Curriculum Vitae

Scott R. Burger

Scott R. Burger, MD has over 25 years of experience developing cell and gene therapy products and has consulted for over 150 companies, from biotech startups to Big Pharma, in North America, Europe, Australia, and parts of Asia, on products from preclinical development through Phase I/II/III, and commercialization. He has directed or consulted on process development, manufacturing, and CMC regulatory aspects of a wide range of cell therapy and gene therapy products, including CAR T-cell, NK, and DC immunotherapies, gene-edited cell therapy products, as well as stem cell- and somatic cell-based regenerative medicine products.

An established regulatory expert in cell and gene therapy, Dr. Burger has consulted on the preparation over 75 regulatory submissions for cell therapy or gene therapy products at all stages of development, and has had numerous productive interactions with FDA-CBER Office of Tissues and Advanced Therapies (OTAT), including INTERACT, pre-IND, EOP2, and Type C meetings.

He has served as an expert witness in cases involving cell and gene therapy intellectual property, commercialization, FDA regulatory affairs, and GMP compliance, and as a subject matter expert for NIH-NHLBI, DMRDP, PACT, and CIRM review panels for development funding. Dr. Burger has performed technical and regulatory due diligence for investment firms and Big Pharma, and provided guidance on investor expectations to cell and gene therapy startups seeking funding.

Present Position

Founder, 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

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 (formerly 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.

Grants and Contracts, continued

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).

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 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.

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 (11/13-11/15)

Longevity Therapeutics, Chicago, Illinois
Scientific Advisory Board (12/11-12/14)

HemaCare Corporation, Los Angeles, California
Chairman, Scientific Advisory Board (4/11-4/16)

Regenerative Medicine Foundation, Winston-Salem, North Carolina
Scientific Advisory Council (7/10-7/12)

Advisory Boards, continued

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-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

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.

Teaching and Invited Presentations, continued

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.

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.

Teaching and Invited Presentations, continued

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.

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.

Teaching and Invited Presentations, continued

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.

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 to 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.

Teaching and Invited Presentations, continued

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.

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.

Teaching and Invited Presentations, continued

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.

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.

Teaching and Invited Presentations, continued

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 (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.

Teaching and Invited Presentations, continued

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 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.

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.

Teaching and Invited Presentations, continued

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.

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 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 Potency Testing for Cell Therapy and Tissue-Engineered Products. Alliance for Regenerative Medicine - Potency Testing Workshop, Washington, DC.

Teaching and Invited Presentations, continued

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.

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.

Teaching and Invited Presentations, continued

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.

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.

Teaching and Invited Presentations, continued

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.

Teaching and Invited Presentations, continued

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.

3/19 Strategies for Successful Cell & Gene Therapy FDA Submissions: Best Practices for Phase I to BLA Approval. CenterWatch/FDAnews webinar.

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

9/19 Raw Material Sourcing and Qualification. BPI CGT Bioprocessing & Commercialization.

9/19 Regulatory Issues and Considerations for Cryopreservation. BPI CGT Bioprocessing & Commercialization.

6/20 US Regulation of Cell and Gene Therapy Products. Markets and Markets conference: Cell and Gene Therapy Bioprocessing.

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

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

11/20 *Ex Vivo* Gene Therapy Analytics. Hanson Wade Gene Therapy Analytical Development conference.

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