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Philadelphia, Pennsylvania, USA



Cell Banking

December 3-5, 2007

Ensuring Suitability, Consistency and Safety

Please join us for this state-of-the-art meeting on the critical issues associated with developing cell banks for the production of biopharmaceuticals.

Using case studies and experimental data, this meeting will contrast traditional methods and the latest approaches to cell bank development, storage, and testing. In addition, there will be in-depth coverage of the current regulatory guidelines, as well as trends that will affect the production and use of banks in the future.

Conference Chair
Jim Moldenhauer, M.S.
Eli Lilly & Company



Topics:

- Characterization
- Traceability
- Cross Contamination
- Cryopreservation
- Testing
- Validation
- Storage
- Data Management
- Reference Materials



Cell Banking

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SUNDAY, DECEMBER 2, 2007

4:00-6:00 pm **Registration and Welcome Reception**

MONDAY, DECEMBER 3, 2007

7:00-8:00 am **Registration, Continental Breakfast - Meeting Room Foyer**

8:00-8:30 am **Introduction**

Keith Carson - Conference Chairman

8:30-9:15 am **Cryopreservation Protocols: Their Genesis and Recent Developments to Improve Them**

Allison Hubel, Ph.D. - University of Minnesota

9:15-10:00 am **Understanding Intracellular Ice Formation and Its Impact on Cell Bank Quality and Stability**

Jens O.M. Karlsson, Ph.D. - Drexel University

10:00-10:30 am **Break - Exhibit Area**

10:30-11:15 am **Facility Design and Equipment Selection for the Modern Bio Repository**

Ian Pope, Ph.D. - Core Cryolab Inc.

11:15-Noon **Testing Strategies for Mammalian Cell Culture Banks**

Michelle Quertinmont - Eli Lilly & Company

Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**

1:30-2:15 pm **Rationales of Gene Design and De Novo Gene Construction: The Better Way to Get Your DNA**

Hans Buegl, Ph.D. - GENEART Inc.

2:15-3:00 pm **Characterization of Cell Lines: What are the Risks of Contamination?**

Martin Wisher, Ph.D. - BioReliance Ltd.

3:00-3:30 pm **Break - Exhibit Area**

3:30-4:15 pm **Characterization of a Madin Darby Canine Kidney (MDCK) Cell Bank Used in the Production of a Live Attenuated Influenza Vaccine (LAIV)**

Sachin Mani, Ph.D. - MedImmune Vaccines Inc.

4:15-5:00 pm **A Genetic Characterization Paradigm for Recombinant Chinese Hamster Ovary Cell Lines Used for Clinical API Production**

Luhong He, Ph.D. - Eli Lilly & Company

5:30-7:00 pm **Reception - Exhibit Area**

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TUESDAY, DECEMBER 4, 2007

- 7:30-8:30 am **Breakfast - Exhibit Area**
- 8:30-9:15 am **Authentication and Characterization of Animal Cell Lines: Impact on Research**
Yvonne Reid, Ph.D. - ATCC
- 9:15-10:00 am **Product Testing and Banking for Cellular Therapies**
Brenton McCright, Ph.D. - FDA/CBER
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:15 am **Development of a Perfusion Process to Generate a PER.C6 Cell Bank**
Alfred Luitjens - Crucell Holland BV
- 11:15-Noon **Characterization of Embryonic Stem Cell Lines by the National Stem Cell Bank**
Derek Hei, Ph.D. - Waisman Clinical Biomanufacturing Facility
- Noon-6:00 pm **Free Afternoon with Recommended Activities**
- 6:00-7:00 pm **Happy Hour**

WEDNESDAY, DECEMBER 5, 2007

- 8:00-9:15 am **Breakfast - Exhibit Area**
- 9:15-10:00 am **Regulatory Guidance on Using New Cell Substrates for Manufacture of Viral Vaccines**
Arifa Khan, Ph.D. - FDA/CBER
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:00 am **Technical Workshop - Cryo Bio System**
- 11:00-Noon **Technical Workshop - BIOLOG**
- Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**
- 1:30-2:15 pm **Characterization of Cord Blood Bank Processing: AXP AutoXpress Platform and BioArchive Technologies**
Philip Coelho, Ph.D. - ThermoGenesis Corporation
- 2:15-3:00 pm **Round Table Discussion: Control Rate Freezing: Fact or Fiction?**
Moderated by: James Moldenhauer, M.S. - Eli Lilly & Company
Held in the Cell Banking Meeting Room
- 3:00-3:30 pm **Break - Exhibit Area**
- 3:30-4:15 pm **Round Table Discussion: Cell Bank Characterization Testing and Stability**
Moderated by: Arifa Khan, Ph.D. and Brenton McCright, Ph.D. - FDA/CBER
Held in the Cell Banking Meeting Room

Due to circumstances beyond the control of the conference organizers, the program is subject to change.