Final Agenda

Register by August 18th and Save up to $200!

Cambridge Healthtech Institute's 2nd Annual

Optimizing Cell Culture Development

September 26-27, 2006 • Hilton Boston Back Bay Hotel • Boston, Massachusetts

Hear Focused Presentations from:

Antisoma plc
AstraZeneca
Cell Genesys
Chromos Molecular Systems Inc.
Fluor Corporation
Genentech
Invitrogen Corporation
Johns Hopkins University School of Medicine
Phyton Biotech, Inc.
SAFC Biosciences
Serono Pharmaceutical Research Institute
Wyeth Biopharma
Wyeth Vaccines

Conference Focus:

• How to make your life easier at the bench
• How to help streamline processes and optimize yield
• What's new in resins and automation
• How to reduce the bottom-line costs

Sessions Include:

Optimizing Processes
Optimizing Cell Lines
Optimizing Yield
Optimizing Medium
Automating Cell Culture
Roundtable Discussions

Join in the information exchange and network with colleagues

Corporate Sponsors:

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Due to the need for parallel development of multiple projects, the production of a new biopharmaceutical candidate requires efficient use of resources and extensive process optimization and characterization in order to ensure a robust manufacturing process. The numerous complex variables to be studied, along with their interaction in the process development stage, can be especially tedious and time consuming to pursue. As a result, it becomes an important issue for Process Development Groups to develop efficient ways to generate high quality data in shortened time frame. This presentation will focus on a strategy that Process Development Groups can utilize to overcome process development, scale-up, technology transfer, validation, and manufacturing process improvement challenges.

Optimizing Processes

1:45 - 2:00 Chairperson’s Remarks
Professor Dr. Ralf Wagner, Chief Executive Officer and CSO, GENEART AG

2:00 - 2:30 Systematic and Logical Strategies to Support Process and Product Development Optimization
Tsu-shun Lee, Ph.D., Deputy Director Principal Scientist US, Manufacturing Technology, sanofi pasteur

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Optimizing Cell lines

8:30 - 8:35 Chairperson’s Remarks

8:35 - 9:05 Screening with Cryopreserved Cells
Louise Stjernborg, Ph.D., Team Leader, Central Cell Facility, Lead Generation Department, AstraZeneca R&D Mölndal

9:05 - 9:35 An Approach to Post-Phase 1 Cell Line Development
Linda Francullo, Senior Research Scientist 1, Drug Substance Development, Wyeth BioPharma

The biopharma industry has experienced a trend towards a more rapid and constrained, “Platform” approach to Phase I manufacturing process development in order to enable faster clinical development of new product candidates and minimize the investment at risk prior to clinical proof of concept. As a result, it is expected that there will typically be significant need/opportunity for post-Phase I process improvements prior to commercialization, including cell line optimization to achieve increased productivity and/or enhanced product quality. This presentation will describe the current Wyeth BioPharma approach to post-Phase I cell line development, including case studies demonstrating the impact of increased selective pressure, cell adaptation and additional subcloning on cell line stability, productivity and product quality endpoints.

9:35 - 10:05 Generation of Stable, High MAb Expressing CHO Cell Lines Using the ACE System
Malcolm Kennard, Ph.D., Director of Cell Line Engineering, Chromos Molecular Systems Inc.

This talk will include a description of the ACE (Artificial Chromosome Expression) system and its application to the generation of recombinant protein expressing mammalian cells. Dr. Kennard will discuss the unique features, timing and advantages of the system and contrast ACE with other expression systems. Case studies will be presented in which CHO cell lines express industry relevant levels (0.5-1.2 g/L) of monoclonal antibodies under non-optimized/non-fed batch shake flask conditions without selection. He will also present data on cell lines that are stable for over 20 generations. Dr. Kennard will also discuss data on fed batch bioreactor studies that show increased expression by 2-3 fold.

4:35 - 5:30 Moderated Roundtable Discussions
To suggest a topic or nominate a moderator, contact Mary Ruberry at mruberry@healthtech.com

5:30 - 5:45 Roundtable Report Out

5:45 - 6:45 Reception in the Exhibit Hall

6:45 End of Day One

7:45 - 8:30 Morning Coffee

8:30 - 8:35 Chairperson’s Remarks

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10:05 - 10:40 Refreshment Break, Exhibit & Poster Viewing

www.healthtech.com
2:00 - 2:05 Chairperson’s Remarks

2:05 - 2:35 Reducing Lot-to-Lot Variations in an Insect Medium by Decreasing Yeastolate Content Through Basal Medium Optimization
Steven C. Peppers, Ph.D., Principal Scientist, Invitrogen Corporation

Lot-to-lot variations in cell growth within serum-free insect media have been a problem generally attributed to differences in yeastolate (YE) lots. To address this, we systematically enhanced our base medium, decreased the amount of YE and introduced synthetic lipids. The optimization resulted in lower coefficients of variation with Sf9 and Sf21 cells among different YE lots and higher overall growth and production capacities.

2:35 - 3:05 Growth Medium Optimization for PER.C6 Cells
Sandy McNorton, Research Scientist, R&D, SAFC Biosciences

The PER.C6™ cell line is derived from human embryonic retinoblastoma cells. This cell line is currently licensed by and available through Crucell in the Netherlands. It is used as an expression platform for the development and manufacture of monoclonal antibodies. SAFC Biosciences™ has developed a robust growth medium to support the Crucell platform. This presentation will detail the optimization of this medium which is designed to quickly adapt from serum-free or serum containing media in the PER.C6™ parental cells as well as a large variety of clones developed from the parental cells.

3:05 - 3:40 Refreshment Break, Exhibit & Poster Viewing

3:40 - 3:45 Chairperson’s Remarks

3:45 - 4:15 The Why, When, and How of an Automated Cell Culture System Implementation
Jean Philippe Stephan, Ph.D., Scientist, Assay and Automation Technology Department, Genentech, Inc.

Although cell-based assays have moved into a modern era, cells are still grown and maintained like decades ago: MANUALLY. This step is now a significant bottleneck for many organizations where cell-based assays are a critical path. This presentation will review the different steps involved with the implementation of an automated cell culture system.

4:15 - 4:45 Controlling Properties of Cells in Culture Using Microfluidically Patterned Substrates
Jan H. Hoh, Ph.D., Department of Physiology, Johns Hopkins University School of Medicine

Eukaryotic cells in culture respond to the composition and spatial organization of proteins on the substrate, and both the structure and the function of cells can be modulated by controlling the local distribution of extracellular matrix proteins. A number of different approaches to patterning proteins have been developed, with different strengths and weaknesses. We will discuss a new microfluidic approach that allows for highly flexible direct “writing” for compositionally and spatially complex patterns with applications in cell culture.

4:45 5:15 Automated Perfusion System for Homeostatic Cell Culture
Dr. H Joon Paek, Senior Scientist, Regenerative Cell Based Therapies, Tissue Genesis Inc.

We developed an automated cell culture system that allows perfusion, closed-circuit feeding, and temperature and pH monitoring. Compared to the traditional static culture method, perfusion and continuous replenishment of the medium facilitate homeostatic culture and approximates physiological conditions.

5:15 - 5:45 Cell Culture Scale Up and Design
Wei Huang, Director of Process Engineering, Fluor Corporation

As the biotech industry matures, companies are evolving from research and development focused business into more clinical and commercial manufacturing driven business models. The challenge of scale-up cell culture processes from bench/pilot scale to production scale requires good understanding of the cell culture process itself as well as knowledge of equipment design and operation logistics. Latest technology breakthroughs in cell culture development have put more pressure on consistency and robustness of large-scale cell culture to meet the high cell density and high titer requirements. The speaker will talk about the critical process parameters unique to cell culture during scale up. Some of the equipment and facility design challenges will be also be discussed in detail.

5:45 End of Conference
Join us as we look at the successes and promise of Baculovirus Technology!

**Baculovirus Technology**
September 25-26, 2006 • Hilton Boston Back Bay Hotel • Boston, MA

*(Held immediately before Optimizing Cell Culture Development)*

Discount Pricing Available for BOTH Events*

**Event Highlights:**

- Histories & Overviews from Seminal Authorities
- Challenges Addressed - Breakthroughs in the Lab
- Case Studies Presented - Current Successes
- Techniques & Technologies - Information Shared

*For more information and to view the event program, visit: www.healthtech.com/2006/bcv

*see registration page for more details

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**Gain Further Exposure - Present a Poster!**

- 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
- Receive $50 off your registration fee

*See registration page for more details

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**PharmaWeek**

Keep up with key industry developments and gain valuable insights through Cambridge Healthtech Institute (CHI)'s new e-newsletter PharmaWeek. Our new e-newsletter provides a top-line look at the week's events in the pharmaceutical world and surrounding arenas. PharmaWeek also delivers weekly exclusive analysis on major trends, key strategies, leading executives, and general business as well as career advice. For more information, visit www.pharmaweek.com

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TRAVEL INFORMATION

Flight Discounts: Discounted 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. Reference the Meeting ID Number 579YS.

HOTEL INFORMATION

Hilton Boston Back Bay Hotel
40 Dalton Street, Boston, MA 02115
Phone: 617-236-1100
Fax: 617-867-6104
Room Rate: $219 s/d
Reservation Cutoff: September 4, 2006

To reserve your sleeping room online, please go to our website and click on the link to the Hilton hotel to ensure the group discount.

Or if you prefer, you may call the hotel directly to reserve your room. Please be sure to request the Cambridge Healthtech Institute group room rate.

For reservations via phone, please call the hotel directly to make your arrangements. 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.

CAR RENTAL INFORMATION

Special discount rentals have been established with AVIS 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 www.avis.com

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Sponsorship packages are designed to achieve your business development and networking goals and objectives. Sponsorship benefits include pre-conference, at-conference and post-conference marketing efforts.

Sponsored Speaking opportunities include:

- Technology Showcase, embedded within the conference program
- Breakfast or Luncheon Workshops, allow for podium time
- Promotional items such as tote bags, lanyards, padfolios, etc.

CHI managers will work closely with you to shape a package that suits your company's objectives and budget. Numerous promotional and sponsorship packages exist.

Please contact Suzanne Carroll to discuss how to participate at 781-972-5452, or email her at scarroll@healthtech.com
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- 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:  
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  - ☐ Visa (13-16 digits)
  - ☐ MasterCard (16 digits)
  - ☐ Diners Club (14 digits)

**PRICING INFORMATION**

- **Commercial**
  - Advance Registration Discount until August 18, 2006: ☐ $1195
  - Registrations after August 18, 2006 and On-site: ☐ $1395
  - Poster Discount: ☐ $50 off

- **Academic, Government, Hospital-Affiliated**
  - Advance Registration Discount until August 18, 2006: ☐ $620
  - Registrations after August 18, 2006 and On-site: ☐ $695
  - Poster Discount: ☐ $50 off

**Advance Registration Discount until August 18, 2006**

- Single Event: Optimizing Cell Culture Development (Sept. 25-26) ☐ $50 off
- Both Events: Baculovirus Technology (Sept. 25-26) and Optimizing Cell Culture Development (Sept. 26-27) ☐ $850

**Poster Discount**

- Single Event: Optimizing Cell Culture Development (Sept. 26-27) ☐ $50 off
- Both Events: Baculovirus Technology (Sept. 25-26) and Optimizing Cell Culture Development (Sept. 26-27) ☐ $925

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**Please refer to the Keycode below:**

- Program and speakers are subject to change.
- Video and audio recording of any kind is prohibited onsite at all CHI events.