

Biomanufacturing Futures Summit

November 5, 2009, MIT Faculty Club

8:30 am - 5:30 pm

Lunchtime Presentation by Professor Phil Sharp

Reception immediately following

Customized Therapies and Biomanufacturing: The Economic, Regulatory and Technological Implications

Personalized healthcare strategies and cell based therapies hold great promise for the effective treatment of disease. However, manufacturing technologies that support the regulatory and economic requirements for successful commercialization are still nascent. Tailored therapeutics may demand batch sizes scaled for use by a single individual, system integration for delivery of medicines to patients (e.g. coupling diagnostics with manufacturing and therapeutic delivery), and innovation associated with making these economies of scale feasible. During this panel discussion, we will consider the manufacturing platforms and operations that will be required, the analytical and monitoring tools that could streamline regulatory requirements, and strategies toward making these economies of scale feasible.

Participants include:

Charis Eng, Sondra J. & Stephen R. Hardis Chair in Cancer Genomic Medicine, Chair and Director, Genomic Medicine Institute, Director, Center for Personalized Genetic Healthcare, American Cancer Society Clinical Research Professor, Cleveland Clinic Lerner Research Institute; **Ian Fitzpatrick**, Manager, Manufacturing Innovation Group, Invetech; **Jerome Kinzel**, Vice President, Bioproduct Research/Development, Eli Lilly; **Raju Kucherlapati**, Paul C. Cabot Professor of Genetics, Professor of Medicine, Harvard Medical School; **Leslie Wolfe**, VP Technology Development, Cell Therapies, Genzyme Corporation; **Mark Trusheim**, Visiting Scientist and Executive-in-Residence, MIT Sloan School of Management; **Heidi Hagen**, SVP Operations, Dendreon Corporation, Moderated by **Wayne Rosenkrans** and **G.K. Raju**

Biomanufacturing and Immunogenicity

With significant growth in the biopharmaceuticals and biosimilars markets expected, early assessment of immunogenicity for protein therapeutics is becoming increasingly important. During biomanufacturing, choice of production strain, growth conditions, purification, and formulation can impact the structural heterogeneity (e.g. glycosylation patterns, aggregation states) and immunogenicity of a protein therapeutic. Effective immunogenicity models could provide a useful tool for the process development environment, for demonstrating comparability after process change during production, and in establishing similarity of follow-on biologics. The presentations in this session will explore the potential for innovative pre-clinical immunogenicity models.

Presenters include:

James Leung, MIT Center for Biomedical Innovation; **Jianzhu Chen**, Cottrell Professor of Immunology, Professor of Biology, MIT; **Mike Rivard**, VP, Corporate Development, VaxDesign

Globalization of Biomanufacturing: Safety and Economic Ramifications

Biopharmaceutical firms are increasingly moving commercial manufacturing offshore. As the center of gravity for offshoring moves toward Asia, opportunities and risks are emerging. This panel discussion will explore projected movement toward Asia for biomanufacturing and the implications for regulatory compliance and safety, supply chain integrity, low-cost global delivery, innovation and firm competitiveness.

Participants include:

Rajesh Beri, Director of Manufacturing and Science Technologies, Lonza Biologics, **Charles Fine**, Chrysler LFM Professor of Management and Engineering Systems, MIT; **Jeff Macher**, Assoc. Professor of Strategy and Economics, McDonough School of Business, Georgetown University, **Elisabeth Beck Reynolds**, Department of Urban Planning and Studies, MIT, Industrial Performance Center, MIT; **Mahender Singh**, Research Director, MIT Supply Chain 2020 Project, MIT Center for Transportation and Logistics, Moderated by **Professor Charles Cooney**

