Co-located with

The Compound Management Forum

Molecular advances in biomedical science require high-quality biospecimens (tissue, body fluid, or other material) which provide macromolecules (DNA/RNA, proteins, enzymes, etc.) that are used for diagnostic, therapeutic, and epidemiologic purposes, allowing researchers to better link molecular and clinical information. Today, biospecimen collections are used by multiple groups for varying aims from basic research through clinical trials. Investigators realize that the proper collection, processing, storage, and tracking of biospecimens are critical components of biomarker-related studies.

Thus, by necessity, biobanking is both a science and a business; therefore, BioBanking: Maximizing Your Investment focuses on both angles.

PLUS! PRE-CONFERENCE SHORT COURSES

SC1 Biostabilization of Biospecimens

SC2 Transitioning a Biobanking Effort with Scientific and Fiscal Responsibility: Creating a Model for Both Academic and Industry Programs
PRE-CONFERENCE SHORT COURSES*

8:00 am  Pre-Conference Short Course One Registration *
8:30-10:30 Short Course One

SC1 BIOSTABILIZATION OF BIOSPECIMENS

Course Instructors:
Alptekin Aksan, Ph.D., Assistant Professor, Mechanical Engineering, University of Minnesota
Allison Hubel, Ph.D., Professor and Director, Biopreservation Core Resource, University of Minnesota

Biospecimens include tissues, cells, bodily fluids and their constituent macromolecules. Biospecimen procurers and users are generally in different physical locations and biospecimens are typically collected for use at a later time. Therefore, the critical properties of each bio-specimen must be preserved during processing, transport and storage. The course provides an important overview of the current state of preservation, the scientific basis for preservation and practical advice for preservation biospecimens and alternative stabilization techniques.

Educational Objectives:
- Describe current pitfalls and needs in biopreservation
- Understand the current scientific basis for preservation at different scales (molecule, cell, tissue)
- Overview starting a biorepository, developing facilities, development of standard operating procedures, and quality control
- Alternative stabilization and storage techniques

Who Should Attend:
- Biorepository managers
- Biospecimen processing and storage technicians
- Scientists involved in biomarker discovery or use
- Biotechnology companies
- Medical device companies

10:30 Refreshment Break and Short Course Two Registration *
10:45-12:45 pm Short Course Two

SC2 TRANSITIONING A BIOBANKING EFFORT WITH SCIENTIFIC AND FISCAL RESPONSIBILITY: CREATING A MODEL FOR BOTH ACADEMIC AND INDUSTRY PROGRAMS

Course Instructor:
Andrew Brooks, Ph.D., Director of Operations, Rutgers University Cell and DNA Repository; Associate Professor, Genetics, Rutgers University

The scientific challenges that biobanks currently face is only half of the problem. The integration of fiscal responsibility for the design, creation and implementation of both small and large biobanks is of paramount importance. This workshop will address the practical operational issues from a scientific and fiscal perspective when creating, transitioning and managing a comprehensive biobanking and lab services program. Tools will be provided to help scientists, managers and business units grow existing programs in a fiscally responsible manner without sacrificing science or sample quality.

Educational Objectives:
- How to evaluate and implement new technologies both operationally and fiscally
- How to build cost structures for comprehensive biobanking services
- When and how to integrate automation without “breaking the bank”
- How to evaluate storage environments to balance cost vs. stability
- How to add services in a scientific and fiscally responsible manner
- How to model your business “around” your science

Who Should Attend:
- Biorepository directors and managers
- Program development managers
- Lead scientists providing/requesting samples from a biorepository
- Business unit heads

* Separate Registration Required

TRAVEL & HOTEL INFORMATION

Conference Hotel
Westin Providence Hotel  |  www.starwoodhotels.com  |  Phone: 401-598-8000
One West Exchange Street  |  Providence, RI 02903

Discounted Room Rate:
$139 s/d

Discounted Room Rate Cut-off Date:
November 8, 2010

Please visit our conference website to make your reservations online or call the hotel directly to reserve your sleeping accommodations. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the reduced room 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.

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THE SCIENCE OF BIOBANKING

Recent advances in molecular high-throughput assays have intensified the need for well annotated, properly preserved biospecimens. A thorough assay often requires samples from both diseased/treated and normal/untreated tissue. The Science of BioBanking addresses methodologies that maximize the quality and utility of biospecimens for biomarker research.

Who Should Attend:
Research scientists working with
- Biospecimens
- Biomarkers
- Bioextraction
- Biopreservation

THE BUSINESS OF BIOBANKING

As biobank repositories grow, the pressure increases for standardization, documentation, protocols, and preservation procedures to efficiently produce the best quality product. In addition, “omics” has complicated the direction of biomedical research, and those managers involved must now negotiate the regulatory, ethical, and legal issues involved in the preservation and use of biospecimens.

Who Should Attend:
Directors, heads, and managers of:
- Biobanks
- Tissue banks
- Biorepositories
- Pathologists

1:30 pm Main Conference Registration

PLENARY OPENING SESSION
INVESTING IN THE FUTURE - MANAGING CHANGE

2:00 Chairperson’s Opening Remarks
2:10 Changing the Paradigm for Biobanking in the U.S.
Helen M. Moore, Ph.D., Director, Biospecimen Research Network, Office of Biorepositories and Biospecimen Research, Office of the Director, National Cancer Institute

Human biospecimens provide the basis for research and development efforts in cancer and all human diseases, and will provide the analytes for patient care in the age of personalized medicine. To produce the high-quality biospecimens needed to achieve advances in R&D and patient care, we must make changes throughout the infrastructure that supports the collection, processing and storage of human biospecimens. The National Cancer Institute leads efforts designed to raise the quality of biospecimens, including producing the NCI best practices for biospecimen resource, sponsoring research through the NCI Biospecimen Research Network, and building a national biobank (“caHUB”).

2:50 A New Concept for Networking Tissue Banks to Overcome Barriers of Language, Standardization and the “My Syndrome”
Peter Riegman, Ph.D., Tissue Resource Manager, Erasmus MC Tissue Bank; Coordinator, European Human Frozen Tumor Tissue Bank (Tubafrost); President, ISBER

Combining the knowledge gained in three European Biobanking projects brought together a format of networking without the need to upload all sample data of all samples in a collection. The biobank manager fills in a questionnaire and the data can be searched for finding the right biobank to request samples. In addition, the database can support separate projects in parallel to aid in sample exchange having their own coordinator. New parameters have been introduced to choose the biobanks for requests and it fits into the competitive research environment and avoids classical bottlenecks.

3:30 Refreshment Break
4:00 Preparing for Next-Generation DNA Sequencing: Sample Quality and Quantity -- When is enough enough?
William Farmerie, Ph.D., Associate Director, Interdisciplinary Center for Biotechnology Research, University of Florida

The rapid evolution of next-generation sequencing (NGS) technology makes genome-scale genetic profiling both an invaluable and a cost-effective tool for clinical and epidemiological investigation. The many varied applications for NGS, and the input needs of the NGS instruments themselves, determine the journey each sample makes from biobank specimen to successful NGS template. What are the major applications for NGS, and how does the specific application guide the upstream preparation of biological samples for downstream analysis? Second-generation DNA sequencing platforms are well-established tools for gene-based research, however emerging third-generation platforms may once again reshape the landscape.

4:40 Planning and Integration of Biospecimen Collection in Clinical and Epidemiology Trials
Stephen M. Hewitt, M.D., Ph.D., Clinical Investigator, Laboratory of Pathology, NCI

Clinical and epidemiology trials are carefully designed and planned to address specific questions. Only within the last decade has collection of biospecimens for molecular analysis evolved and become an element of nearly all trials. As these specimens have been collected and analyzed, the limitations of this approach have been uncovered. Not all biospecimens are equal. The goal is to minimize the impact of pre-analytic variables. Critical decisions are required to address choices such as the use of residual clinical specimens or collection of dedicated research specimens. Means of processing, shipping and storage of specimens generate a decision tree that must be explored before the first specimen is collected. Application of a fit-for-purpose model allows all variables to be addressed with the goal of a feasible biospecimen collection and utilization strategy.

5:20-6:30 Networking Reception with Exhibit and Poster Viewing
Tuesday, December 7, 2010

8:15 BioBanking Brainstorming Breakthroughs

Grab a cup of coffee and join a table discussion. These focused groups are designed for conference attendees to discuss important and interesting topics related to biospecimens from procurement, preservation, biomolecular extraction, and biomarkers. These are moderated discussions with brainstorming and interactive problem solving, allowing conference participants from diverse areas to exchange ideas, experiences, and develop future collaborations around a focused topic.

### Science

**UTILIZATION OF BIOSPECIMENS FOR DRUG DEVELOPMENT**

9:15 Chairperson’s Opening Remarks

9:20 Access to High Quality, Well-Annotated Specimens as a Critical Success Factor for Successful Registration and Commercialization of Candidate Drugs and Diagnostics

John C. Bloom, V.M.D., Ph.D., President, Bloom Consulting Services, LLC; Special Government Employee, FDA

Access to well-annotated, appropriately collected and stored specimens from clinical trial subjects, as well as those from external biorepositories and clinical services, are increasingly critical to successful registration and commercialization of today’s candidate drugs and diagnostics. In addition to providing a means for new target identification, validation and characterization, applications include the prospective and retrospective development of novel biomarkers and diagnostics that predict efficacy and/or toxicity, and enable patient stratification, regulatory/safety risk management, product differentiation and personalized medicine. In addition to the above, specimens banked from clinical trials provide an important “insurance policy” that enables sponsors to address claims relating to genetic and other associations with outcomes of their marketed drugs. Despite the financial, logistical, organizational and political challenges routine banking and specimen acquisition poses, the value proposition is compelling and one that drug hunters today cannot ignore.

9:50 Early Learnings in Integrating Second Generation Sequencing with Molecular Pathology in the Development of Novel Cancer Chemotherapeutics

Keith Robinson, Ph.D., Lead Senior Scientist, Bioinformatics, Infinity Pharmaceuticals, Inc.

This presentation will review the challenges faced in applying second generation sequencing to pre-clinical and clinical samples for informing clinical development of compounds with novel mechanism-of-action. These would include challenges in obtaining high-quality DNA from suitably consented samples, considerations in the choice of targeted sequencing strategies and downstream informatics. Vignettes from 1-3 pilot studies using different targeted sequencing technologies will be presented.

10:20 Drug Rescue and the Value of Biobanking

L. Scott Clark, Ph.D., Chief Scientific Officer, Gentris Corporation

For every 5,000 drug candidates that enter pre-clinical testing, only one will receive FDA approval. Pharmaceutical organizations are under pressure to reduce costs and address key reasons for drug failure – adverse drug reactions, lack of efficacy, and unfavorable pharmacokinetics/drug metabolism properties. Banking a consented pharmacogenomic sample becomes invaluable for any of the above scenarios. Analysis or re-analysis of stored samples can rescue a failed drug by eliminating re-recruiting, re-consenting, and re-enrolling patients.

10:35 Morning Coffee Break with Exhibit and Poster Viewing

### Business

**INVESTING IN THE FUTURE - QUALITY PRODUCTS**

9:15 Chairperson’s Opening Remarks

9:20 The Benefits of Biospecimen Banking Standardization and Regulation for Cellular Therapy

Daniel Powell, Ph.D., Research Assistant, Professor, Pathology, Laboratory Medicine, Obstetrics and Gynecology, University of Pennsylvania

9:50 Global Quality Control: Best Practices in Standardization Efforts

Andrew Brooks, Ph.D., Director of Operations, Rutgers University Cell and DNA Repository; Associate Professor, Genetics, Rutgers University

Best practices efforts and global standard operating procedure deployment are helping the biorepository community achieve a level of performance and reproducibility previously unattainable. With that said, the standardization of sample collection procedures and processing guidelines is only one part of a much larger issue: sample quality control. This session will look at technologies, procedures and collaborative efforts to develop global, application-specific metrics allowing for the more direct comparison of samples across studies, and most importantly, across biorepositories.

10:20 Sponsored Presentation (Sponsorship Opportunity Available)

Contact Jon Stroup at 781-972-5483 or jstroup@healthtech.com for information

10:35 Morning Coffee Break with Exhibit and Poster Viewing

11:15 Best Practices for Biological Resource Centers (BRCs)

Yvonne A. Reid, Ph.D., Manager, Scientist, Cell Biology Program, American Type Culture Collection

There are several Biological Resource Centers (BRCs) throughout the world, yet there are very few that adhere to the Best Practices for BRCs as defined by the best practice guidelines, a consensus document published by the Organization for Economic Co-Operation and Development (OECD) in 2007. The best practices guidelines ensure that biological materials are of the highest standard and are authentic; the preservation techniques used retain important functional biological characteristics ensuring consistency among centers supply them; ensure protection of the health of laboratory personnel, the public and the environment. These topics will be discussed in context of current activities at ATCC, a BRC.

11:45 Panel Discussion: Navigating the Road of Regulations

Selected speakers discuss the challenges, best practices, and future developments for navigating regulations, standardizations, and quality control.

12:15 pm Close of Morning Session

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

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 materials, your abstract must be submitted, approved and your registration paid in full by November 10, 2010. Register online, or by phone, fax or mail. Indicate that you would like to present a poster and you will receive abstract submission instructions via email.
BIOMOLECULAR PROCESSING AND EXTRACTION

2:00 Chairperson's Opening Remarks
2:05 Realistic and Cost-Effective Strategies to Extend "Next-Generation Surveys" Using Fresh Frozen and Paraffin-Embedded Tissue Samples
Galen Hesteter, M.D., Associate Investigator, Integrated Cancer Genomics Division; Head, colorectal Cancer Research; Director, Tissue Microarray Core, TGen

Historically, genome and transcriptome profiles were limited to large frozen-fresh tumors where intact DNA and RNA could be readily extracted. Our research activities have focused on extending discovery-based array CGH surveys using fresh frozen and paraffin-embedded tissue aliquots, and more recently to the methylene blue utilizing same patient tumor and normal FFPE samples. We review DNA extraction and processing steps and the quantitative and qualitative measures to ensure suitable template for downstream applications.

2:35 Proteomic Sample Collection, Processing, and Storage for Cancer Biomarker Discovery
Farid E. Ahmed, Ph.D., Director, GEM Tox Consultants & Labs, Inc.

This presentation will describe methods of proteomic sample collection, processing and storage with focus on techniques employed for cancer biomarker discovery. Technologies employing cold chain logistics biostorage will be elucidated. Emphasis will be placed on the relevance of these approaches to personalized medicine and cancer biomarker discovery.

3:05 Optimizing a Proteomics Platform for Urine and Other Biofluids
Towia A. Libermann, Ph.D., Associate Professor, Medicine, Beth Israel Deaconess Medical Center

Urine and other biofluids from patients with cancer are collected using developed protocols. Information pertaining to biospecimens are collected using a biospecimen database. Biospecimens, clinicopathological data, and follow-up information are well annotated for optimal biomarker discovery. We have explored various parameters with regard to urine and other biofluids for optimizing quantitative proteomics approaches for biomarker discovery. Sample preparation and extraction methods for enhancing reproducibility and protein detection will be discussed.

3:35 Refreshment Break with Exhibit and Poster Viewing

4:00 The Proteomic Sample: Factors that Impact Accuracy and Variability in Mass Spectrometry Based Measurements
Iulia M. Lazar, Ph.D., Associate Professor, Biological Sciences, Virginia Bioinformatics Institute, Virginia Polytechnic Institute and State University

Large scale proteome experiments conducted with mass spectrometry instrumentation involve multiple level decisions that affect sample collection, storage, preparation, analysis and computational data processing. This presentation will review critical steps that impact severely the outcome of such experiments and the interpretation of results. Technological advances that could improve the accuracy and minimize the variability of mass spectrometry measurements will be evaluated.

4:30 Sponsored Presentations (Opportunities Available)
5:00 Utility of Biospecimens for Epidemiologic Research: Experience from the PLCO Trial
Wen-Yi Huang, Ph.D., Epidemiologist, Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS

Large scale epidemiological studies conducted with mass spectrometry instrumentation involve multiple level decisions that affect sample collection, storage, preparation, analysis and computational data processing. This presentation will review critical steps that impact severely the outcome of such experiments and the interpretation of results. Technological advances that could improve the accuracy and minimize the variability of mass spectrometry measurements will be evaluated.

5:00 Close of Day

INVESTING IN THE FUTURE - BIOPRESERVATION

2:00 Chairperson's Opening Remarks
2:05 Biopreservation: Entering the Post-Genomic Era
John G. Baust, Ph.D., UNESCO Chair & Professor; Director, Institute of Biomedical Technology, Binghamton University; Editor-in-Chief, Biopreservation & Biobanking

Until very recently, efforts to "optimize" preservation protocols were constrained by a biophysical paradigm which assumes that cells are essentially "biologically but not structurally passive" to the freeze-thaw process. It is now recognized, to the contrary, that the management of the cell's molecular-based stress responses is paramount to functional preservation and post-banking utility. Key elements necessary to establish post-genomic functionality in cryopreserved samples will be reviewed.

2:35 Droplet-Based High-Throughput Cryopreservation of Clinical Samples
Utkan Demirci, Ph.D., Assistant Professor, Medicine, Brigham and Women's Hospital; Harvard-MIT Health Sciences and Technology, Harvard Medical School

Blood shortages present a major global health problem. The long term cryopreservation of red blood cells provides a supplementary inventory to help meet demand during such shortages. We introduce a new ultra-rapid vitrification method using RBC encapsulating droplets that can be performed at high throughput. This method could also be designed to entail minimal labor, making it attractive for routine clinical use. Our novel approach could also be applied to storage of samples through automated methods in small scale volumes.

3:05 Advances in Biopreservation of Biofluid Biospecimens
Allison Hube1, Ph.D., Professor and Director, Biopreservation Core Resource, University of Minnesota

Biofluid biospecimens (plasma, serum, urine, bronchial lavage fluid, tear fluid, seminal fluid, and ascites fluid) contain not only cells but also proteins, enzymes, lipids, metabolites and peptides, which can be utilized as biomarkers of health and disease. Currently, millions of biofluid biospecimens are stored by freezing without following any preservation protocol and in the absence of any stabilizing agents. We will describe best practices on preservation of biofluid specimen in order to optimize quality and therefore value of the biofluid biospecimen.

3:35 Refreshment Break with Exhibit and Poster Viewing

4:00 Why Are Prospective Clinicopathological Data as Important as Specimens?
Iman Osman, M.D., Director, Interdisciplinary Melanoma Cooperative Group; Associate Professor, Dermatology and Oncology, New York University Langone Medical Center

We describe our experience in developing a prospective clinicopathological and biospecimen database. Biospecimens, clinopathological data, and follow-up information are collected using developed protocols. Information pertaining to biospecimens is recorded in 35 fields, and clinicopathological information is recorded in 371 fields. Investigators conducting research utilizing the IMGC biospecimen resource are blind to clinicopathological information, and molecular data generated using biospecimens are linked independently with clinicopathological data by biostatistics investigators. The presentation will focus on the importance of linking the specimen to prospective well annotated clinicopathological information.

4:30 Contemporary Access to Historical Biospecimen Collections
Leslie Carroll, Senior Systems Analyst, NHLBI Biologic Specimen and Data Repository Information Coordinating Center (BioLinc) Information Management Services, Inc.

Legacy biospecimen studies are notoriously hard to utilize for modern day research; however, a wealth of information resides in these historical biospecimens and associated longitudinal data. This discussion will focus on the methods and key concepts used by the NHLBI BioLinc team to streamline biospecimen collections and make them available through a website to the wider scientific community.

5:00 The International Serious Adverse Events Consortium
Arthur L. Holden, Chairman and CEO, ISAE

The ISAE is an international nonprofit organization comprised of leading international pharmaceutical companies, the Wellcome Trust, research networks from around the world, and the U.S. Food and Drug Administration (FDA). The ISAE has recently funded and is launching the second phase of research into the genetics of drug induced SAFEs. This presentation will summarize the status of this novel banking and research initiative, its results to date, and its research plans for its second phase. Specifically, the presentation will focus the development and international expansion of our SAF research cohorts sourced from academic networks, member pharmaco, and innovative new partner relationships which leverage EMRs.

5:30 Dedicated Poster Viewing with Wine & Cheese Reception In Exhibit Hall

6:00 Close of Day
8:30am Morning Coffee (Sponsorship Opportunity Available)

**Science**

**INTERROGATING THE BIOSPECIMEN - TOOLS AND PLATFORMS**

8:45 am Chairperson's Opening Remarks
8:50 Extrinsic and Intrinsic Controls for Measurement of Protein Analyte Concentrations in Tissue Slides
Allison Welsh, Ph.D., Candidate, Pathology, Yale University School of Medicine
Measurement of protein on slides by traditional immunohistochemistry has historically been a highly subjective process. Now tools are available for accurate measurement that use standardization methods and result in reproducibility that is similar to that seen in ELISA assays or flow cytometry. This lecture will describe the use of the AQUA method for automated analysis and illustrate findings that have been elusive using traditional immunohistochemistry. This method is especially important in that it can sense and potentially adjust for the problems of pre-analytic variation often seen in specimens in paraffin archive biobanks.

9:20 Genomic Evolution, Progression and Metastasis in Breast Tumors
James B. Hicks, Ph.D., Research Professor, Genetics, Cold Spring Harbor Laboratory
The genomic evolution of solid tumors can be tracked by copy number profiling at genome level and tracked spatially through the tumor itself. The discussion will focus on the application of ‘next-generation’ high-throughput sequencing methods to assay genomic copy number and epigenetic variation (DNA methylation) in tumors, including the evolution of tumors at the single cell level.

9:50 Mass Spectrometric Analysis of Proteins from FFPE- or OCT-Embedded Tissues
Hui Zhang, Ph.D., Assistant Professor, Pathology & Clinical Chemistry, Johns Hopkins University School of Medicine
Formalin-fixed-paraffin-embedded (FFPE) tissues and OCT-embedded tissues, archived with pathological and clinical information processed by universal standard methodology, are used worldwide in hospitals and tissue banks, and present a rich resource of specimens for biomarker discovery. Mass spectrometric analysis of proteins isolated from FFPE-embedded or OCT-embedded tissues from specific disease are likely to detect proteins and protein post-translational modifications as clinically relevant protein markers for disease diagnosis. We have tested the feasibility and established a workflow for proteomic analysis FFPE- or OCT-embedded tissues using mass spectrometry.

10:20 Morning Coffee Break with Exhibit and Poster Viewing

11:00 Biosensing in Thermal Space: Multiplexed Highly Sensitive Detection of Multiple Biomarkers Using Phase Change Nanoparticles
Ming Su, Ph.D., Assistant Professor, NanoScience Technology Center, Department of Mechanical, Materials, Aerospace Engineering, University of Central Florida
Although many biomarkers have been identified with certain specificity to detect cancers at early stage, it is clear that no individual biomarker is ideal to distinguish lethal cancers from indolent ones due to lack of tumor specificity. This talk will describe a new biosensing technique, i.e., biosensing in thermal space, where a series of composition-encoded solid to liquid phase change nanoparticles will be modified with a series of ligands, and used for in vitro detection of multiple biomarkers.

11:30 CometChip: High-Throughput DNA Damage Analysis
David M. Weingart, Engelward Laboratory, Biological Engineering, MIT
In collaboration with Sangeeta Bhatia, the Engelward Lab has developed a high-throughput version of the single cell gel electrophoresis “comet” assay. Cells are arrayed in microwells in order to fully automate imaging/analysis and enable a 96-well format for simultaneous assaying of multiple cell types, drugs, or other conditions. Given its sensitivity, robustness and versatility, it is anticipated that this new technology will help to advance studies of chemical toxicology.

12:00 pm Close of Morning Session
12:15 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

**Business**

**BIOBANK MANAGEMENT: EXPERIENCE MAKES THE DIFFERENCE**

8:45 am Chairperson’s Opening Remarks
8:50 Lessons Learned in Biobanking at the Marshfield Clinic
Cathy McCarty, Ph.D., M.P.H., Senior Research Scientist, Center for Human Genetics, Marshfield Clinic Research Foundation
The Marshfield Clinic Personalized Medicine Research Project, launched in 2002, comprises more than 20,000 participants aged 18 years and older with DNA, plasma, serum samples, questionnaires, and access to comprehensive electronic health records. More than 20 active studies are underway using the biobank. Policies and processes are in place to facilitate use of the samples. Lessons learned in the first ten years of the biobank will be shared.

9:20 Innovation in the Sample Lifecycle and Research Workflow
Lynn Bry, M.D., Ph.D., Director, Crimson Bio-Specimen Core, Partners Healthcare Systems

9:50 Biobanking and Biospecimen Processing at the Mayo Clinic
W. Edward Highsmith, Jr., Ph.D., Co-Director, Molecular Genetics Laboratory, Mayo Clinic
Four formal biobanking initiatives are currently active at the Mayo Clinic. The largest is the Mayo Community Biobank, which is conducting a pilot study accruing 20,000 adults from the community. There are three disease specific biobanks: bipolar disease, cardiovascular disease, and mitochondrial disease. All four biobanks have specimen accessioned, processed, tracked, and stored and prepared for specific studies by the Biospecimens Accessioning and Processing (BAP) laboratory. The BAP facility has developed a suite of QA/QC procedures and technical protocols for the biobanking efforts at the Mayo Clinic.

10:20 Morning Coffee Break with Exhibit and Poster Viewing
11:00 Business of Biobanking: Perspective from a CRO Central Lab
Barbara E. Glazer, MT(ASCP), Director, Pre-Analytical Services, Global Central Laboratories, Quintiles
This discussion will highlight the unique considerations of biobanking and biospecimen management in support of global clinical trials. As pharmaceutical companies expand and even shift their sites to new countries, the requirements to support their efforts must be combined. This presentation will include logistics and customs with an eye on budget, decisions of where and how frequently to test in light of study requirements for inclusion/exclusion criteria or reporting criteria, flexibility in data management and combining data from different laboratories into a unified database.

11:30 The Challenges of Multiuser Repositories for Inherited Disease Research
Jay Tischfield, Ph.D., Professor, Pediatrics & Psychiatry, Robert Wood Johnson Medical School, University of Medicine and Dentistry New Jersey; Genetics, Rutgers University
Large numbers of biosamples and associated clinical data from affected individuals and their relatives are required for association and genetic linkage studies aimed at identifying gene variants that play a role in causation of common diseases. Collecting, processing, storing and distributing DNA, RNA, cDNA and other derivative products of uniformly high quality and maximum utility for the end user presents unique long-term challenges. We will describe what we have learned after two decades and over 300,000 individual samples.

12:00 pm Close of Morning Session
12:15 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own
This session brings together scientists who use biospecimens for research (“biousters”) with operation managers who collect and store the biospecimens (“biobankers”). Biobankers and biousters elaborate on the characteristics of their working relationship as they address the following issues:

- How does this partnership work?
- What are the bottlenecks?
- What does each member bring to the table?
- What does each member need from the other?
- Ultimately, what are the scientific results?

1:30 Chairperson’s Opening Remarks
1:35 Yale University Co-Presentation

Alexander Vortmeyer, Ph.D., Director, Fresh and Frozen Tissue Procurement and Distribution, Yale University
Tobias Curling, M.D., Ph.D., Assistant Professor, Surgery, Director, Yale Endocrine Neoplasia Laboratory, Yale University School of Medicine

Diseased and normal control human tissues are an invaluable resource for diagnostic procedures and research. Traditional pathologic procurement techniques cause partial biochemical destruction of tissues, while research interests frequently require optimal biochemical preservation. Modifications of traditional procurement techniques are proposed for the benefit of both research analysis and molecular diagnostic evaluation.

2:30 Quintiles Co-Presentation

Barbara E. Glazer, MT(ASCP), Director, Pre-Analytical Services, Global Central Laboratories, Quintiles
Karl Kammerhoff, MBA, Associate Research Scientist, Discovery Medicine & Clinical Pharmacology, Research & Development, Bristol-Myers Squibb

Collaboration is key in developing the partnership between the biobanker and the biouster. This session explores what each party contributes to the relationship and how the requirements of the individual parties contribute to the end result. Consideration will be given to initial collection of the biospecimen, training of collection sites, anonymization, data provision, among others. What are the bottlenecks that can occur, and ultimately, how does all of this translate to quality scientific results?

3:35 Refreshment Break – Last Chance for Poster and Exhibit Viewing
4:00 Millennium Presentation

Samples, Assays and Data: Bio-Repository Practices to Maintain Sample Integrity, Enable Genomic Testing, Data Integration and Utility for Translational Medicine

Erik Koenig, Senior Manager, Molecular Technologies, MILLENNIUM: The Takeda Oncology Company

With the increase in outsourcing in the Bio-Pharmaceutical industry, biorepositories are required to coordinate sample tracking, sample testing and retesting within and throughout several laboratories. Biorepository practices, from Millennium: ‘The Takeda Oncology Company, to maintain sample integrity throughout outsourced genomic testing to support translational medicine will be discussed.

4:40 The Broad Institute Co-Presentation

Kristin Ardlie, Ph.D., Director, Biological Samples Program, The Broad Institute of MIT and Harvard
Jordi Barretina, Ph.D., Research Scientist, Cancer Program, The Broad Institute of MIT and Harvard

5:20 Conference Wrap-up
5:30 Close of Conference

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Sponsored Presentation
Present your scientific research and solutions for 15 or 30 minutes as part of the conference program, ensuring your audience is seated and ready to listen.

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Invite session delegates to enjoy lunch on your company’s behalf while you give a 30-minute presentation. Your workshop concludes with 15 minutes of Q&A, allowing you to interact with your customer base. Presentation opportunities are limited, so reserve your talk today to ensure participation!

Invitation-Only VIP Dinner/Hospitality Suite
Sponsor will select invites from the conference pre-registration list for an evening of networking at the hotel or a top local venue. Cambridge Healthtech Institute will extend invitations, conduct follow-up and monitor responses. Reminder cards will be placed in the badges of those delegates who will be attending.

Exhibitor Information
Exhibitors will enjoy face-to-face networking with qualified end-users. Showcase your latest technologies or solutions and walk away with new business leads. We can customize any opportunity to meet your current marketing objectives and budget. To find out more about our comprehensive sponsorship and exhibit packages, please contact:

Jon Stroup | Manager, Business Development
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The Compound Management Forum December 7-8

Industry experts and academic leaders in the fields of compound and special library management will present on best practices that are key to creating and maintaining a flexible, functional, state-of-the-art facility for serving internal clients and improving drug discovery. Hear the latest in informatics for both biologic and chemical compounds, learn how novel analytical methods can improve your collection, participate in an expert panel discussion on engaging and retaining your most valuable asset: your staff, and network with peers and leaders in the field.

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HOW TO REGISTER: Online: www.healthtech.com/bnk
Email: reg@healthtech.com       Phone: 781-972-5400 Option 1  Fax: 781-972-5425

Yes! Please register me for BioBanking: Maximizing Your Investment [Key Code BNK F]

REGISTRATION INFORMATION
Mr.  Ms.  Mrs.  Dr.  Prof.
Name ____________________________  Div./Dept.________________
Company ____________________________
Address ____________________________
City/State/Postal Code ____________
Telephone ____________________________

How would you prefer to receive notices from CHI?  Email: ☐ Yes  ☐ No  Fax: ☐ Yes  ☐ No
Email* ____________________________  Fax ____________________________

*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, networking opportunities and requested eNewsletters.

SHORT COURSE PRICING – December 6, 2010

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<th>Commercial</th>
<th>Academic, Government, Hospital Affiliated</th>
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<tr>
<td>Single Short Course</td>
<td>$495</td>
<td>$295</td>
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<tr>
<td>Two Short Courses</td>
<td>$795</td>
<td>$495</td>
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Please make your short course selection:
☐ SC1 Biostabilization of Biospecimens  ☐ SC2 Transitioning a Biobanking Effort

CONFERENCE PRICING – December 6-8, 2010

Advance Registration Deadline until October 29, 2010

imentary, Government, Hospital Affiliated

Commercial

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<td>$1995</td>
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Registrations after October 29, 2010 and on-site

$2195  $945

REQUIRED: Please select the one meeting you will most likely attend.
☐ The Business of Biobanking  ☐ The Science of Biobanking

POSTER DISCOUNT

☐ $50 off

POSTER 3 - 4th IS FREE

Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply. Please reproduce this registration form as needed.

GROUP DISCOUNTS AVAILABLE! Special rates are available for multiple attendees from the same organization.

For more information on group discounts contact David Cunningham at 781-972-5472

☐ I cannot attend but would like to purchase BioBanking: Maximizing Your Investment conference materials for $350 (plus shipping). Massachusetts delivery will include 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)

Card #

Cardholder ____________________________
Signature ____________________________
Cardholder’s Address (if different from above) ____________________________
City/State/Postal Code ____________________________
Country ____________________________

Please refer to the Registration Code below:

Key Code BNK F

Mail Registration to:
Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
T: 781.972.5400 | Toll-free in the U.S. 888.999.6288
F: 781.972.5425  | www.healthtech.com

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 materials, your abstract must be submitted, approved and your registration paid in full by November 10, 2010. Register online, or by phone, fax or mail. Indicate that you would like to present a poster and you will receive abstract submission instructions via email.

I am interested in presenting a poster at

☐ The Business of Biobanking
☐ The Science of Biobanking

Title ____________________________

Conference Registration

CHI Insight Pharma Reports

A series of diverse reports designed to keep life science professionals informed of the salient trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets.

For a detailed list of reports, visit InsightPharmaReports.com, or contact Rose LaRaia, daras@healthtech.com, 781-972-5444.

Barnett Educational Services

Barnett is a recognized leader in clinical education, training, and reference guides for life science professionals involved in the drug development process. For more information, visit www.barnettinternational.com.

Additional Registration Details

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access

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.

Substitution/Cancellation Policy

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 ($250) 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 audio recording of any kind is prohibited onsite at all CHI events.