

2009 Conference Program

Sunday May 3, 2009 - Pre-Conference Day

6:30am-7:30pm	Registration Bayview Foyer
8:00am-12:00pm	Flow Cytometry Workshop (Separate Registration Fee Required) Nautilus 4 & 5
	6:30am-7:45am Registration (Separate Registration Fee Required)
	7:45am-8:20am Preparation of Regulatory T Cells for Therapy - Kevin Sheehan PhD, Stanford University School of Medicine
	8:20am-8:55am cGMP Facilities for Cell Processing and Flow Cytometry - Gerhard Bauer, Asst. Professor, Director, GMP Facility, University of California Davis Stem Cell Program
	8:55am-9:30am Induced Progenitor Cell Therapy for Sickle Cell Disease - Tim M. Townes PhD, University of Alabama at Birmingham
	9:30am-9:45am Coffee Break
	9:45am-10:20am Stem Cells and HIV Disease: More Than Immune Reconstitution - Jerome Zack, PhD, UCLA David Geffen School of Medicine
	10:20am-10:55am Functional assays & phosphoflow in translational cellular immunotherapy - Mark Lowdell, PhD FRCPATH, Department of Haematology, UCL Medical School
	10:55am-11:30am Title TBA
	11:30am-11:55am Panel Discussion/Q&A (All Speakers)
11:55am-12:00am Closing Remarks	
8:00am-2:30pm	Global Regulatory Perspectives Workshop (Separate Registration Fee Required) Grande Ballroom A
	7:30am-8:00am Registration (Separate Registration Fee Required) Bayview Foyer
	8:00am-8:15am Introduction Scott Burger, MD - Advanced Cell & Gene Therapy, USA
	8:15am-9:15am Session I: Global Regulatory Update Moderator: Kurt Gunter, MD - Interim Vice President, Global Regulatory Affairs, Hospira Inc, USA Speakers: Christopher Bravery, PhD - Director of Regulatory Affairs, ERA Consulting, UK • Peta O'Connell, PhD A/g Director, Cell and Tissue Therapies Section, TGA, Australia • Der-Yuan Wang, PhD - Chief, Section of Blood Products & In Vitro Diagnostics, Bureau of Food and Drug Analysis, Taiwan
	9:15am-10:45am Session II: Preclinical Models and Requirements for Gene Therapy Products Moderator: Ineke Slaper-Cortenbach, PhD - University Medical Center, Utrecht, The Netherlands Speakers: Yuji Heike, MD, PhD - Division of Hematology/Hematopoietic Stem Cell Transplantation, National Cancer Center, Japan • Maria Cristina Galli, PhD - Vicechair of Gene Therapy Working Party, EMEA, Italy • Theresa Chen, PhD, FDA/CBER/OCTGT
	10:45am-11:00am Coffee Break
	11:00am-12:30pm Session III: Global Challenges in Product Characterization and Manufacturing Compliance Moderator: Scott Burger, MD - Advanced Cell & Gene Therapy, USA Speakers: Giovanni Migliaccio, PhD - Head, Section of Gene and Cell Therapy Dept. of Cell Biology and Neuroscience Istituto Superiore di Sanità, Italy • Kimberly Benton, PhD - FDA/CBER/OCTGT • Susanne Douglas - Audit Team Manager, Blood and Tissues Audit Team, TGA, Australia
	12:30pm-1:00pm Lunch
	1:00pm-2:30pm Session IV: Case Studies: Manufacturing, Preclinical, Testing, Recalls Moderator: Dominic Wall, PhD - Peter MacCallum Cancer Centre, Australia Case Study 1 - Manufacturing Panelists: Sean O'Bryan - Associate Director, Regulatory Affairs, Genzyme Biosurgery, USA • Susanne Douglas - Audit Team Manager, Blood and Tissues Audit Team, TGA, Australia Case Study 2 - Recalls Panelists: Der-Yuan Wang, PhD - Chief, Section of Blood Products & In Vitro Diagnostics, Bureau of Food and Drug Analysis, Taiwan • TBA Case Study 3 - Testing Panelists: Kimberly Benton, PhD - FDA/CBER/OCTGT • TBA Case Study 4 - Clinical Trial Panelists: Giovanni Migliaccio, PhD - National Delegate, Committee for Advanced Therapies, EMEA, Italy • Rebecca Prue, PhD - Mater Medical Research Institute, Australia Additional Panelists: Arpah Abas - Head, Biotechnology Section, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia • Mickey Koh, MD, MRCP, MRCPath, PhD - Vice Director of Center for Transfusion Medicine, Health Science Authority, Singapore • Kellathur Srinivasan, PhD - Health Science Authority, Singapore

Sunday May 3, 2009 - Pre-Conference Day *continued*

3:00pm–5:00pm	Symposium (Refer to Corporate Program)
7:30pm–9:30pm	Welcome Reception Pavilion

Monday May 4, 2009

6:30am–6:00pm	Registration Bayview Foyer				
7:30am–8:30am	Tutorial (Refer to Corporate Program) Nautilus 4	Technical Breakfast 1 Nautilus 1 A Discussion of Alternate FBS-free Media for Culture Expansion of MSCs and Their Potential Use in Clinical Trials Chairs: Massimo Dominici, MD, Ingo Müller, MD, MS	Technical Breakfast 2 Nautilus 2 Ex vivo Genetically Modified Cells for Clinical Therapy Chair: John Rasko, MBBS PhD FRCPA FRACP Speakers: Dominic Wall, PhD, Una O'Doherty, MD, PhD	Technical Breakfast 3 Nautilus 3 Post Natal Tissues – Banking, Diagnostics and Therapy Chair: Robert Deans, PhD Speakers: Morey Kraus PhD, Phil Paul, PhD, Gregory Russotti, PhD	Technical Applications Track 1 Grande Ballroom A The Effect of Mobilization and Collection Technique on HPC-A Product Composition Chair: Richard Meagher, PhD Speaker: Renee Smilee, MT(ASCP)
8:45am–9:00am	Welcome and Opening Remarks Grande Ballroom B & C				
9:00am–10:30am	Plenary Session 1 – Mesenchymal Stem Cells Grande Ballroom B & C Chair/Basic Up-To-Date Overview: Darwin J. Prockop, MD, PhD, Texas A&M Health Science Center, College of Medicine Clinical Trials/Applications: Edwin Horwitz, MD, PhD, Abramson Research Center, The Children's Hospital of Philadelphia Practical, Methodological, Regulatory Aspects: Robert Deans, PhD, Athersys, Inc.			Technical Applications Track 2 Grande Ballroom A Raw Materials Sourcing and Qualification Chair: Karen Edward, BSc, MT(ASCP) Speakers: Scott Burger, MD and Julia Goldstein, MD	
10:00am–6:00pm	Exhibits Pavilion				
10:30am–11:00am	Coffee Break in Exhibition Hall Pavilion				
11:00am–12:15pm	Oral Abstract Presentations 1 Mesenchymal Stem Cells Grande Ballroom B	Oral Abstract Presentations 2 Immunotherapy & Dendritic Cells Grande Ballroom C	Oral Abstract Presentations 3 Lab Practices Grande Ballroom A		
12:15pm–1:30pm	Lunch in Exhibition Hall Pavilion			Tutorial (Refer to Corporate Program) Nautilus 2	
1:45pm–3:15pm	Plenary Session 2 – Gene Transfer: Hematopoietic Stem Cells Grande Ballroom B & C Chair/Basic Up-To-Date Overview: Hans-Peter Kiem, MD, FACP, Fred Hutchinson Cancer Research Center Clinical Trials/Applications: John A. Zaia, MD, City of Hope Practical, Methodological, Regulatory Aspects: Dave DiGiusto, PhD, City of Hope			Technical Applications Track 3 Grande Ballroom A Cord Blood: Thaw/Infusion Practical Methods Chairs: Eddie Jacildo, MT(ASCP) DLM, MBA, Michele Sugrue, MS, MT(ASCP)SBB, Speakers: Donna Regan, MT(ASCP)SBB, Joanne Kurtzberg, MD	
3:15pm–3:45pm	Coffee Break in Exhibition Hall Pavilion				
3:45pm–5:15pm	Workshop 1 Nautilus 1 Nuts and Bolts of Operational Planning and Implementation of MSC Clinical Trials Chair: Robert Deans, PhD Speakers: Robert Preti, PhD, Lary Couture, PhD, EJ Read, MD	Workshop 2 Nautilus 2 Dealing With Myeloid Suppressors in Cell Therapy Chair: Allan Dietz, PhD Speakers: Yi Lin, MD, PhD, Srinivas Nagaraj, MS, PhD	Workshop 3 Nautilus 3 Safety and Monitoring of Gene Modified Cells Chair: Hans-Peter Kiem, MD, FACP Speakers: Derek Persons, MD, PhD, David DiGiusto, PhD	Workshop 4 Nautilus 4 Pharmaceutical Perspectives on Cell Therapies: Participation and Partnering Chair: Alan Lewis, PhD Speakers: Alain Vertes, PhD, MBA, Kenneth Aldrich	Technical Applications Track 4 Grande Ballroom A Quality Investigations: Root Cause Analyses with Examples Co-Chairs: Jim Williams, PhD, Donna Rill, BS, MT(ASCP) Speakers: Deborah Lyon, MT(ASCP) CLSp(MB)

Monday May 4, 2009 *continued*

5:15pm–6:15pm	Poster Session 1 <i>Pavilion</i>
6:30pm–7:30pm	<p>Embryonic Stem Cells: Where Are We Going? <i>Grande Ballroom B & C</i></p> <p>Evan Snyder MD, PhD, Burnham Institute for Medical Research Marie Csete MD, PhD, California Institute for Regenerative Medicine</p> <p>Open to the Public</p>

Tuesday May 5, 2009

7:00am–6:00pm	Registration <i>Bayview Foyer</i>					
7:30am–8:30am	<p>Tutorial (Refer to Corporate Program) <i>Nautilus 5</i></p>	<p>Technical Breakfast 4 <i>Nautilus 1</i></p> <p>Monitoring of Gene-Modified Cells; Tissue-Specific Expression; Immunotherapy</p> <p>Chair: Bruce Levine, PhD Speaker: David DiGiusto, PhD</p>	<p>Technical Breakfast 5 <i>Nautilus 2</i></p> <p>Circulating Tumor Cells</p> <p>Chair: Klaus Pantel, MD, PhD Speaker: Catherine Panabières, PhD</p>	<p>Technical Breakfast 6 <i>Nautilus 3</i></p> <p>Bottlenecks in Clinical Source Material Acquisition</p> <p>Chair: Marta Schilling Speakers: Aby Mathew, PhD, Nancy Dock, PhD</p>	<p>Technical Breakfast 7 <i>Nautilus 4</i></p> <p>Cord Blood Stem Cell and Adoptive Cell Therapy</p> <p>Chair: Mitchell Cairo, MD Speakers: Yangling Liao, PhD, Joanne Kurtzberg, MD</p>	<p>Technical Applications Track 5 <i>Grande Ballroom A</i></p> <p>Validation and Qualification</p> <p>Co-Chairs and Speakers: Federico Rodriguez, MT(ASCP)SBB, Lizette Caballero, BS, MT(ASCP)</p>
8:45am–10:15am	<p>Plenary Session 3 – T Cells <i>Grande Ballroom B & C</i></p> <p>Chair/Basic Up-To-Date Overview: Hermann Einsele, MD, PhD, University Hospital Würzburg</p> <p>Clinical Trials/Applications: Michael Jensen, MD, City of Hope</p> <p>Practical, Methodological, Regulatory Aspects: Bruce Levine, PhD, Division of Hematology/Oncology, University of Pennsylvania</p>					<p>Technical Applications Track 6 <i>Grande Ballroom A</i></p> <p>Environmental Monitoring: Practical Applications</p> <p>Chair: Lizette Caballero, BS, MT(ASCP) Speakers: Paul Eldridge, PhD, Doug Padley, MT(ASCP), Carlos Lee, BS, J. Wade Atkins, MS, MT(ASCP)SBB</p>
9:45am–6:00pm	Exhibits <i>Pavilion</i>					
10:15am–10:45am	Coffee Break in Exhibition Hall <i>Pavilion</i>					
10:45am–12:15pm	<p>Oral Abstract Presentations 4 Mesenchymal Stem Cells <i>Grande Ballroom B</i></p>		<p>Oral Abstract Presentations 5 Immunotherapy & Dendritic Cells and Translational Process Development <i>Grande Ballroom C</i></p>		<p>Technical Applications Track 7 (10:45am-12:00pm) <i>Grande Ballroom A</i></p> <p>Product Recall Management</p> <p>Co-Chairs: Karen Nichols, Esq., RAC, J. Wade Atkins, MS, MT(ASCP)SBB Speaker: Mary Beth Fisk, BSc, MT(ASCP)</p>	
12:15pm-1:30pm	Annual General Meeting <i>Nautilus 4</i>					
12:15pm-1:30pm	Lunch in Exhibition Hall <i>Pavilion</i>					
12:30pm-1:30pm	<p>Tutorial (Refer to Corporate Program) <i>Nautilus 1</i></p>	<p>Tutorial (Refer to Corporate Program) <i>Nautilus 2</i></p>	<p>Tutorial (Refer to Corporate Program) <i>Nautilus 3</i></p>			

Tuesday May 5, 2009 *continued*

1:30pm–3:00pm	Plenary Session 4 – Islet Cells <i>Grande Ballroom B & C</i> Chair/Basic Up-To-Date Overview: Gordon Weir, MD, Joslin Diabetes Research Center, Harvard Clinical Trials/Applications: Bernhard Hering, MD, University of Minnesota Practical, Methodological, Regulatory Aspects: Bob Elliott, MD, Medical Director, Living Cell Technologies Group					Technical Applications Track 8 <i>Grande Ballroom A</i> Quality Program Implementation Chair: Elizabeth Konecki, MS, MT(ASCP), SBB Speakers: Maria Vittoria Gazzola, PhD, Doug Padley, MT(ASCP)
3:00pm–3:30pm	Coffee Break in Exhibition Hall <i>Pavilion</i>					
3:30pm–5:00pm	Workshop 5 <i>Nautilus 1</i> Dendritic Cell Based Cancer Vaccine Trials Chair: Derek Hart, MB, ChB, FRCS, DPhil Speakers: Edgar Engleman, MD, David Urdal, PhD	Workshop 6 <i>Nautilus 2</i> Adipose Stromal / Stem Cell Biology and Therapy: Using Fat for Good Health-Biology and Plasticity of Adipose Stromal Cells (IFATS) Chair: Keith March, MD, PhD Speakers: Albert Donnenberg, PhD, Ramon Lull, MD, PhD, Elizabeth Floyd, PhD	Workshop 7 <i>Nautilus 3</i> Balancing Regulatory Expectations and Industry Realities in Proof of Concept Studies and Pre-Clinical Data. Chair: Darin Weber, PhD Speakers: James Campanelli, PhD, Holger Karsunky, PhD, David Pepperl, PhD	Workshop 8 <i>Nautilus 4</i> The Role of Tumor-Borne and T Reg-Cell-Borne Adenosine in Suppression of T Cell Response Chair: Jonathan Powell, MD, PhD Speakers: Simon C. Robson, MD, PhD, Theresa Whiteside, PhD	Workshop 9 <i>Nautilus 5</i> Corporate and Clinical Strategies for Evidence-Based Reimbursement Submissions. Co-Chairs: Lee Buckler, BEd, LLB, Dawn Driscoll, PhD, MBA Speakers: Geoff McKay, Eric Faulkner, MPH, Simon C. Robson, MD, PhD, FRCP, Leonide Saad, PhD	Technical Applications Track 9 <i>Grande Ballroom A</i> Regulatory Issues in a Product Life Cycle Chair: Nancy H. Collins, PhD Speakers: Grace Kao, MD, Robert Preti, PhD, Yong Fan, MD
5:00pm–6:00pm	Poster Session 2					
7:00pm–midnight	Banquet and Awards Presentation Dinner (<i>Banquet Tickets available for purchase at the Registration Desk</i>) <i>Grande Ballroom B</i>					

Wednesday May 6, 2009

7:00am–2:30pm	Registration <i>Bayview Foyer</i>				
7:30am–8:30am	Technical Breakfast 8 <i>Spinnaker</i> Cell Therapy Cost of Goods Chair: Lee Buckler, BEd, LLB Speaker: Jon Rowley, PhD, Andrew Balber, PhD	Technical Breakfast 9 <i>Grande Ballroom C</i> How to Grow Regulatory T Cells for Clinical Use Chair: Bruce Levine PhD Speaker: Amy Putnam, BS	Technical Breakfast 10 <i>Seabreeze</i> A Snapshot of Tools/ Reagent Roles in Cell Therapy Development Chair: Sarah Haecker, PhD Speakers: Aby Mathew, PhD, Charles O'Hanlon, Ian Fitzpatrick, MSc	Technical Applications Track 10 <i>Grande Ballroom A</i> Clean Room Techniques and Behaviors Chair: Fran Rabe, BA Speaker: Diane Kadidlo, MT (ASCP)SBB	
9:00am–10:30am	Plenary Session 5 – Neural Stem Cells <i>Grande Ballroom B & C</i> Chair/Basic up-to-date overview: Evan Snyder, MD, PhD, Burnham Institute for Medical Research Clinical Trials/Applications: Karen Aboody, MD, City of Hope Practical, Methodological, Regulatory Aspects: Larry Couture PhD, City of Hope				Technical Applications Track 11 <i>Grande Ballroom A</i> Product Transportation and Distribution (AABB) Chair: Donna Regan, MT(ASCP)SBB Speakers: John Miller, MD, PhD, Zbigniew Szczepiorkowski, MD, PhD, FCAP

Wednesday May 6, 2009 *continued*

9:30am–1:00pm	Exhibits <i>Pavilion</i>			
10:30am–11:00am	Coffee Break in Exhibition Hall <i>Pavilion</i>			
11:00am–12:00pm	Oral Abstract Presentations 6 Hematopoietic Stem Cells <i>Grande Ballroom B</i>	Oral Abstract Presentations 7 Legal and Regulatory Affairs <i>Grande Ballroom C</i>	Technical Applications Track 12 <i>Grande Ballroom A</i> ISBT 128 for Cellular Therapy: Implementation/ Applications Chair: Leigh Sims Poston, BS, MT(ASCP) Speakers: Zbigniew Szczepiorkowski, MD, PhD, FCAP, Ineke Slaper-Cortenbach, PhD	
12:00pm–1:00pm	Lunch in Exhibition Hall <i>Pavilion</i>		Tutorial (Refer to Corporate Program) <i>Grande Ballroom B</i>	
1:00pm–2:30pm	Workshop 10 <i>Spinnaker</i> Biomarkers Co-Chairs: Bruce Torbett, PhD, MSPH, Panteli Theocharous, PhD Speakers: William Wikoff, PhD, Morgan Mathieu, PhD, MRes	Workshop 11 <i>Grande Ballroom B & C</i> The Use of Stem Cells for Regenerative Medicine and Tissue Repair. Chair: Joanne Kurtzberg, MD Speaker: Andrew Balber, PhD	Workshop 12 <i>Marina 6</i> Genetic Engineering of Cells Chair: David DiGiusto, PhD Speaker: Philip Gregory, PhD, Daniel Hollyman, PhD, Ian Phillips, PhD, DSc	Technical Applications Track 13 <i>Grande Ballroom A</i> Preparation and Maintenance of Quality and Manufacturing Regulatory Submissions (CMCs) Chair: Steve Binion, PhD, MBA Speakers: Darin Weber, PhD, Joyce Frey-Vasconcells, PhD, Christopher Bravery, PhD
2:30pm–4:00pm	Presidential Plenary Session - Mary Laughlin, MD - ISCT 2008-2010 President <i>Grande Ballroom B & C</i> UCB Hematopoietic Stem Cell Transplantation: Retrospective Analyses and New Horizons Vanderson Rocha, MD, PhD, Hôpital Saint-Louis, Paris, France John Wagner, MD - University of Minnesota, Minneapolis, MN Robert Baitty, MPP, Health Resources and Services Administration (HRSA) Division of Transplantation, Rockville, MD Hal E. Broxmeyer, PhD, Indiana University School of Medicine, Indianapolis, IN			