

Cambridge Healthtech Institute's Second Annual

CELLutions SUMMIT

The Future of
STEM CELL SCIENCES

August 20-23, 2007 • World Trade Center • Boston, MA

Pre-Conference Short Courses

Survive & Thrive (Part 1)

TOOLS AND STRATEGIES TO TAKE
CELL-BASED THERAPIES TO
THE NEXT LEVEL

Incubating Viable Business Models

Five @ Five (Part 2)

PARTNERSHIPS AND COLLABORATIONS
FROM CELL-BASED ENTERPRISES

Start-Up and Early Stage Company Showcase

Third Annual

STEM CELL SOURCES

Targeting Cell-Based
Regenerative Therapies

Fourth Annual

STEM CELL AND 3D MODELS FOR THERAPEUTIC SCREENING

Engineering *in Vitro* to Emulate *in vivo*

Inaugural

CELL THERAPIES

The Path to Clinical Success and Commercialization

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Dear Colleague:

Cambridge Healthtech Institute's Second Annual CELLutions SUMMIT provides in-depth scientific coverage of stem cell sciences and business strategies to achieve the necessary funding and collaborations to enable therapeutic cell-based research. Join us for invaluable networking and learning opportunities.

Focused scientific meetings address the development of technologies to:

- isolate, culture, manipulate, and differentiate stem cells
- understand the molecular processes that afford them such unique attributes for therapies or screening
- explore the future of limitless therapeutic potential

Pre-conference short courses congregate entrepreneurial academics, as well as start-up and early stage company entrepreneurs to showcase their viable solutions and case studies assisting your navigation of successful financial, business, and scientific investments.

CHI is pleased to be working with the Tissue Engineering Resource Center (TERC) at Tufts University to offer delegates a hands-on experience with important aspects of stem cell culture and 3D tissue engineering. This workshop SOLD OUT in 2006! Confirm your space early!

We encourage all participants to share their research at the Poster Session. Dedicated poster viewing time is scheduled. In addition, Roundtable Discussions, Panels, and Exhibit Hall functions allow you to network with your peers, colleagues, and industry leaders.

The CELLutions SUMMIT provides five interactive days of solutions to support your current and future endeavors in stem cell sciences.

We look forward to seeing you in Boston! For up-to-date summit information, visit our website www.CELLutionsSUMMIT.com.

Sincerely,



Mary Ann Brown
Senior Conference Director
Cambridge Healthtech Institute

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TOOLS AND STRATEGIES TO TAKE CELL-BASED THERAPIES TO THE NEXT LEVEL

Incubating Viable Business Models

PARTNERSHIPS AND COLLABORATIONS FROM CELL-BASED ENTERPRISES

Start-Up and Early Stage Company Showcase

August 20, 2007

1:00 pm - 4:00 pm

In recognition of its overwhelming potential, there has been an increase in research funding across the world for cell research, including stem cell research. Apart from venture capitalists taking interest in this area, government funding agencies, foundations, and even the biopharmaceutical companies are working in partnerships with academic institutes, research centers, and other biopharmaceutical companies to fund cell-based research, in particular stem cell research, and company development.

This program will address:

- The challenges and demands of financing cell and tissue-based, especially stem cell research, companies.
- Why IP is the most valuable asset of any company and how to protect your IP through relationships and activities.
- The benefits and value of partnering relationships in this unique industry.

Join entrepreneurial academics, start-up, and early stage company entrepreneurs for an invaluable program filled with viable solutions and successful case presentations about funding strategies and opportunities to create partnerships and collaborations.

Faculty representing biopharma, finance, business and legal have been carefully selected to assist you in the navigation of financial, business, and scientific investments.

Case Presentations

Regenerative Medicine -- The Business Model Problem

Bruce Cohen, President & Chief Executive Officer, Cellerant Therapeutics, Inc.

Emerging Trends in Cell-Based Therapies

Bruce M. Wentworth, Ph.D., Director, Cardiovascular Research, Genzyme Corp.

Panel Discussion

How to Put it Together & Make it Work for You

Co-Moderators:

Teo Forcht Dagi, M.D., MPH, MBA, FACS, FCCM, Partner, HLM Venture Partners & Harvard – MIT, Division of Health Sciences and Technology Faculty
Rosemarie Hunziker, Ph.D., Program Director, Tissue Engineering & Regenerative Medicine, NIH NIBIB

Panelists:

Bruce Cohen, President & Chief Executive Officer, Cellerant Therapeutics, Inc.
Douglas M. Fambrough, Ph.D., Partner, Oxford Bioscience Partners (invited)
Eve Herold, Science Journalist, Director, Public Policy Research & Education, Public Policy, Genetics Policy Institute
John P. Iwanicki, Esq, Senior Partner, Banner & Witcoff, Ltd.
Michele Keane-Moore, Senior Consultant, The Biologics Consulting Group, Inc.
John May, Principal, New Vantage Group (invited)
Bruce M. Wentworth, Ph.D., Director Cardiovascular Research, Genzyme Corp.

Topics to Be Discussed:

- Making sure your startup's technology is truly protected
- Who is buying into stem cell? Why and why not.
- Filing a Phase 1 IND in cell therapies - even if you can do it, should you?
- Mechanism of Actions in cell therapies - why are they important?

5:00 pm - 7:00 pm

Due to political fallout and some controversial concerns, financial entities have hesitated to commit to stem cell research. Despite this bleak atmosphere, there is active research and many companies are trying to turn the stem cell breakthroughs into a viable business. This pre-conference event will feature promising companies showcasing their new ventures in therapeutics, tools and services. Learn about their latest strategies for successfully navigating life sciences through the rigors of discovery and development, clinical trials, approval and liquidity. Explore possible partnerships to move this sector of the industry forward.

The unique format of this program will be a series of:

- 5 minute "elevator" presentations
- 5 Powerpoint slides
- @ 5 pm

Moderator: Annette Reynolds, Executive Director, 128 Innovation Capital Group

Alumni Welcome Presentation: Uday C. Gupta, President, Global Cell Solutions

Company Presentations:

Cellix, LTD

Vivienne Williams, MSc., Chief Executive Officer

Glycosan BioSystems

Anna Scott, Ph.D., Director of Operations

Inception Biosciences Inc.

Laura Grey, Ph.D., Vice President, Business Development, R&D

NanoCulture, LLC

Melvin Schindler, Ph.D., President

Additional Five @ Five Presentation Opportunities are Available:

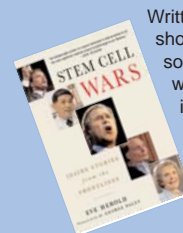
CEO's from leading startups and early stage companies in three critical stem and cell-based categories: Sources, Screening, Therapeutics are encouraged to submit their company's technology for review by the advisory committee for consideration of presentation. Please visit www.healthtech.com/2007/Cellutions/five.asp for further information.

Who Should Attend:

Decision makers and experts in licensing, alliance management, business development, strategic planning, technology evaluation, technology transfer, and portfolio management. Capital funding firms including venture capitalists, public & private investors, angel investors, government funding agencies, corporate governance, incubators, and technology transfer centers. And other academic entrepreneurs, executives from start-up, early stage, established small to large biotech, pharmaceutical companies and related companies and organizations interested in potential partners or to expand their technology portfolio.

Visit www.CELLutionsSummit.com periodically to preview the exciting companies presenting in this program.

Stem Cell Wars Book Offer



Written in accessible language that anyone can understand, this book shows how cutting-edge science is propelling humanity to reexamine some of its most cherished assumptions. Today's controversy is placed within a historical context of periodic upheavals set off by new scientific discoveries, from Galileo to Dolly the sheep. Ms. Herold explains how the issue has been hijacked by the modern right-to-life movement, and tells the stories of the patients and their advocates who are fighting to end government restrictions on the research that could save their lives. Along the way, readers are forced to examine their own closely-held assumptions in light of how profoundly affected each of us will be by this revolutionary science.

CHI is pleased to offer registered delegates a special discount rate of 50% off of the cover price. Order your book now and receive it upon check-in at the conference.

Cambridge Healthtech Institute's Third Annual
STEM CELL SOURCES:
TARGETING CELL-BASED REGENERATIVE THERAPIES
Tuesday, August 21

There are three classes of stem cells: totipotent, multipotent, and pluripotent, each with their own advantages and disadvantages. Due to their limitless therapeutic potential, stem cells continue to be of enormous public, scientific, and clinical interest. Researchers are discovering new sources of stem cells daily. However, the initial excitement generated by the identification of novel stem cell sources must give way to focused efforts on methods to manipulate their differentiation and self-renewal capabilities. The best thing is to have a variety of stem cell sources to provide the best stem cell for potential patient therapy. The focus of CHI's Third Annual Stem Cell Sources: Targeting Cell-Based Regenerative Therapies meeting is on the development of technologies to isolate, culture, manipulate, and differentiate stem cells. Technological progress brings fundamental understanding and will provide the foundation for more rapid advances toward the clinic.

Scientific Advisory Committee:

Jonathan Garlick, Ph.D., DDS, Professor, Division of Cancer Biology and Tissue Engineering, Tufts University

Rosemarie Hunziker, Ph.D., Program Director, Tissue Engineering and Regenerative Medicine, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health

David Kaplan, Ph.D., Professor and Chair, Department of Biomedical Engineering, Science and Technology Center, Tufts University School of Engineering

Mark E. Levenstein, Ph.D., Research Scientist, WiCell Research Institute

Brock C. Reeve, M.Phil., MBA, Executive Director, Harvard Stem Cell Institute

7:30-8:30 am Registration and Morning Coffee

Tools to Support the Science

8:30 Chairperson's Opening Remarks

8:45 Technology Insight: *in Vivo* Cell Tracking by Use of MRI

Joseph Frank, Ph.D. Chief, Experimental and Neuroimaging Section, National Institutes of Health

Magnetic labeling of stem cells provides the ability to monitor their temporal spatial migration *in vivo* MRI. Various methods have been used to magnetically label cells using coated superparamagnetic iron oxide (SPIO) nanoparticles. In this presentation, I will describe the different approaches used to label cells and show MRI and histologic results in various animal disease models and clinical studies. Magnetic Tagging of stem cells has the potential for guiding future cell-based therapies in humans and for the evaluation of cellular based treatment effects in disease models.

9:15 Novel X-Ray System for Tracking the Delivery and Distribution of Stem Cells

Dara L. Kraitchman, V.M.D., Ph.D., Associate Professor, Radiology, Johns Hopkins University School of Medicine

The administration of stem cells for cardiovascular applications using X-ray-based interventional techniques is well accepted. However, the ability to track stem cell biodistribution and engraftment is limited using these techniques. Classical direct labeling of stem cells with radiopaque contrast agents to enable visibility with X-ray imaging has not been performed due to the high toxicity of

these agents. A novel approach to enhance stem cell survival and make stem cells X-ray visible for fluoroscopic and computed tomography (CT) applications will be discussed. Because this approach uses FDA-approved agents on a familiar imaging platform to clinicians, the translation of these techniques to stem cell therapeutic administration are expected to be rapid.

9:45 Evaluating the *in Vivo* Differentiation Potential of Osteoprogenitor Cells

David Rowe, Professor, Reconstructive Sciences, University of Connecticut Health Center

We have developed histological techniques for imaging GFP in adult tissues that can be co-localized with standard cell identification methods to assist in the interpretation of transplantation experiment. Multiplexed GFP reporters that mark stages of bone cell development or different cell types identify the differentiation outcome after transplantation. When the donor and host bone cells carry a distinguishable GFP marker, the contribution of each cell source to a tissue repair model can be assessed. Two color strategies can directly contrast two sources of progenitor cells.

10:15 Technology Watch: The Use of Emit® Technology in the Generation of Functional Hepatocytes from hES Cells

Stephen Hammond, Ph.D., CEO, Cell Biology, StemCell Services

To understand how a stem cell differentiates into a specific tissue-cell requires not only knowledge concerning the molecular pathways of differentiation, but also the identification of the combination of signals the stem cell requires to become a specific type of a differentiated cell tissue. StemCell Services' Emit® (Emission Identification Technology) enables direct non-invasive monitoring of the development process of human stem cells as they differentiate. Emit® technology depends on the creation of a range of fluorescent proteins controlled by a set of specific promoters able to identify those chemical signals most relevant for the conversion of a stem cell into a mature, fully functional cell. As the stem cell progresses through each stage, it expresses these specific sets of proteins, and in the process switches on one of our fluorescent detector proteins. By following the sequential switching on of individual Emit® detectors in hES cells destined to become hepatocytes we were able to precisely track hepatocyte development. We were then able to look for these triggers in our specially constructed focused ligand collections and growth factor panels.

10:30 Coffee Break, Poster and Exhibit Viewing

11:00 A Two-Stage Perfusion Bioreactor System for Mass Production of Embryonic Stem Cells

Shang-Tian Yang, Ph.D., Professor, Chemical and Biomolecular Engineering, The Ohio State University

For mass production of undifferentiated embryonic stem (ES) cells, a two-stage perfusion bioreactor system is developed with fibroblast feeder cells grown in the first reactor to condition the medium without leukemia inhibitory factor (LIF) or other expensive growth factors and the second reactor grows ES cells in a three-dimensional PET fibrous matrix. The system can expand ES cells ~200-fold to 2 billion cells in a 10-ml reactor in 15 days while maintaining their pluripotency. The produced ES cells can be used for cell therapy and other biomedical applications.

11:30 Cryopreservation and hESCs

Carol Ware, Ph.D., Research Associate Professor, Comparative Medicine; Director, Human ES Cell Core, Institute for Stem Cell and Regenerative Medicine, University of Washington

Human embryonic stem cells (hESC) have proven refractory to cryopreservation by standard tissue culture protocols. Whereas, they survive well when frozen using techniques devised for freezing mammalian embryos. Survival of hESC frozen using slow, controlled-rate freezing allows ~80% survival upon thaw with no trend toward differentiation. Effective cryopreservation allows initial maintenance of low passage cells and improves flexibility in experimental design.

12:00 pm Panel Discussion

12:30 Lunch on Your Own
(Luncheon Technology Workshop Sponsorships Available)

Therapeutic Stem Cell Sources

2:00 Chairperson's Remarks

Keynote Presentation

2:05 Amniotic Fluid and Placental Stem Cells and Their Potential for Therapy



Anthony Atala, M.D., Director, Wake Forest Institute for Regenerative Medicine, Wake Forest University School of Medicine

Recent work shows that clonally derived stem cells from the amniotic fluid and placenta can be differentiated into derivatives from all three germ layers, are telomerase positive and have a great capacity for self renewal. The cells double in number every 36 hours and do not form teratomas *in vivo*. The cells are easily harvested, and with over 4 million births per year, an ample supply may be readily available in the future for therapy.

2:45 Regenerative Potential of Cardiosphere-Derived Cells Expanded from Adult Human Percutaneous Endomyocardial Biopsies

Rachel Ruckdeschel Smith, Ph.D. Candidate, Johns Hopkins School of Medicine

Percutaneous endomyocardial biopsy specimens grown in primary culture readily develop multi-cellular clusters known as cardiospheres, which are plated to yield cardiosphere-derived cells (CDCs). Cardiospheres are a niche-like environment containing populations of cardiac-committed progenitors and cardiac mesenchymal cells. Cardiospheres and CDCs form cardiomyocytes *in vitro* and *in vivo*. CDCs engraft long-term in a mouse infarct model, acting to preserve heart function and attenuate ventricular remodeling over a period of 6 weeks. CDCs are an attractive autologous source for the treatment of acute myocardial infarction.

3:15 Technology Spotlight (Sponsorship Available)

3:30 Refreshment Break, Poster and Exhibit Viewing

4:00 Progress in Dental Tissue and Whole Tooth Regeneration and Repair

Pamela C. Yelick, Ph.D., Director, Division of Craniofacial and Molecular Genetics, Tufts University

Dr. Yelick's major research interests are molecular genetic analyses of craniofacial cartilage, bone, and tooth development and regeneration. Her research focuses on two areas: 1) manipulating mammalian postnatal dental stem cells for whole tooth tissue engineering applications; and 2) using the zebrafish, *Danio rerio*, as a model for craniofacial and tooth development and regeneration. The goals of this research include devising methods to generate bioengineered reparative dental tissues and whole teeth, and to induce replacement tooth formation in the human jaw.

4:30 Panel of Experts

5:15 Solutions at CELLutions - Break-out Discussions with Panel of Experts

6:30 Networking Reception in the Exhibit Hall

7:30 Close of Day

STEM CELL AND 3D MODELS FOR THERAPEUTIC SCREENING: ENGINEERING *IN VITRO* TO EMULATE *IN VIVO*

Wednesday, August 22

Drug development is a time and money consuming process. Stem cell and 3D models that capture both the organization and multicellular complexity of the target provide the most powerful tools for screening the effects of therapeutic candidates.

The development of functional screening models has:

- Reduced cost and time to identify new drug candidates
- Drove more selective/predictive screens for selection of compounds
- Reduced animal testing
- Yielded more predictive data
- Improved efficiency
- Decreased time to market

CHI's Fourth Annual Stem Cell and 3D Models for Therapeutic Screening weaves together tissue engineers who are developing the 3D tissue models with biologists who are studying healthy vs. diseased states and pharmacologists who are utilizing high-throughput screening assays. As with any model, each specialty provides insight into the complete system.

Scientific Advisory Committee:

Jonathan Garlick, Ph.D., DDS, Professor, Division of Cancer Biology and Tissue Engineering, Tufts University

David Kaplan, Ph.D., Professor and Chair, Department of Biomedical Engineering, Science and Technology Center, Tufts University School of Engineering

Melvin Schindler, Ph.D., President, Nanoculture LLC

8:00 am Registration and Morning Coffee

Stem Cells for Screening

8:30 Chairperson's Remarks

Featured Presentation

8:35 Applications of Human Stem Cells for Research and Drug Discovery



Stephen Minger, Ph.D., Senior Lecturer, Director, Stem Cell Biology, Kings College London

Somatic cells derived from human embryonic stem cells offer great potential for drug screening as well as for fundamental biomedical research. In addition, disease-specific human stem cell lines encoding known genetic mutations can be used for elucidating pathophysiological mechanisms as well as for identifying novel disease-specific therapies. This talk will provide an update on progress to generate specific populations of cells for drug discovery and regenerative medicine.

9:05 Potential Applications of Stem Cells in the Pharmaceutical Industry

Huseyin Mehmet, Ph.D., Director, Apoptosis Research, Merck Research Laboratories

Stem cells can differentiate into numerous types of cells with specific functions. It is well documented that stem cells might be of therapeutic

value in the direct treatment of diseases including Parkinson's, Alzheimer's, diabetes, cancer, heart disease, spinal cord injury, and multiple sclerosis, as well as in organ transplantation and wound healing. However, stem cells are also a valuable source of material in drug discovery, where they can provide model systems for understanding disease mechanisms, for high-content screening assays, and in toxicology studies. In this presentation, I will discuss some of the non-therapeutic applications of the use of stem cells.

9:35 Therapeutic Targeting of a Stem Cell Niche

David T. Scadden, Ph.D., Professor of Medicine, Center for Regenerative Medicine & Technology, Mass General Hospital (invited)

10:05 Human Embryonic Stem Cells: Bridging Animal Models and Cell-Based Preclinical Safety Assessment of Chemicals

Gabriela Cezar, DVM, Ph.D., Assistant Professor, Stem Cell Safety Sciences, Department of Animal Sciences, University of Wisconsin, Madison

10:35 Technology Spotlight (Sponsorship Available)

10:50 Coffee Break, Poster and Exhibit Viewing

11:30 Using Embryonic Stem Cells for Drug Discovery

Amy Sinor, Ph.D., Assay Development Scientist, Harvard Stem Cell Institute, Harvard University

Embryonic Stem (ES) cells can be used as a valuable tool in drug discovery. We currently use ES cells to generate cultures that are highly enriched for motor neurons. This provides us with a unique opportunity to perform high throughput screening experiments because we are able to generate large quantities of motor neurons. Spinal Muscular Atrophy (SMA) and Amyotrophic Lateral Sclerosis (ALS) are two diseases in which motor neurons are the cell type that is affected. In SMA, although the SMN protein is ubiquitously expressed, its deficiency in motor neurons is directly linked to disease severity and progression. Previously, fibroblasts from patients afflicted with SMA were utilized in drug screening efforts. We have devised a novel approach that involves using motor neurons derived from mouse ES cells to screen for small molecules that may increase either motor neuron survival or SMN protein levels. As these cultures represent the actual cell type that is affected during the progression of SMA, we believe this is a more straightforward and relevant background with which to perform screening experiments. Since ES cells have the ability to differentiate into many different neuronal cell types, we expect this model system will be valuable for screening drugs for many other neurodegenerative diseases.

12:00 pm Stem Cells and Biomaterials

Karen J.L. Burg, Ph.D., Hunter Endowed Chair and Professor of Bioengineering, Clemson University

Three dimensional biomaterials systems have been used for the rapid expansion of cells and as the template or scaffold in tissue engineering systems. The scaffold material design is crucial as it affects cellular attachment, proliferation, and differentiation and may be used as a tool with which to "tune" cellular behaviors. Microfabrication tech-

niques such as cellular printing provide tools with which to precisely position and explore the interactions of anchorage-dependent cells with their *in vitro* environment, where spatial control of the substrate chemistry, pattern, and mechanical properties can provide new insights into fundamental aspects of stem cell-surface interactions.

12:30 Luncheon Technology Workshop

Sponsored by  invitrogen™

Optimization of Stem Cell Growth and Scaffold Selection for 3-D Constructs

Paul J. Price, Ph.D., Chief Scientific Officer, D-Finitive Cell Technologies

The cell culture medium and the physical environment play key roles in the optimization of cell growth and function in either 2D or 3D formats. This seminar will cover the basics of the cell culture medium, factors for optimal viability and media performance and the selection of the proper scaffold or matrix for the desired outcome.

Engineering Effective 3D Models to Enhance Cell-Based Screening

2:00 Chairperson's Remarks

Featured Presentation

2:05 Engineered Human 3D Tissue Platforms for Drug and Product Screening



Jonathan Garlick, Ph.D., DDS, Professor, Division of Cancer Biology and Tissue Engineering, Tufts University

Engineered 3D human tissue platforms that mimic their *in vivo* counterparts are powerful tools that provide more reliable correlations between *in vitro* screening systems and *in vivo* tissue outcomes. These tissues are now playing a strategic role in moving translational research into paradigms that will enable more predictive target validation before embarking on human, clinical trials. This presentation will discuss a variety of biologically-relevant, human 3D tissue platforms that now serve as assays to screen compounds that may modulate wound repair, sun damage, stem cell fate and cancer progression. These 3D tissues provide novel "pre-clinical" settings that are poised to streamline the drug and product development pipelines.

2:35 Taking Cancer Biology to the Third Dimension

Keiran Smalley, Ph.D., Senior Scientist, Program of Molecular Oncogenesis, The Wistar Institute

It is becoming more apparent that the responses of cancer cells to novel targeted therapies are determined by their interaction with neighboring tumor cells and the extracellular matrix. Recent work from our laboratory has demonstrated that culture of tumor cells under 3D spheroid and organotypic culture conditions dramatically alters both cell phenotype and drug response. I will discuss the practical application of these techniques to cancer biology and drug discovery, and show how these methods are more predictive of anti-cancer drug activity *in vivo*.

3:05 Tissue Engineering and 3-D Cell Culture Using Hyaluronan-Based Hydrogels

Anna Scott, Ph.D., Director of Operations, Glycosan BioSystems

We have recently developed a novel approach to the creation of a fully

synthetic, covalently crosslinked extracellular matrix known as Extracel. Extracel can be crosslinked under ambient, physiological conditions *in situ* in the presence of cells to provide an injectable cell-seeded hydrogel for tissue repair *in vivo* or three-dimensional (3-D) cell culture *in vitro*. The hydrogel is composed of thiol-modified hyaluronan, thiol-modified gelatin (denatured collagen), and polyethylene glycol diacrylate (biocompatible, polyvalent electrophile that reacts with the thiol residues to crosslink the hydrogel). Extracel hydrogels and sponges (lyophilized hydrogels) support *in vivo* growth of healthy, cellularized tissues and *in vitro* growth of primary human hepatocytes, human dermal fibroblasts, mesenchymal stem cells and many other primary cells and cell lines. For tissue engineering, Extracel impregnated with cells dramatically improves repair of bone and cartilage defects and aids in the regeneration of functional liver tissue.

3:20 Refreshment Break, Poster and Exhibit Viewing

4:00 Tissue Architecture Linked to Epigenetic Control of Therapeutic Response

Kelvin K.C. Tsai, Ph.D., Postdoctoral Fellow, Surgery and Center for Bioengineering and Tissue Regeneration, University of California, San Francisco

Using three-dimensional tissue culture as a model system, we report that tissue organization is associated with profound resistance to multiple death inducers, which is functionally-linked to transcriptional reprogramming of cellular pro-apoptotic/anti-apoptotic pathways by the nuclear receptor corepressor SMRT (silencing mediator of retinoic acid and thyroid hormone receptor). The SMRT-mediated death resistance was found to be functionally-linked to chromatin remodelling-mediated transcriptional regulation through activation of the histone deacetylase-3, and is usurped by malignant tumor cells during their phenotypic evolution of multi-drug resistance. Our findings provide a novel example in which tissue architecture and microenvironmental heterogeneity is tied to *in vivo* selection of drug resistance.

4:30 3D Scaffolds with Inverted Colloidal Crystal Geometry for *ex vivo* Drug Screening Assays

Nicholas Kotov, Professor, Chemical Engineering, University of Michigan

Efficacy of *in-vitro* testing can be significantly improved provided that better *ex vivo* models for different organs and tissues are developed. A large body of research indicates that cultured cells organized in three-dimensions (3D) behave a lot more closely to the original tissues and retain more natural functions than the cells in 2D cultures. However the currently available 3D scaffolds have either poor optical properties or impair cellular migration. Both of these factors are detrimental for scaffold utilization for rapid drug screening currently used in industry. A new type of scaffold was developed based on inverted colloidal crystal (ICC) topology, which can resolve these issues and result in adequate *ex vivo* models with 3D cellular organization resembling that of original organs. Additionally, the ICC scaffolds can be standardized exceptionally well, which is critical for reproducibility of the drug screening assays. The *ex vivo* replicas of liver and bone marrow made in well plate format adaptable for drug screening will be demonstrated.

5:00 Panel of Experts

5:30 Close of Day

CELL THERAPIES: THE PATH TO CLINICAL SUCCESS AND COMMERCIALIZATION

Thursday, August 23

There is no denying that cell therapy has the potential to be one of the most powerful therapeutic options available. Cell therapy can take several forms and serve many purposes including altering normal cell response, stimulating native signaling cascades, performing missing metabolic functions, restoring lost tissue, or changing the normal course of repair into true regeneration. Designing and implementing a plan for commercialization takes many paths, each with their own set of biological, technical and regulatory considerations. CHI's Inaugural Cell Therapies – The Path to Clinical Success and Commercialization continues the communication required for both clinical and commercial success. Learn from savvy seasoned experts as they share their experiences and achievements.

Scientific Advisory Committee:

Lee Buckler, BED, LLB, Progenitor Cell Therapy

Rosemarie Hunziker, Ph.D., Program Director, Tissue Engineering and Regenerative Medicine, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health

Alan K. Smith, Ph.D., President, Cognate BioServices, Inc.

Bruce M. Wentworth, Ph.D., Director, Cardiovascular Research, Genzyme Corp.

8:00 am Registration and Morning Coffee

Perspectives on the Paths to Commercialization

8:30 Chairperson's Remarks

8:35 Challenges of Translational Cell Therapy

Leslie E. Silberstein, M.D., Director, Center for Human Cell Therapy, Principal Investigator, CBR Institute for Biomedical Research; Program Head, Translational Research, Harvard Stem Cell Institute; and Professor of Pathology, Harvard Medical School

The presentation will give a brief overview of the current projects at the Center for Human Cell Therapy and the individual challenges that each of them face. Touching on communication with the FDA, project equipment needs and costs (such as nucleofection), and research development. In addition, I will also address consulting/collaborating with local biotech companies.

9:05 Bridging the Gap between Research and Manufacturing: The Role of Product and Process Development

Katie Faria, Director, Process Development, Research and Development, Organogenesis Inc.

Using the Organogenesis experience we will discuss the process flow from research and development, process optimization, validation, FDA registration and through to implementation into manufacturing. Specific steps that will be reviewed; identifying and defining potential process issues early on to develop strategies to avoid production, regulatory and/or GMP compliance issues. Researching and evaluating potential solutions, selecting the process solution that best fits operational and quality requirements, designing the process validations and completing the technical transfer into cGMP manufacturing.

9:35 Major Company Perspective

Geoff Symonds, Ph.D., Senior Research Director, Johnson & Johnson Research

Cell Therapy represents a different treatment paradigm and the presentation will address how Big Pharma develops and views Cell

Therapy. Similarities and differences to small molecule and biologics development will be discussed, as well as the means by which Cell Therapy can be 'incubated' to a point that it can stand alone.

10:05 Coffee Break, Poster and Exhibit Viewing

10:45 Regulatory Perspective

Joyce L. Frey-Vasconcells, Ph.D., Executive Director, Pharmanet Consulting

Cell therapies as market products is very new. There is currently only one approved cell therapy in the United States. As a result there is very little precedent to gain an understanding of the regulatory requirements. This presentation will discuss some of the regulatory considerations that should be considered as one advances a cell therapy through the development phases towards marketing.

Tools to Support the Science

11:15 Technology Spotlight (Sponsorships Available)

11:45 Cell Characterization Using DNA Methylation Analysis in Cell Therapy

Ulrich Hoffmueller, Ph.D. MBA, Chief Business Officer and Founder, Epiontis GmbH

Specific DNA methylation patterns correlate with differentiation states, cell type and long-term cell functions and therefore, offer a large potential for cell characterization. Upon genome wide marker discovery and validation DNA methylation markers are applicable to determine identity, purity and potency of cellular therapeutics. The application of the DNA methylation technology is presented on two examples: (1) The results of the collaboration between Genzyme and Epiontis, demonstrating how DNA methylation analysis can be applied for testing the chondrocyte product Carticel®. (2) Marker discovery for a panel of primary human cells comprising 12 cell types from mesenchymal and hematopoietic lineages. These results indicate that DNA methylation analysis qualifies as a suitable technique for cell characterization and routine release quality control tests for products in tissue engineering and regenerative medicine.

12:15 Lunch on Your Own (Luncheon Technology Workshop Sponsorships Available)

Paths to the Pre-Clinic

1:30 Chairperson's Remarks

1:35 Allogeneic Bone Marrow Repairs Human Islet Damage: A New Approach for Cell Therapy in *ex Vivo*

LuGuang Luo, Assistant Professor, Research, Roger Williams Hospital

The main roadblock for human islet transplantation is the gradual diminishing of islet function initiated by islet cell death in the short term which results from the islet isolation process. Developing a method to repair islet injury would overcome this problem. In our group, we utilized allogeneic bone marrow cells to co-culture with human islets and showed that human islets are able to survive and function in the long term. The mechanism studies indicate that bone marrow interacts with human islets in the culture condition (time lapse microscope tracing cell-cell interaction), suppresses islet inflammatory factor production (IL-1 beta) and reduces cell apoptosis while stimulating islet growth. This novel concept and method established by this group will provide a new direction for cell therapy.

2:05 Bone Marrow-Derived Stem Cells for CNS Therapy

Casey Case, Ph.D., Vice President Research, SanBio Inc.

We have developed a scalable method for deriving neural progenitor cells from adult bone marrow aspirates. These cells have been successfully employed in animal models of Parkinson's disease (6-hydroxydopamine lesions in rats), spinal cord injury (contusion injury model in NOD/SCID mice), and stroke (MCA occlusion model in rats). Data from these studies and the experience of transferring the production methods to a contract manufacturer will be shared. A phase I clinical trial in stable stroke is scheduled to initiate early 2008.

2:35 Using Adult Tissues to Generate New Organs: Autologous Cell Replacement Therapy for Diabetes

Sarah Ferber, Ph.D., Director, Molecular Endocrinology, Sheba MDC and Diabetes Research Institute (DRI) Miami

We were the first to demonstrate the capacity of inducing a functional pancreatic lineage in adult liver in mice and human tissues. This capacity has been confirmed now in many labs around the world (Ferber et al Nat Medicine 2000 and Sapir et al PNAS 2005). We presented the efficacy of inducing functional endocrine pancreas in adult human liver cells by nuclear reprogramming. These developmentally shifted human liver cells produce insulin, process the hormone and secrete it in a glucose regulated manner. The human derived cells ameliorate diabetes when implanted in immunodeficient SCID-NOD mice for long periods. The mechanism of this developmental redirection process will be disclosed.

3:05 Refreshment Break, Last Chance for Poster and Exhibit Viewing

Successes in the Clinic

3:30 TRC Products as an Emerging Therapy for Regenerative Medicine

Ronnda L. Bartel, Ph.D., Vice President, Research and Development, Aastrom Biosciences

Aastrom's Tissue Repair Cell (TRC) products are derived from a small amount of bone marrow collected from the patient, which is cultured to generate a unique cell mixture containing large numbers of stem and progenitor cells. TRC-based products have been used to treat over 240 patients, and are currently in clinical trials for bone regeneration (osteonecrosis of the femoral head, long bone fractures and spine fusion) and vascular regeneration (critical limb ischemia) applications. Aastrom has reported positive interim clinical trial results for TRC-based products suggesting both the clinical safety and the ability of TRCs to promote healing. The Company is also developing clinical programs for TRC therapies to address cardiac and neural regeneration indications.

4:00 Advancing a Clinical Pipeline of Cellular Medicines

Ed Field, MBA, President & COO, Aldagen, Inc.

ALDAGEN is advancing a clinical pipeline of regenerative therapies focused on vascular disorders and cord blood transplantation. The Company has three product candidates in clinical development. ALDAGEN's products are based on a proprietary technology platform that selects and delivers potent, adult stem and progenitor cells for therapeutic use. The platform is further differentiated by its ability to obtain a broad range of therapeutic cells that can be used rapidly, without culture or expansion. The presentation will focus on the design of and data from the three clinical trials with particular emphasis on the critical limb ischemia and chronic heart failure trials.

4:30 Panel Discussion: Moving Cell Based Therapies into the Market

Cell therapies present a unique and exciting twist in scientific paradigms and clinical modalities. Equally as true will be the uniqueness of the business models wrapped around these therapies. While there are many similarities with predecessor biotech sectors, cell therapies present unique challenges in the areas of regulation, product characterization, delivery, reimbursement, cost of goods, etc that will challenge the most creative business executives to create and develop business models which succeed in bringing cell therapies to market. This panel will explore the various perspectives of stakeholders that will be critical to moving cell therapies into the market: venture capital, cell therapy business executives, large biotech/pharma, and insurers. The panel-based discussion will focus on the primary challenges, business models, and strategies for commercializing cell therapies.

Moderator: Lee Buckler, BEd, LLB, Progenitor Cell Therapy LLC

Panel Members:

Ronnda Bartel, Ph.D., Vice President, Research and Development, Aastrom Biosciences

Ed Field, MBA, President & COO, Aldagen, Inc.

Geoff Symonds, Ph.D., Director, Cell Therapy Research, Johnson & Johnson

Paul J. Schmitt, Managing Director, PA Early Stage Partner

Joyce Frey, Ph.D., Executive Director, Pharmanet Consulting

Bruce M. Wentworth, Ph.D., Senior Director, Cardiovascular Research, Genzyme Corp.

Naomi Aronson, Ph.D., Executive Director, Technology Evaluation Center, Blue Cross Blue Shield Association (invited)

5:30 Close of Conference

Conference Venue

World Trade Center
200 Seaport Blvd.
Boston, MA 02210

Host Hotel

Seaport Hotel
One Seaport Lane (directly across the street)
Boston, MA 02210
Ph: 617-385-4000
Fax: 617-385-4001
Room Rate: \$210 s/d
Room Block Cutoff: July 25, 2007



To book your reservations on-line go to www.seaportboston.com. Enter in your arrival and departure dates as well as the group code C081807

For phone reservations: call 617-385-4000 and ask for the Cambridge Healthtech Institute group rate.

Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space and-rate availability basis. Rooms are limited, so please book early.

For additional transportation information, parking garage options & driving directions to the Seaport Hotel please visit their website www.seaportboston.com

Travel Information

Discount fares available on United, Express, United code share flights (UA*) operated by US Airways, and US Airways Express. Receive up to a 15% discount by calling United's toll-free number 1-800-521-4041 and reference the Meeting ID Number 579YS.

Car Rental Information

Special discount car rentals have been established with AVIS for this conference. To make reservations call AVIS directly at 800-331-1600. Reference AVIS Worldwide Discount (AWD) Number J868190.

Hands-On Workshop



As a CELLutions SUMMIT delegate you're invited to attend a Hands-On Workshop organized by the Tissue Engineering Resource Center (TERC) at Tufts University.

AUGUST 19 – 20, 2007

Exploring Stem Cells

Cell culture (expansion, differentiation media, FACS, maintenance media, scale-up, counting, storage, cell-specific assays, transformation/transfection, RT-PCR quantification)

- Adipose Stem Cells
- Peri-natal Stem Cells
- Mesenchymal Stem Cells
- Embryonic Stem Cells

Imaging - Sample preparation and basic techniques tailored to imaging stem cells with:

- Scanning Electron Microscopy
- Multiphoton/Confocal Microscopy
- UV- and inverted-fluorescence Microscopy
- Atomic Force Microscopy

Continuous and Co-cultures – demonstration and review of bioreactor systems to improve *in vitro* culture conditions, promote stem cell viability and differentiation.

- Spinner flasks and rotating vessels
- Multi-well shear devices
- Round perfusion reactors
- Removable rod reactors
- Bioreactors with electrical stimulation
- Reactor design and modeling

Co-culture techniques with stem cells, as well as incorporation with bioreactors to grow tissues *in vitro* will be addressed.

Expert "show and tell" - Putting stem cells to work

- Immunofluorescence and 3D
- Skin models
- Disease models
- Cardiac tissue engineering
- Lentiviral transfection systems
- Stem cells from cord and placenta tissue
- Microfluidic systems and cell migration
- Legalities of stem cell research

Note - Limited space is available. All payments must be paid in full to process your registration. For further information, please visit www.CELLutionsSUMMIT.com.

Reasons You Should Present Your Research Poster at CELLutions SUMMIT 2007:

- Your poster will be exposed to over 250 delegates
- Receive \$50 off your registration fee
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- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

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SPONSORSHIP AND EXHIBIT INFORMATION

Sponsorship programs are designed to achieve your lead generation, business development and networking goals and objectives. Meet all your objectives through varied sponsorship and promotional programs as well as a booth on the exhibit floor. CHI will support your Sponsorship and brand your company with strong marketing programs before, during and after the event. The earlier you secure your sponsorship, the more opportunity for exposure.

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Present your science or technology to delegates with a 15-30 minute podium presentation during the scientific program, or during a breakfast or luncheon workshop.

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Place your corporate logo on the final conference brochure, event web site, conference CD, Program & Event Guide, and signage on-site. Benefits include exhibit space, conference registrations, use of pre and post conference mailing lists and a cooperative promotional mailing to your prospect list.

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Select targeted delegates from the pre-registration list.

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- Tote Bags
- Conference Padfolios
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For more information, contact
David Cunningham 781-972-5472

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Would you like to receive event updates via fax? Yes No _____ Fax _____

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**Email is not a mandatory field. However by excluding your email you will not receive notification about online access to pre-conference presenter materials, conference updates and networking opportunities.*

PRICING INFORMATION

Commercial

Academic & Government

Pre-Conference Short Course Pricing

Survive & Thrive Partnering Forum (August 20, 1-4pm)	<input type="checkbox"/> \$545	<input type="checkbox"/> \$295
Five @ Five Showcase (August 20, 5-8pm)	<input type="checkbox"/> \$545	<input type="checkbox"/> \$295
Attend Both Short Courses	<input type="checkbox"/> \$995	<input type="checkbox"/> \$545
TERC Course	<input type="checkbox"/> \$1095	<input type="checkbox"/> \$795

As a CELLutions SUMMIT delegate you're invited to attend this Hands-On Workshop organized by the Tissue Engineering Resource Center (TERC) at Tufts University (Full days August 19-20)

Note - Limited space is available. All payments must be paid in full to process your registration. For further information please visit www.ase.tufts.edu/terc

Gold Package (includes access to three conference days) August 21-23

Early registration by May 25, 2007	<input type="checkbox"/> \$1445	<input type="checkbox"/> \$795
Advance registration by July 13, 2007	<input type="checkbox"/> \$1595	<input type="checkbox"/> \$845
Registration After July 13 and On-site	<input type="checkbox"/> \$1795	<input type="checkbox"/> \$925

Silver Package (includes access to two conference days)

Early registration by May 25, 2007	<input type="checkbox"/> \$1095	<input type="checkbox"/> \$595
Advance registration by July 13, 2007	<input type="checkbox"/> \$1195	<input type="checkbox"/> \$745
Registration After July 13 and On site	<input type="checkbox"/> \$1395	<input type="checkbox"/> \$895

Please select the two conferences you will attend

Stem Cell Sources Cell Screening Cell Therapies
August 21 August 22 August 23

Bronze Package (includes access to one conference day)

Early registration by May 25, 2007	<input type="checkbox"/> \$845	<input type="checkbox"/> \$495
Advance registration by July 13, 2007	<input type="checkbox"/> \$995	<input type="checkbox"/> \$595
Registration After July 13 and On site	<input type="checkbox"/> \$1195	<input type="checkbox"/> \$695

Please select the one conference you will attend

Stem Cell Sources Cell Screening Cell Therapies
August 21 August 22 August 23

Book Offer *Stem Cell Wars* \$12 \$12
Registered delegates only. All book will be delivered upon check in.

Poster Discount \$50 off \$50 off

I cannot attend but would like to purchase the conference proceedings for \$500 (plus shipping). Massachusetts delivery will include 5% sales tax.

Please send information on exhibiting and opportunities to present workshops.

PAYMENT INFORMATION

Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.

Invoice me, but reserve my space with credit card information listed below. **Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount.**

If you plan to register on site, please check with CHI beforehand for space availability.

Please charge: AMEX (15 digits) Visa (13-16 digits) MasterCard (16 digits) Diners Club (14 digits)

Please send information about related conferences and reports:

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 Cell - Based Assays for HTS (HTS)

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PRESENT A POSTER AND SAVE \$50

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference CD, your abstract must be submitted, accepted and registration paid in full by **July 24, 2007**. Register online to use the Poster Abstract Submission form or, if you register by phone, fax, or mail, you will receive Poster Abstract Submission guidelines via email.

I am interested in presenting a poster at CELLutions SUMMIT and will submit a completed one-page abstract by **July 24, 2007** (Please Note: Registration must be paid in full to present poster.)

Title _____

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Special rates are available for multiple attendees from the same organization. Contact David Cunningham at 781-972-5472 to discuss your options and take advantage of the savings.



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In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

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In the event that you need to cancel a registration, you may:

- Transfer your registration to a colleague within your organization
- Credit your registration to another Cambridge Healthtech Institute program
- Request a refund minus a \$100 processing fee per conference
- Request a refund minus the cost (\$500) of ordering a copy of the CD

NOTE: Cancellations will only be accepted up to two weeks prior to the conference.

Program and speakers are subject to change.

Video and/or audio recording of any kind is prohibited onsite at all CHI events.

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