



 Cambridge Healthtech Institute's Seventh Annual
**Systems Integration
in Biodefense**
Addressing Technology Gaps and Challenges
August 18-19, 2008 • The Ritz-Carlton Hotel • Washington, D.C.

KEYNOTE SESSION:



**DARPA Technology Programs in Biodefense:
A Strategic Technology View**
Ms. Barbara McQuiston, Director of the Strategic Technology Office (STO), Defense Advanced Research Projects Agency (DARPA)



Systems Biology in Medical Development
Joseph M. Palma, MD, MPH, CPE, Senior Medical Advisor, USA Medical Research & Materiel Command

Analysis of the Department of Homeland Security's Detect-to-Protect (D2P) Biological Sensor Field Tests
Michael Finnin, Research Staff Member, Institute for Defense Analyses



Building an Effective Partnership between the Private Sector and Government for Biodefense Countermeasure Development
Bradley T. Smith, Ph.D., Assistant Professor, Center for Biosecurity, University of Pittsburgh Medical Center



Technology Challenges in Biological Threat Characterization
J. Patrick Fitch, Ph.D., Laboratory Director, National Biodefense Analysis and Countermeasures Center, Managed and Operated for DHS by BNBI, President, Battelle National Biodefense Institute, LLC (BNBI)

“The Systems Integration in Biodefense Program provides the best overview available of the state of the biodefense area”

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At this year's Systems Integration in Biodefense meeting, we will hear from industry leaders about their strategy for meeting the needs of the community and bridging the technology gaps that still exist. New assays will be introduced that are highly multiplexed, integrated and field deployable. Technology developments in sample prep, signal transduction and amplification will be showcased, and specific examples of integrated systems will be presented. Dual-use application is an essential feature for products to have utility in biodefense and clinical settings. A discussion on getting products to market and facing commercialization, collaboration, and business challenges will be addressed. The meeting will be followed by the 2nd Annual Enabling Point-of-Care Diagnostics to elucidate the transition from biodefense to a clinical setting, and the tactical issues of implementation.

Scientific Advisory Board

Steven Buchsbaum, Ph.D., Senior Program Officer, Global Health Technologies, Bill & Melinda Gates Foundation

John C. Carrano, Ph.D., Vice President, Research and Development, Luminex Corporation

Kenton L. Lohman, Ph.D., Senior Biotechnology Advisor, Midwest Research Institute, National Capital Region Division

Lloyd J. Whitman, Ph.D., Head, Surface Nanoscience and Sensor Technology Section, Naval Research Laboratory

Monday, August 18

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

KEYNOTE SESSION:

NEXT KEY TECHNOLOGY CHALLENGES IN BIODEFENSE RESEARCH

8:30 Chairperson's Opening Remarks

John C. Carrano, Ph.D., Vice President, Research and Development, Luminex Corporation

8:40 DARPA Technology Programs in Biodefense: A Strategic Technology View



Ms. Barbara McQuiston, Director of the Strategic Technology Office (STO), Defense Advanced Research Projects Agency (DARPA)

New concepts in the approach in biodefense are needed as our world and technology changes. This presentation will look into the general concerns and potential new arenas in the area of biodefense. A review of several enabling DARPA technologies being pursued will be included.

9:15



Albert Churilla, Ph.D., J.D., Chief, Medical S & T, Chem/Bio Technologies Directorate, Defense Threat Reduction Agency

9:50 Systems Biology in Medical Development



Joseph M. Palma, M.D., MPH, CPE, Senior Medical Advisor, USA Medical Research & Materiel Command

This presentation will highlight the Army's growing program focused on the application of Systems Biology tools to both the discovery of network biology lead candidates and to the development of pharmaceuticals.

10:25 Coffee Break

11:00 Analysis of the Department of Homeland Security's Detect-to-Protect (D2P) Biological Sensor Field Tests

Michael Finnin, Research Staff Member, Institute for Defense Analyses

The Institute for Defense Analyses (IDA) was asked by Department of Homeland Security (DHS) S&T Directorate and the Edgewood Chemical Biological Center to coordinate, collect, and analyze field data from deployments of DHS's detect-to-protect (D2P) biological detection sensors under development. IDA has characterized the field sites (buildings, subways, airports) and analyzed the resulting data in order to understand the origins of silent internal alarms recorded by sensors during month-long deployments. This analysis will be used for the development of a system integration plan to develop biological detection systems for DHS's customers by characterizing the background in various field settings.

11:30 Building an Effective Partnership between the Private Sector and Government for Biodefense Countermeasure Development



Bradley T. Smith, Ph.D., Assistant Professor, Center for Biosecurity, University of Pittsburgh Medical Center

Identification and investment in next generation technologies for biodefense is critical if we are to successfully prepare for current and future threats. Key to the success of current and future medical countermeasure (MCM) development is a strong partnership between the government and private-sector developers. Efforts at the Department of Health and Human Services (HHS) to engage with the private sector as HHS administers BioShield, BARDA, and related MCM development programs will be discussed and lessons for the future will be proposed.

12:00 pm Technology Challenges in Biological Threat Characterization



J. Patrick Fitch, Ph.D., Laboratory Director, National Biodefense Analysis and Countermeasures Center, Managed and Operated for DHS by BNBI, President, Battelle National Biodefense Institute, LLC (BNBI)

Scientific discoveries and technologic innovations are occurring at a rapid pace. Several different strategies may be needed to anticipate and address biological threats arising from these advancements. Strategies that NBACC is considering will be presented.

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

AUTOMATED SAMPLE PREP

2:00 Chairperson's Remarks

Kenton L. Lohman, Ph.D., Senior Biotechnology Advisor, Midwest Research Institute, National Capital Region Division

2:10 Fully Automated DNA Preparation Microsystem for Air Samples

Marion Ritzi, Ph.D., Head of Fluidics Group, Fluidics & Simulation, Institut Für Mikrotechnik Mainz GmbH

A fully-automated system for DNA preparation from airborne bacteria is presented. It enables the capture and lyses of germs and the following binding, washing and eluting steps of the therefore purified DNA. The disposable part of the system comprises a polymer chip that contains filters, mixings structures, turning valves, optical detection structures, a DNA binding matrix and buffer reservoirs with stored liquids. The instrument consists of syringe pumps for liquid transport inside the chip system, motors for valve actuation, heaters with temperature sensors and optical devices for detecting the position of the sample plug inside the chip system.

2:40 One-Step Pathogen Specific DNA Extraction from Whole Blood on a Centrifugal Microfluidic Device

Yoon-Kyoung Cho, Ph.D., Bio & Health Lab, Samsung Advanced Institute of Technology

We will report a fully integrated pathogen specific DNA extraction device utilizing centrifugal microfluidics on a CD platform. Using the innovative Laser Irradiated Ferrowax Microvalves (LIFM) together with the rapid cell lysis method using laser irradiation on magnetic particles, we could, for the first time, demonstrate a fully integrated pathogen specific DNA extraction from whole blood on a CD. As a model study, DNA extraction experiments from whole blood spiked with Hepatitis B virus (HBV) and *E.coli* were conducted. The total process of the plasma separation, mixing with magnetic beads conjugated with target specific antibodies, removal of plasma residual, washing, and DNA extraction was finished within 12 minutes with only one manual step of loading 100 μ L of whole blood. Real-time PCR results showed that the concentration of DNA prepared on a CD was as good as that of the samples prepared in conventional bench top method. It demonstrates that our novel centrifugal microfluidics design enables a full integration of complex biological reactions that require multi-step fluidic control.

NOVEL APPROACHES TO TRANSDUCTION & MULTIPLEXING

3:10 Collection, Focusing, and Metering of DNA in Microchannels Using Addressable Electrode Arrays for Portable Low-Power Bioanalysis

Victor M. Ugaz, Ph.D., Assistant Professor, Chemical Engineering, Texas A&M University

We describe a focusing method based on a device design incorporating arrays of addressable on-chip microfabricated electrodes that concentrate charged biomolecules (DNA, proteins) by electrophoretically sweeping them along the length of a microchannel. We have also harnessed this effect to develop a new label-free method to detect charged biomolecules in free solution. Here, an electrode array is designed to generate localized zones where the biomolecules become ultra-concentrated (a million-fold or more), resulting in formation of a mesophase that is visible under ordinary white light. The use of very low potentials and currents (e.g. equivalent to a single AA-size battery) combined with ease of fabrication makes this technology broadly applicable as a highly efficient mechanism to achieve sample focusing, as well as a robust label-free method to enable minute sample quantities to be detected in portable bioanalysis systems without the use of chemical fluorophores.



3:40 Identification of Biothreat Agents Using Gel-Drop Microarrays in a Microfluidic Format

Christopher Cooney, Ph.D., Director of Engineering, Akonni Biosystems, Inc.

We have developed a portable, easy-to-use, inexpensive microfluidic flow cell that harbors our gel-drop microarrays (TruArrays™) for rapid microbial detection and identification. The biodefense microarray panel includes *Y. pestis*, *B. anthracis*, Variola major, and VEE. A commercial panel includes Adenovirus, *C. pneumoniae*, Flu A, Flu B, RSV, and Coronavirus. The high signal-to-noise ratios of the gel-drop microarrays enable identification of these agents using our low-cost optical reader. We have also developed a simple, inexpensive sample preparation device (TruPrep™), which does not require centrifugation and can process complex samples such as blood, sputum, nasal washes and buccal swabs. TruPrep™ has been configured in a hand-held format and as a module in an automated, integrated platform. Nucleic acid extraction and concentration from large volume samples has been demonstrated using TruPrep™ in as little as 7 minutes.

4:10 Refreshment Break, Exhibit and Poster Viewing

ISOTHERMAL AMPLIFICATION

4:45 A Simple Cassette for the Processing of Nucleic Acids Present in Human Fluid Samples

Haim H. Bau, Ph.D., Professor, Department of Mechanical Engineering and Applied Mechanics, University of Pennsylvania

We describe a point of care, microfluidic system for the detection of nucleic acids in fresh samples of saliva laden with cells and/or viruses. The cassette consists of a single reaction chamber equipped with an alumina membrane for the isolation of nucleic acids. The chamber also contains thermally-released, dry-stored reagents needed for the PCR process. The cassette accepts a raw sample of oral fluid, mixes the sample with stored lysis buffer, and transmits the mixture through the alumina membrane, which retains the nucleic acids. Then, the membrane is washed thoroughly. Next, the wash solution is replaced with water, the chamber is heated to release the PCR reagents, and the temperature of the chamber is cycled to induce DNA amplification. The amplicons can be either detected *in situ* or discharged into a detector. The yet unoptimized process lasts less than an hour.

5:15 Rapid SNP Diagnostics Using Asymmetric Isothermal Amplification and a New Mismatch-Suppression Technology

Yoshihide Hayashizaki, Ph.D., Project Director & Chief Scientist, Genome Science Laboratory, RIKEN Yokohama Institute

We have developed a sensitive, accurate, rapid, and simple DNA amplification scheme that shows potential for translational medicine from pharmacogenomics-based drug discovery thru to point-of-care diagnostics. Called the SMart Amplification Process (SMAP), the method employs a new DNA polymerase, unique primer design and background suppression technology that can amplify target sequences from crude cell lysates without thermocycling. The specificity of the SMAP assay enables detection of single-nucleotide differences, such as somatic mutations in tumors and SNP variants. Because mis-match amplification can be completely suppressed in SMAP, a reliable diagnostic result can be achieved based exclusively on amplification alone. From sample preparation to detection, amplification and hence diagnostic determination can be achieved in as little as 30 minutes from raw blood. SMAP is a new tool available to the research and medical community; it achieves a highly desirable single-step process goal for molecular diagnostics where “amplification equals detection”.

5:45 Networking Reception

6:45 Close of Day One

“An integrated conference showcasing the “big picture” and one source to learn and gather information about the nation’s biodefense programs”

Head, Virology, National Biodefense Analysis and Countermeasures Center

Tuesday, August 19

8:00 am Morning Coffee

INTEGRATED SYSTEMS- FROM SAMPLE TO OUTPUT

8:30 Chairperson’s Remarks

Kevin P. O’Connell, Ph.D., Visionary Solutions Architect, In-Q-Tel, Inc.

8:40 Microfluidic Biothreat Detection and Forensic Identification Systems

Joanne Horn, Senior Staff Scientist, Microchip Biotechnologies, Inc.

Microchip Biotechnologies Inc. (MBI) is developing a universal sample preparation system based on proprietary Micro On-chip Valve (MOV) technology that has been coupled with a variety of detection and separation systems. The technology provides a flexible, robust and cost effective approach to target isolation with a clean transition to identification. Bead based DNA and immunochemistry isolations have been integrated with a robust, versatile fluorescence detection system to provide sensitive, high dynamic range quantification of labeled beads, antibodies, PCR and qPCR products as well as micro channel and capillary separation outputs.

9:10 A High-Speed Biothreat Detection System Using Silicon Chip-Based PCR

Joel Grover, Ph.D., Chief Executive Officer, Thermal Gradient Inc

SAIC and Thermal Gradient are working to develop technologies for a high speed “detect-to-protect” aerosol biothreat detection system employing a flow-through silicon chip to perform multiplex PCR amplification of threat-specific genomic nucleic acid. Candidate applications for the system include attack alert for high value office buildings and transportation facilities. The system is designed as an integrated trigger/confirmer device using a front-end UV Laser-Induced Fluorescence (UV-LIF) detector as a trigger and multiplex PCR for threat detection and ID. Upon alert from the trigger, the confirmer performs high volume sampling of the air to collect an aerosol sample. Particulates are extracted from the sample and processed to yield amplifiable nucleic acid. The PCR chip, a multilayer flow-through device, performs 30 or more PCR cycles in five minutes to amplify multiple genomic nucleic acid targets found only in biothreats. After these targets are amplified to detectable levels, detection is performed using a multi-color fluorescence readout approach. End-to-end processing time from trigger alert to threat confirmation is about ten minutes.

9:40 Coffee Break, Exhibit and Poster Viewing

10:10 Detection of Nucleic Acid and Toxin Targets on an Automated Portable System

Shuqi Chen, Ph.D., Chief Executive Officer, IQuum, Inc.

The Liat™ system is an integrated system for rapid identification and diagnostic confirmation of biological agent exposure or infection. Based on IQuum’s Lab-in-a-tube technology, the Liat system is a man-portable, fully-automated device capable of accepting a raw sample and rapidly and simultaneously identifying multiple Biological Warfare agents (BWA) and other pathogens or toxins of operational concern using state-of-the-art laboratory chemistries such as real-time polymerase chain reaction. The system consists of the disposable Liat Tube with pre-packed reagents, and a stand-alone Liat Analyzer, a highly integrated and miniaturized sample processor, which includes an embedded computer for automation control and readout display, as well as built-in network connectivity. The system can be operated in fixed medical laboratories and deployed medical units to fully support bio-defense and military medical diagnostic needs.

10:40 Near Real-Time Biological Threat Detection for Commercial Building Security Applications

Joe Hernandez, President and Chief Executive Officer, Innovative Biosensors

An integrated biological aerosol collector and identification system is now available for rapid, sensitive detection and identification of biological threat agents. This system integrates biological aerosol sample collection and concentration functions and a novel cellular based bioluminescent immunoassay method for cost effective, near real-time biological detection and identification. Incorporated into a sophisticated building security system, the device provides area-wide biological monitoring information as part of an integrated CBRNE protection system.

11:00 Total Facility System Integration and Response for Biologics Threat Detection

Anthony D. Bashall, Executive Vice President, SecureTeq Corporation

What is described here is an approach to integrate the entire threat detection information and data within a single platform. A plethora of detectors and sensors provide a vast array but very little actionable intelligence. The threat detection platform outlined is able integrate and assimilate data from a multitude of CBRNE detectors at the same time fully integrating live video feeds. The system can also utilize apparently disparate such as wind direction, wind speed, time of day, global threat levels, occupancy levels, etc., to provide a more intelligent Standard Operating Procedure (SOP).

**11:20 Expert Panel:
COLLABORATION AND BUSINESS CHALLENGES: Gap Analysis and Investment Perspective**

Cole Van Nice, Partner, Chart Venture Partners

Penrose "Parney" Albright, Managing Director and Vice Chairman, Civitas Group LLC

12:10 pm Luncheon Presentation (Sponsorship Available) or Lunch on Your Own

FILLING THE TECHNOLOGY GAPS IN BIODEFENSE AND POINT-OF-CARE DIAGNOSTICS

(Shared Session with Enabling Point-of-Care Diagnostics conference)

1:30 Chairperson's Remarks:

Steven Buchsbaum, Ph.D., Senior Program Officer, Global Health Technologies, Bill & Melinda Gates Foundation

1:40 Technical Hurdles Facing Homeland Security Bio-Countermeasures Development



Keith B. Ward, Ph.D., Chief, Chem-Bio R&D Branch, Science and Technology Directorate, Department of Homeland Security

DHS customers comprise a diverse group having wide ranging requirements.

Low cost and low probability of false alarms are particularly challenging for detection platforms and will require innovative solutions. Understanding how best to address novel engineered and emerging threats effectively also will require overcoming numerous technical hurdles.

2:15 NIAID Biodefense Diagnostic Program: Filling the Technology Research Gaps

Maria Y. Giovanni, Ph.D., Assistant Director for Microbial Genomics & Advanced Technology, Division of Microbiology and Infectious Diseases, NIAID/NIH/DHHS (tentative)

Presentation will describe NIAID/NIH comprehensive diagnostic program that spans a broad spectrum of projects from emerging technologies to further advanced product development of established technologies and platforms for Biodefense. Cooperative grant programs will be highlighted that describe successful partnering with the scientific community, industry, government agencies and others.

“ A highly informative and pragmatic conference that succeeds in integrating top management insights of all players with state-of-the-art R&D results to “see around the corner” to next generation biodefense programs ”

Program Manager, Department of Homeland Security

“ A great balance of key stakeholders and thought leaders from both government and industry ”

President, BioPharm Services

HELD IMMEDIATELY PRIOR TO

Second Annual Enabling Point-of-Care Diagnostics

August 19-20, 2008

www.healthtech.com/poc/overview.aspx

and

Inaugural Future of Cancer Diagnostics: Molecular Technologies for Prognosis and Risk Assessment

August 21-22, 2008

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PACKAGE PRICING AVAILABLE

2:50 Leveraging Cell Phone Technology to Make Point-of-Care Diagnostics Accessible in the Developing World



Boris Nikolic, M.D., Senior Program Officer, Bill & Melinda Gates Foundation

In order to establish the broadest access for the developing world, we are exploring the use of mobile technology for health care applications. One of our current areas of focus is the use of cell phone technology as related to health information systems and health care diagnostics. Specifically, we are exploring the integration of mobile point-of-care devices that could leverage the cell phone for computation, control, data download and upload. In addition to strictly diagnostic devices, we are also exploring an integration of a wide range of devices and systems from the most cost-effective integration of biometrics into the cell phone (for the identification of the patients and health care providers, identification of counterfeit drugs), to data security, transfer and management in the context of diagnostic test provision. Our goal is to help create and bring effective and appropriate medical tests to areas in need in the developing world.

3:20 Refreshment Break, Exhibit and Poster Viewing

4:00 Expert Panel:

REIMBURSEMENT AND REGULATORY ISSUES

Moderator: Kathleen Claessens, MS, RN, Reimbursement Affairs, Roche Diagnostics

- New guidance for waived testing under CLIA
- Reimbursement for point-of-care vs centralized testing

Panelists:



Steven I. Gutman, M.D., Director, Office of in Vitro Diagnostic Device Evaluation and Safety, Food & Drug Administration



Paul Radensky, M.D., J.D., Partner, McDermott Will & Emery LLP



Thomas A. Gustafson, Ph.D., Senior Policy Advisor, Arnold & Porter, LLP

5:00 Close of Conference





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For more information, please contact

Katelin Fitzgerald
Manager, Business Development
at 781-972-5458
kfitzgerald@healthtech.com

HOTEL INFORMATION

Hotel Venue:

The Ritz-Carlton, Washington, DC
1150 22nd Street, NW
Washington, DC 20037
Tel: 202-835-0500
Fax: 202-835-1588
Room Rate: \$195 s/d
Res Cutoff: July 30, 2008

To reserve your hotel room, please call the hotel directly to make your room reservation. 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.

TRAVEL INFORMATION

Flight Discounts:

Special Airline Discounts Available. Discounts fares are available on United, United Express, United code share flights (UA*) operated by US Airways, and US Airways Express. You can receive up to a 15% discount if you or your travel agent calls United's toll-free number 1-800-521-4041 and refer to the Meeting ID Number 579YS.

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Special discount rentals have been established withAVIS for this conference. Please call AVIS directly at 800-331-1600 and you must reference your Avis Worldwide Discount (AWD) Number J868190 or go to <http://www.avis.com/AvisWeb/html/meetings/go2.html?AWD=J868190&NAME=Cambridge+Healthtech+Institute++2008+Conferences&FDATE=01012008&TDATE=12312008&LOCATION=various&EVENT=1>

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Reasons You Should Present Your Research Poster at **Systems Integration in Biodefense:**

- ◇ Your poster will be exposed to close to 200 delegates
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- ◇ Your poster abstract will be published on our conference CD
- ◇ Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. Please submit your abstract and register for the meeting. To secure a poster board and inclusion in the conference CD, your abstract must be submitted, accepted and registration paid in full by **July 28, 2008**.

Systems Integration in Biodefense

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847 F

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PRICING INFORMATION

Platinum Package (AUGUST 18-22, 2008)

Includes access to Systems Integration in Biodefense (August 18-19), Point-of-Care Diagnostics (August 19-20), and Cancer Diagnostics (August 21-22)

	Commercial	Academic, Government, Hospital-Affiliated
Early Registration Deadline until June 6, 2008	<input type="checkbox"/> \$2390	<input type="checkbox"/> \$1095
Advance Registration Deadline until July 18, 2008	<input type="checkbox"/> \$2550	<input type="checkbox"/> \$1195
Registrations after July 18, 2008 and onsite	<input type="checkbox"/> \$2695	<input type="checkbox"/> \$1295

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Standard Package: Includes access to two conferences

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REQUIRED – Please select the two conferences you will be attending? (Please choose one option)

- Systems Integration in Biodefense (August 18-19) and Point-of-Care Diagnostics (August 19-20)
 Point-of-Care Diagnostics (August 19-20) and Cancer Diagnostics (August 21-22)

Basic Package: Includes access to one conference

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Poster Discount \$50 off \$50 off

- I cannot attend but would like to purchase the Systems Integration in Biodefense conference CD for \$500 (plus shipping). Massachusetts delivery will include 5% sales tax.
 Please send information on exhibiting and opportunities to present workshops.

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 Invoice me, but reserve my space with credit card information listed below.
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- Systems Integration in Biodefense and will submit a completed one-page abstract by **July 28, 2008**. (Please Note: Registration must be paid in full to present a poster.)

Title _____

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A series of reports that evaluate the salient trends in pharmaceutical technology, business, and therapy markets. Keep abreast of the latest advances in pharmaceutical R&D, their potential applications and business impacts, and their current and future position in the marketplace. For a list of reports, visit InsightPharmaReports.com, or contact Rose LaRaia, rlaraia@healthtech.com, 781-972-5444

Additional Registration Details

Each registration includes all conference sessions, posters and exhibits, food functions, and a copy of the conference CD.

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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 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.

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