



Cell Banking

Ensuring Suitability Consistency and Safety

MONDAY, DECEMBER 1, 2008

4:00-6:00 pm **Registration**

TUESDAY, DECEMBER 2, 2008

7:00-8:00 am **Registration, Breakfast**

8:00-8:30 am **Introduction by Conference Chairs**

James Moldenhauer - *Eli Lilly & Company*

Jeri Ann Boose, PhD - *BioReliance Corporation*

8:30-9:15 am **Advances in Screening Mammalian Cell Culture for Adventitious Microbial Contaminants**

Houman Dehghani - *Amgen Inc.*

9:15-10:00 am **Optimization of Cryopreservation Process Parameters**

Jens O.M. Karlsson, PhD - *Villanova University*

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

10:30-11:15 am **The Effects of Cell Line Development on Clinical Trial Manufacturing: A Case Study from the Contract Manufacturer's Perspective**

Terry Cochrane - *QSV Biologics*

11:15 am-Noon **Cell Bank Characterization: Integrated and Non-Integrated Cell Banks**

Elena Jouravleva, PhD - *Cogenics*

Noon-1:30 pm **Lunch**

1:00-1:30 pm **Poster Session**

1:30-2:15 pm **Receipt, Testing, and Disposition of Raw Materials**

Mervin Browning - *Amgen, Inc.*

2:15-3:00 pm **Genetic Stability Testing: Future Technologies**

Alison Armstrong, PhD - *BioReliance Corporation*

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

3:30-5:00 pm **Panel Discussion**



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WEDNESDAY, DECEMBER 3, 2008

- 7:30-8:30 am **Breakfast**
- 8:30-9:15 am **Case Study: Development and Troubleshooting for an ADC-Free HEK 293 GMP Banking Process**
Claudia Buser, PhD - *Genzyme Corporation*
- 9:15-10:00 am **Cryopreservation of Biological Materials - The Viability Imperative**
Ian Pope, PhD - *Core Cryolab, Inc.*
- 10:00-10:30 am **Break**
- 10:30-11:15 am **US Regulatory Perspective on Cell Bank Testing**
Arifa S. Khan, PhD - *US Food and Drug Administration*
- 11:15 am-Noon **A Novel Tool to Speed Up Screw-Top Cryovial Filling for Cell Banks**
Susan Baird - *The Automation Partnership*
- Noon-6:00 pm **Free Afternoon with Recommended Group Activities**

THURSDAY, DECEMBER 4, 2008

- 7:30-8:30 am **Breakfast**
- 8:30-9:15 am **The Potential Risk Associated with Residual Cellular DNA Present in Vaccines Produced from Continuous MDCK Cell Lines**
Sachin Mani, PhD - *MedImmune Vaccines Inc.*
- 9:15-10:00 am **Cryopreservation of Mammalian Cells and Tissues**
Lloyd Wolfenbarger, Jr., PhD - *BioScience Consultants LLC*
- 10:00-10:30 am **Break**
- 10:30-11:15 am **Insect Cell Banking: Development of Subunit Vaccines Using Stably-Transformed Drosophila S2 Cells**
David Clements, PhD - *Hawaii Biotech*
- 11:15 am-Noon **Technical Workshop**
- Noon-1:30 pm **Lunch**
- 1:00-1:30 pm **Poster Session**
- 1:30-2:15 pm **Root Cause Investigation of a Viral Contamination Incident During Master Cell Bank Testing - A Case Study**
James Moldenhauer - *Eli Lilly & Company*
- 2:15-3:00 pm **Taking a 1980's Hybridoma Cell Bank into the 21st Century - A Case Study**
Blair McNeil, PhD - *Cook Pharmica*
- 3:00-3:30 pm **Break**
- 3:30-5:00 pm **Cell Banking/Cell Engineering - Combined Panel Discussion**