Curriculum Vitae

Scott R. Burger, M.D.

- Consultant on manufacturing, regulatory, and strategic aspects of cell and gene therapy products. Over 30 years of experience developing advanced therapies. Have served over 200 companies, from biotech startups to Big Pharma, in North America, Europe, Asia, and Australia, working on products from preclinical development through Phase I/II/III, and commercialization.
- Directed or consulted on process development, GMP manufacturing, and CMC regulatory aspects of CAR T-cell, TCR-T cell, TIL, NK, and DC immunotherapies; gene-edited cell therapy products, AAV and AV gene therapy products; stem cell- and somatic cell-based regenerative medicine products including placental and umbilical cord MSCs, iPSCs, HSCs, retinal stem cells.
- Deep knowledge and extensive experience with closed-system processing, scale out/scale up, automation, potency testing, and comparability.
- Established regulatory expert in cell and gene therapy, has consulted on preparation of over 100 regulatory submissions for cell therapy or gene therapy products at all stages of development. Numerous productive interactions with FDA-CBER Office of Therapeutic Products and its predecessors, Office of Tissues and Advanced Therapies (OTAT) and Office of Cellular, Tissue and Gene Therapies (OCTGT).
- Extensive experience performing technical and regulatory due diligence for investment firms and Big Pharma. and providing guidance on investor expectations to cell and gene therapy startups seeking funding.
- Experienced expert witness in cases involving cell and gene therapy intellectual property, commercialization, FDA regulatory affairs, and GMP compliance.

Present Position

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

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celltherapy@ac-gt.com
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
4/03-4/08	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 University of Minnesota 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

Expert Witness Experience

Excludes cases in progress. Parties supported are shown in boldface.

- Memorial Sloan Kettering Cancer Center and **Eureka Therapeutics** v. Juno Therapeutics – contract dispute
  Susman Godfrey. April 2024
  - Background research, wrote rebuttal of opposing expert witness report

- **Lyell Immunopharma** v. PACT Pharma – contract dispute
  Sidley Austin, September 2021-April 2022
  - Testified before tribunal and in deposition
  - Background research, wrote three expert witness reports and rebuttals of opposing expert witness reports
  - Guidance for counsel on scientific and technical aspects of cell and gene therapy
  - Comments on transcripts of opposing witness depositions, suggested questions for depositions and cross-examination

- **University of North Carolina** v. Vesta Therapeutics – contract dispute
  Robinson Bradshaw and University of North Carolina at Chapel Hill general counsel, January 2021-March 2023
  - Wrote three expert witness reports and rebuttals of opposing expert witness reports
  - Guidance for counsel on stem cells, cell therapy product development, and regulatory pathway. Suggested questions for depositions.

- Restem v. **Jadi Cell** – stem cell patent dispute
  Thorpe North & Western, December 2021-December 2022
  - Testified in deposition
  - Wrote expert witness reports including rebuttal of opposing expert witness
  - Reviewed and researched patents and related publications, guidance for counsel on stem cells and cell therapy product development

- **Mitsubishi Tanabe Pharma Corporation** v. Kolon Life Science – contract dispute
  Sidley Austin, June 2019-February 2020
  - Testified before tribunal
  - Background research, wrote three expert witness reports and rebuttals of opposing expert witness reports
  - Guidance for counsel on cell and gene therapy and CGT product development
  - Comments on transcripts of opposing witness depositions, suggested questions for depositions and cross-examination

- **Atara Biotherapeutics** v. Allogene Therapeutics –trademark case
  Sheppard Mullin, June 2020-September 2020
  - Testified in deposition
  - Wrote expert witness reports including rebuttal of opposing expert witness
  - Reviewed transcript of opposing expert witness deposition, suggested questions for cross-examination.

- **MediciNova** v. Genzyme Corporation - gene therapy patent case
  Sheppard Mullin, August 2017-June 2019
  - Testified in two depositions
  - Testified in court twice (tutorials on gene therapy for judge, by request)
  - Wrote multiple expert witness reports and rebuttals of opposing expert witness
  - Reviewed and researched patents, contracts, and supporting documents

Honors and Awards

1983	Distinctive honors in Biology, Tulane University
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

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 (8/2002-12/2004)

International Society for Cellular Therapy (ISCT)
Gene Therapy Committee (6/1995-5/2004), Legal and Regulatory Affairs Committee (5/2003-2008), Commercialization Committee (8/2006-4/2016), Product and Process Development Subcommittee (8/2010-present), Global Regulatory Perspectives Workshop Organizing Committee (1/2008-present; co-chair, 10/2007-5/2012)
Advisory Board (5/2000-5/2002), Executive Committee (5/2001-8/2005)
Editorial Board, Cytotherapy (5/2002-5/2005)
Editorial Board, Telegraft (1/1999-8/2006; editor, 5/2001-8/2005)

U.S. Pharmacopeia (USP)
Cell, Gene, and Tissue Therapies Expert Committee (4/2005-5/2010)

Williamsburg BioProcessing Foundation
Editorial Board, BioProcessing, (4/2002-6/2004)

Advisory Boards (excludes non-disclosable board participation)

BioLife Solutions, Seattle, Washington
Scientific Advisory Board (9/2007-present)

Carolina BioOncology Institute – BioCytics
Scientific Advisory Board (6/2022-present)

BioCision, San Rafael, California
Scientific Advisory Board (11/2013-11/2015)

Longevity Therapeutics, Chicago, Illinois
Scientific Advisory Board (12/2011-12/2014)

HemaCare Corporation, Los Angeles, California
Chairman, Scientific Advisory Board (4/2011-4/2016)

Regenerative Medicine Foundation, Winston-Salem, North Carolina
Scientific Advisory Council (7/2010-7/2012)

Opexa Therapeutics, The Woodlands, Texas
Clinical and Scientific Advisory Boards (4/2005-4/2008)

Johnson & Johnson Stem Cell Internal Venture, Radnor, Pennsylvania
Scientific Advisory Board (4/2004-4/2008)

Advisory Boards, continued

Johnson & Johnson Pharmaceutical R&D – T Cell Immunotherapy, La Jolla, California
Scientific Advisory Board (10/2006-7/2007)

Schering AG, Berlin, Germany
Spheramine Scientific Advisory Board (7/2003-7/2006)

BioE, Inc., White Bear Lake, Minnesota
Scientific Advisory Board (9/2002-12/2004)

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-National Institutes of Health (NHLBI-NIH)
National Marrow Donor Program (NMDP)

Professional Societies and Organizations

International Society for Cellular Therapy (ISCT)

Military Service

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

Patents

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

8/21/01 Infusible grade short-term cell storage medium. Patent #6,277,557. Scott R. Burger, Allison Hubel, Jeffrey McCullough.

Invited Presentations (selected from over 100)

6/99 cGMP Cellular Engineering for Transplantation. Mayo Clinic-Luther Forum on Hematopoietic Stem Cells, Rochester, MN.

5/01 Translational Development of Novel Cell Therapies. Somatic Cell Therapy meeting and workshop, Captiva Island, 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 to Dendritic Cells - Gene Therapy Workshop. International Society for Cellular Therapy (ISCT) 2002 annual meeting, Barcelona, Spain.

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.

11/02 Advanced Cellular Therapies - Translational Development and GMP Production. Scientific symposium, International Society for Pharmaceutical Engineering 2002 annual meeting, Lake Buena Vista, FL.

6/03 Advances in Cellular Immunotherapy. Georgetown University Medical Center, Current Topics in Histocompatibility and Transplantation audioconference.

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 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

6/05 Regulatory Pathway for Cell Therapy Products. Stem Cells for Treatment of Neurological Diseases, BIO 2005 annual meeting, Philadelphia, PA.

Invited Presentations, selected (continued)

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 (ISCT) 2006 annual meeting, Berlin, Germany.

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 New Approaches to Product Characterization. Technical Session, International Society for Cellular Therapy (ISCT) 2007 annual meeting, Sydney, Australia.

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 Contract Manufacturing of Cell Therapy Products - Pros, Cons, and Strategies for Success. Industry Symposium, 3rd World Congress on Regenerative Medicine, Leipzig, Germany.

1/08 Managing Change and Assuring Comparability Throughout Clinical Development. Phacilitate Cell & Gene Therapy Forum 2008, Washington, DC.

1/09 Due Diligence for Cell and Gene Therapy. Phacilitate Cell & Gene Therapy Forum 2009, Washington, DC.

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.

6/10 US Regulatory Requirements for Gene Therapy INDs and BLAs. DIA 2010 annual meeting, Washington, DC.

10/10 Pharma's Growing Investment in Regenerative Medicine: Effective Strategic Partnerships. World Stem Cell Summit, Detroit, MI.

Invited Presentations, selected (continued)

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.

12/10 Characterizing 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 Global Regulatory Update (speaker and session chairman). Phacilitate Cell & Gene Therapy Forum 2011, Washington, DC.

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.

10/11 Global Regulatory Issues in Cell Therapy (speaker and session chair). Asian Cellular Therapy Organization (ACTO) 2011 annual meeting, Miyazaki, Japan.

11/11 Potency Testing. International Society for Cellular Therapy (ISCT) webinar.

12/11 Due Diligence for Cell Therapy Products. Informa Cell Therapy Manufacturing Europe, Brussels, Belgium.

1/12 Building the Characterization Package Throughout Product Development. Phacilitate Cell & Gene Therapy Forum 2012, Washington, DC.

12/12 Roadblocks to Translation - Effective Characterization and Potency Testing (speaker and session chair). World Stem Cell Summit 2012, West Palm Beach, FL.

6/13 Potency Assay Development for Cell Therapy Products. FDA Cell Therapy Working Group, Office of Cellular, Tissue and Gene Therapies, Rockville, 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.

12/14 Demonstrating Comparability: Mitigating Risk of Process Changes in Preclinical and Clinical Development. Informa Cell Therapy Manufacturing Conference, Brussels, Belgium.

2/16 Raw Materials for Cell Therapy Products: Regulatory and Manufacturing Considerations. Genetic Engineering & Biotechnology News (GEN) webinar.

8/16 Comparability: Mitigating Risk of Manufacturing Process Changes. CHI Bioprocessing Summit, Boston MA.

Invited Presentations, selected (continued)

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.

1/17 Demonstrating Comparability in Manufacturing Cell and Gene Therapy Products. Phacilitate Cell & Gene Therapy World 2017, Miami FL.

5/18 Regulatory Expectations for Manufacturing Control Strategy. ISCT Annual Meeting, Montreal, Canada.

12/19 Navigating the Regulatory Pathway for Cell and Gene Therapy Products: Strategies for Successful Cell & Gene Therapy BLA Submissions. CenterWatch/FDAnews webinar.

7/20 Demonstrating Comparability in Manufacturing Cell and Gene Therapy Products. FDAnews webinar.

8/20 Apheresis Collection for Cell and Gene Therapy Manufacturing. CHI Bioprocessing Summit, Boston, MA.

10/20 Starting Material Standardization for Autologous and Allogeneic Cell Therapies. Informa Cell & Gene Therapy Bioprocessing & Commercialization, Boston, MA.

10/21 Raw Materials for Cell and Gene Therapy Products: Regulatory Perspective and Comparability Considerations. Korea NIFDS-USP joint workshop.

12/22 Update on Comparability in Manufacturing Cell and Gene Therapy Products. FDAnews webinar.

8/23 Overview of FDA Draft Guidance on Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products. CHI Bioprocessing Summit.

8/23 Technology Transfer for Cell and Gene Therapy Products. CHI Bioprocessing Summit.

8/23 Decentralized Manufacturing of Cell Therapy Products: Comparability Considerations. CHI Bioprocessing Summit.

8/23 - Regulatory Expectations for Potency Testing Development. Hanson Wade Gene Therapy Potency Testing conference.

11/23 Manufacturing Changes and Comparability for Cell and Gene Therapy Products. Hanson Wade Gene Therapy Analytical Development conference.

11/23 Applying Biologics Development Practices to Gene Therapy Products: Quality by Design. Hanson Wade Gene Therapy Analytical Development conference.

8/24 Effective CMC Due Diligence for Cell and Gene Therapy Products and Technology. CHI Bioprocessing Summit, Boston, MA.

Invited Presentations, selected (continued)

8/24 US Regulatory Update 2024: New Guidance Documents from FDA OTP. CHI Bioprocessing Summit, Boston, MA.

10/24 Regulatory Considerations for Process Automation: Comparability to Bridge Process Changes. BioProcess Development Workshop - Automation in Cell Therapies: Common Pitfalls and How to Avoid Them. North Carolina Biotechnology Center, Durham, NC.

11/24 Localization and Technology Transfer of CAR-T Cell Therapies. Saudi FDA workshop.

11/24 Starting Materials Considerations for Cell and Gene Therapy Manufacturing. Charles River Laboratories webinar.

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 promotor 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.

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.

Publications, continued

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, Panoskaltsis-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.

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.

Publications, continued

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.

45. Bravery CA, Robinson S, Burger SR. Making the grade: untangling the myths of raw materials used for the manufacture of cell- and gene-based medicinal products. Cell and Gene Therapy Insights 2018;4(3), 207-225.

46. Holmberg JA, Henry SM, Burnouf T, Devine D, Marschner S, Boothby TC, Burger SR, Chou ST, Custer B, Blumberg N, Siegel DL, Spitalnik SL. National Blood Foundation 2021 Research and Development summit: Discovery, innovation, and challenges in advancing blood and biotherapies. Transfusion. 2022;62(11), 2391-2404.

47. Janssen WE and Burger SR. Producing cell-based therapeutic products with lot-to-lot consistency from highly variable starting cell products. Cell & Gene Therapy Insights 2022;8(10), 1277–1281.

48. Janssen WE and Burger SR. The living cell supply chain: a product-specific, rational approach to management of cellular starting material donors and donations. Cell & Gene Therapy Insights 2022; 8(10), 1375–1379.

49. Janssen WE and Burger SR. Analytics for cell and gene therapy products in early development: points to consider before preparing an IND for a first-in-human clinical trial. Cell & Gene Therapy Insights 2024; 10(8), 1237–1245.

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.

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