, Stokes KH, Wood R, Burger SR, Coghlan P, Boyce N. Cell processing for clinical trials and commercial manufacture. *Cell & Gene Therapy* 2004;1:15-21.
36. Steward CG, Blair A, Moppett J, Clarke E, Virgo P, Lankester A, Burger SR, Sauer MG, Flanagan AM, Pamphilon DH, Orchard PJ. High peripheral blood progenitor cell counts enable autologous backup before stem cell transplantation for malignant infantile osteopetrosis. *Biol Blood Marrow Transplant* 2005;11:115-21.
37. Burger SR. 2009. Commercial manufacturing of cell therapy products: considering the options. In *World Stem Cell Report 2009*, (Bernard Siegel, ed.). Genetics Policy Institute, Wellington, FL.
38. Deans R, Gunter KC, Allsopp T, Bonyhadi M, Burger SR, Carpenter M, Clark T, Cox CS, Driscoll D, Field E, Huss R, Lardenoije R, Lodie TA, Mason C, Neubiser R, Rasko JE, Rowley J, Maziarz RT. A changing time: the International Society for Cellular Therapy embraces its industry members. *Cytotherapy* 2010;12:853-6.

**Publications, continued**

39. Kao GS, Kim HT, Daley H, Ritz J, Burger SR, Kelley L, Vierra-Green C, Flesch S, Spellman S, Miller J, Confer D. Validation of short-term handling and storage conditions for marrow and peripheral blood stem cell products. *Transfusion* 2011;51:137-47.
40. Brandenberger R, Burger S, Campbell A, Fong T, Lapinskas E, Rowley J. Cell Therapy Bioprocessing. *BioProcess International* 2011;9(S1):30-37.
41. Carmen J, Burger SR, McCaman M, Rowley JA. Developing assays to address identity, potency, purity and safety: cell characterization in cell therapy process development. *Regenerative Medicine* 2012;7(1):85-100.
42. Bravery CA, Carmen J, Fong T, Oprea W, Hoogendoorn KH, Woda J, Burger SR, Rowley JA, Bonyhadi ML, Van't Hof W. Potency assay development for cellular therapy products: an ISCT review of the requirements and experiences in the industry. *Cytotherapy* 2013;15(1):9-19.
43. Eaker S, Armant M, Brandwein H, Burger S, Campbell A, Carpenito C, Clarke D, Fong T, Karnieli O, Niss K, Van't Hof W, Wagey R. Guidance in developing commercializable autologous/patient-specific cell therapy manufacturing. *Stem Cells Translational Medicine* 2013;2(11):871-83.
44. Aghayan HR , Arjmand B, Burger SR. 2016. GMP Facilities for Clinical Cell Therapy Product Manufacturing: A Brief Review of Requirements and Design Considerations. In *Perinatal Tissue-Derived Stem Cells*. Babak Arjmand, ed. Humana Press, Cham, 215-228.

## 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.
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+/HLA-DR- 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.

**Abstracts, continued**

13. Stroncek DF, R Konz, S Burger, R McGlennen, H Noreen, J Wagner, J McCullough. 1995. Post-transfusion salvage of umbilical cord blood cell DNA for molecular phenotyping. American Society of Hematology annual meeting. *Blood* 86:991a.
14. Shankar RA, DF Stroncek, D Pan, S Burger, J McCullough, C Whitley. 1995. Expansion and transduction of peripheral blood leukocytes with retroviral vector using a hollow-fiber bioreactor. American Society of Hematology annual meeting. *Blood* 86:1005a.
15. Haley R, J McCullough, G Moroff, M Clay, S Burger, S Wagner, I Feller, R Davey. 1997. Peripheral blood progenitor cell freezing: four methods. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 6:387.
16. Burger SR, D Kadidlo, A Hubel, C Whitley, D Stroncek, J McCullough. 1997. Serum-free expansion of transduced lymphocytes for gene therapy. American Association of Blood Banks annual meeting. *Transfusion* 37:80S.
17. Reiland J, JB McCarthy, SR Burger. 1997. E-selectin and  $\alpha 4$  integrin function in homing-like adhesion of KG-1a cells to activated endothelial monolayers. American Association of Blood Banks annual meeting. *Transfusion* 37:79S.
18. Burger SR, G Herr, A Hubel, J McCullough. 1997. Development of an infusible-grade hematopoietic cell storage solution. American Association of Blood Banks annual meeting. *Transfusion* 37:63S.
19. Burger SR, SK Fautsch, D Kadidlo, J McCullough. 1998. Standardization and control of the hematopoietic progenitor cell assay. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 7:274.
20. Burger SR, D Kadidlo, P Brodsky, T Coburn, J McCullough. 1998. Development of a computer software system for graft engineering. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 7:275.
21. Burger SR, D Kadidlo, J Wagner, J McCullough. 1998. Graft engineering for transplant at distant centers. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 7:288.
22. Burger SR, A Hubel, J McCullough. 1998. Development of an infusible-grade hematopoietic cell storage solution II. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 7:296.
23. Mascotti K, J McCullough, SR Burger. 1998. Cell viability measurement: trypan blue vs. acridine orange/propidium iodide. International Society for Hematotherapy and Graft Engineering annual meeting. *Journal of Hematotherapy* 7:296.
24. Burger SR, D Kadidlo, J Wagner, J McCullough. 1998. Graft engineering for transplant at distant centers. National Marrow Donor Program Council meeting.

**Abstracts, continued**

25. Burger SR, SK Fautsch, D Kadidlo, J McCullough. 1998. Standardization and control of the hematopoietic progenitor cell assay. National Marrow Donor Program Council meeting.
26. Burger SR, A Hubel, J McCullough. 1998. Development of an infusible-grade hematopoietic cell storage solution. National Marrow Donor Program Council meeting.
27. Heapy KM, J Reiland, JB McCarthy, SR Burger. 1998. Soluble factors from marrow stromal cells modulate marrow endothelial cell adhesive phenotype. American Association of Blood Banks annual meeting. *Transfusion* 38:95S.
28. Schmid J, J McCullough, SR Burger. 1998. Validation of an infusible-grade cell storage solution for bone marrow. American Association of Blood Banks annual meeting. *Transfusion* 38:95S.
29. Burger SR, D Kadidlo, P Brodsky, T Coburn, J McCullough. 1999. Development of a computer software system for graft engineering II. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 1:219.
30. Burger SR, D Kadidlo, and J McCullough. 1999. Clinical experience with T-lymphocyte depletion by counterflow elutriation. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 1:220.
31. Schmid J, J McCullough, SR Burger. 1999. Validation of an infusible-grade cell storage solution for bone marrow. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 1:220.
32. Heapy KM, J Reiland, JB McCarthy, SR Burger. 1999. Soluble factors from marrow stromal cells modulate marrow endothelial cell adhesive phenotype. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 1:243.
33. Haley NR, McCullough JJ, Moroff G, Burger S. 1999. A comparison of progenitor cell freezing methods at two years: is 10% dimethyl sulfoxide the best cryoprotectant? International Society for Experimental Hematology annual meeting.
34. Burger SR, Schierman T, Kadidlo D, Chrysler GR, Booher J, Clay ME, Herr G, McCullough J. 1999. Efficiency of post-cryopreservation umbilical cord blood progenitor cell recovery. American Association of Blood Banks annual meeting. *Transfusion* 39:101S.
35. Burger SR, Kadidlo D, McCullough J. 1999. Clinical experience with T-lymphocyte depletion by counterflow elutriation. American Association of Blood Banks annual meeting. *Transfusion* 39:102S.
36. Haley NR, McCullough JJ, Moroff G, Burger SR, Clay M. 1999. A comparison of progenitor cell freezing methods at two years: is 10% dimethyl sulfoxide (DMSO) in LN2 the best cryoprotectant? American Society of Hematology annual meeting. *Blood* 94:553a.

**Abstracts, continued**

37. Burger SR, Bostrom N, Kadidlo DM, Gordon K, Orchard P. Thymidine kinase transduction and expansion of allogeneic T-lymphocytes for management of graft-vs.-host disease. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 2:317, 2000.
38. Burger SR, Kadidlo DM, Fautsch S, Burns L, Weisdorf D, Miller JS. Activation and expansion of immune effector cells for post-transplant immunotherapy. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 2:317, 2000.
39. Goodell WM, Burger SR. 2000. Expression of the Stromal-Derived Factor-1 receptor CXCR4 on CD34+ cells as a function of hematopoietic recovery following bone marrow transplantation. International Society for Hematotherapy and Graft Engineering annual meeting.
40. Kruel K, Van Orsow E, Kadidlo DM, Burger SR. Product storage conditions to prevent cell clumping during CD34+ selection. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 2:343, 2000.
41. Bachowski GJ, Kadidlo DM, Burger SR. Evaluation of Gram-stained buffy-coat preparations for real-time detection of microbial contamination in engineered cell products. American Association of Blood Banks annual meeting, 2000.
42. Burger SR, Bostrom N, Kadidlo DM, Gordon K, Orchard P. Thymidine kinase transduction and expansion of allogeneic T-lymphocytes for management of graft-vs.-host disease. American Association of Blood Banks annual meeting, 2000.
43. Moppett J, Blair A, Clarke E, Virgo P, Pamphilon D, Lankester A, Burger SR, Orchard PJ, Steward CG. Peripheral blood: a rich source of progenitor cells in children with malignant infantile osteopetrosis (MIOP). American Society of Hematology annual meeting, 2000.
44. Burger SR, L Basso, NJ Bostrom, DM Kadidlo, P Orchard. Decreased culture duration, IL-2 concentration, and CD3/CD28-mediated activation enhances function of thymidine kinase-transduced, expanded T-cells. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 3:512, 2001.
45. Minster NI, KS Bailey, SM Reinacher, CE Smith, G Ishioka, J Fikes, NJ Bostrom, EA Van Orsow, DM Kadidlo and SR Burger. Development of an HLA-A2 peptide-pulsed dendritic cell tumor vaccine. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 3:535, 2001.
46. Bostrom NJ, SK Fautsch, DM Kadidlo, SR Burger, IJ Okazaki, JS Miller. Enzymatic and mechanical tumor cell dispersion for tumor vaccine production. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 3:534, 2001.
47. Kadidlo DM, K Kruel and SR Burger. Deviation management in a GMP cell engineering clinical laboratory. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 3:531, 2001.



**Abstracts, continued**

48. van Orsow EA, DM Kadidlo and SR Burger. Cell engineering in a GMP environment: the Fairview-University Medical Center experience. International Society for Hematotherapy and Graft Engineering annual meeting. *Cytotherapy* 3:531, 2001.
49. Orchard PJ, J Miller, L Basso, C Eide, DM Kadidlo, N Bostrom, SR Burger and J Wagner. Development of a successful clinical scale procedure for activation, transduction and selection of human T cells: factors affecting cellular function. American Society of Hematology annual meeting, 2001.
50. Burger, SR. Enabling commercialization of clinical cell and gene therapies - challenges and strategies. *Regenerate* 2004.
51. Beal J, M Herco, K Johnson, J Richards, M Endejann, A Mitchell, SR Burger, KB Johnson. Isolation and Expansion of Human Skeletal Muscle Precursor Cells: Process Development and Optimization. International Society for Cellular Therapy (ISCT) annual meeting, 2011.
52. Herco M, J Beal, K Johnson, J Richards, M Endejann, A Mitchell, SR Burger, KB Johnson. Extended stability study of a human skeletal muscle precursor cell therapy product using CryoStor10 and Hypothermosol-FRS. International Society for Cellular Therapy (ISCT) annual meeting, 2011.
53. Bayer RJ, P van der Wal, SR Burger, A Stock. Sourcing Human Blood-Derived Raw Material: Optimization, Qualification and Control. International Society for Cellular Therapy (ISCT) annual meeting, 2011.
54. McPherson G, P van der Wal, D De Leonardis, SR Burger, A Stock. Sourcing Human Blood-Derived Raw Material: Optimization, Qualification and Control. Society for Immunotherapy of Cancer (SITC) annual meeting, 2011.