



**The Mandarin Oriental Hotel, Washington D.C.
(Oriental Ballroom B)**

Conference Day One: Monday, November 12th, 2012

8:00 Registration and coffee

9:00 Chairperson's opening remarks

Justin Hutchinson, Associate Director, Product Management, Thermo Scientific Cell Culture & BioProcessing

CELL LINE DEVELOPMENT

9:10 Evaluation of High-Throughput Technologies in Designing a Cell Line Development Platform

Sanjay Patel, Director of Cell Engineering and Purification, Takeda Pharmaceutical

9:40 New Technologies for CHO Cell Line Development

Sheri Nidositko, Lab Head - Cell Line Development and Protein Production, Novartis

10:10 Speed networking

10:40 Morning networking break

11:10 Tools for Improving Cell-Line Development, Scale-Down, and Process Optimization

Wes Conrad, Manager, Small-Scale Technologies, Applikon Biotechnologies

LEVERAGING FROM HIGH VOLUME YIELDS

11:40 Improving shared technical change agendas across all stakeholders when outsourcing

Rajesh Krishnan, Associate director, Upstream Process Development, Gilead Sciences

12:10 Looking from West to East: Cell-culture and biologic development from a Chinese market perspective

Changlin Dou, Chief Technology Officer, Luye Pharma Group

12:40 Panel session: How can upstream and downstream work together to improve processes into manufacturing

Changlin Dou, Chief Technology Officer, **Luye Pharma Group**

Sheri Nidositko, Lab Head - Cell Line Development and Protein Production, **Novartis**

Sanjay Patel, Director of Cell Engineering and Purification, **Takeda Pharmaceutical**

1:20 Networking Lunch

CELL-BASED BIOLOGIC SAFETY

2:20 Quantitative aspects of viral safety assurance and emerging analytics for virus detection

Paul Duncan, Senior Investigator, Vaccine Bioprocess Research and Development, **Merck**

2:50 Moving forward in an era of emerging technologies for Adventitious Agent Testing and Cell Substrate Characterization - A 21st Century Paradigm Shift

James Richardson, Director of Quality Assurance, **ABL Inc.**

3:20 Afternoon Networking Break

3:50 The safe use of animal derived materials: Yesterday, Today and Tomorrow

Rosemary Verstegeen, Chief Executive Officer, **International Serum Industry Association**

4:20 Panel Discussion: Envisioning a future state in assuring the biological safety of biologics and vaccines made in animal cell cultures

Paul Duncan, Senior Investigator, Vaccine Bioprocess Research and Development, **Merck**

James Richardson, Director of Quality Assurance, **ABL Inc.**

Rosemary Verstegeen, Chief Executive Officer, **International Serum Industry Association**

5:00 Chairperson's closing remarks

5:05 Around the World cocktail reception followed by sit-down networking dinner

7:00 End of conference day one

Conference day two: Tuesday, November 13th, 2012

8:00 Registration and coffee

9:00 Chairperson's opening remarks

Justin Hutchinson, Associate Director, Product Management, **Thermo Scientific Cell Culture & BioProcessing**

COMPLYING WITH QUALITY BY DESIGN

Session chair: Mindy Goldsborough, VP & GM of ATCC Cell Systems, **ATCC**

9:10 Fast to market by lean development approaches in the era of quality-by-design: a mission impossible?

Stefanos Grammatikos, Head of Biological Process Development, **UCB Pharma S.A.**

9:40 QbD Flow for a mAb development project

Balrina Malik Gupta, Associate Principal Scientist, **Merck and Co.**

10:10 Panel Discussion: Quality by design: When, why and how?

Stefanos Grammatikos, Head of Biological Process Development, **UCB Pharma S.A.**

Balrina Malik Gupta, Associate Principal Scientist, **Merck and Co.**

Rajesh Krishnan, Associate director, Upstream Process Development, **Gilead Sciences**

11:10 Networking coffee break

ADVANCING DEVELOPMENT WITH NEW CAPABILITIES

11:40 A New Milestone: Increasing efficiency into Phase II by reducing material and increasing titer

Jon Coffman, Associate Research Fellow, **Pfizer**

12:10 Stainless vs. Single-Use-- A Case Study of Production of a Non-Antibody Glycoprotein Therapeutic

Michiel Ultee, Chief Scientific Officer, **Laureate Biopharmaceutical Services**

12:40 Networking lunch

1:40 Enhanced productivity of recombinant mammalian cells by culture medium additives

Amar Tung, Associate Professor, Department of Chemistry, **Lincoln University**

2:10 Micropatterns for Structural Guidance of Cells

Lisa Minor, Principal Scientist, **Cytoo**

2:40 Single-Use versus Stainless Steel Bioprocess Components: "or" / "and"?

Peter Kraemer, IA C&B-Engineering Development, Sanofi Aventis

3:10 Chairperson's closing remarks

3:30 End of conference
