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Austin, Texas, USA



Conference Chairman
John Hennessey, Ph.D.
Merck & Company, Inc.

Sponsored By:



Topics:

- Analytical Bridging Between Phases
- Functional Assays to Determine Effect of Biochemical / Biophysical Changes
- Product Comparability Assessments
- In-Process Monitoring
- Product Characterization Precedence
- Process Change Implementation
- Clinical Validation
- Rapid Analysis and Screening
- Documentation and Regulatory Submissions
- Trends in Biological Comparability
- Unique Challenges with Cellular and Viral Products
- Risk Assessment and Management

Characterization and Comparability for Complex Biological Products

November 1-2, 2007

Establishing Methods to Better Define Products and Demonstrate Comparability

Of particular interest will be the developments in rapid analytical methods and in-process monitoring. We'll also evaluate the progress that is being made in validating product comparability for a number of product types, including the clinical methodologies that are providing the most meaningful results. To support the actual data, we will cover the more effective documentation and regulatory submission approaches that have been used to show comparability for established products. Finally, we will have exhibits and workshops from the industry's leading technology suppliers so that the latest analytical tools and capabilities can be evaluated.

Please join us as we analyze the issues relating to the characterization of complex biologicals and explore the problems associated with establishing biological product comparability. Our primary focus will be on the more complex products such as cellular and viral therapeutics, where the more difficult challenges lie and the most comprehensive understanding of the concepts can be developed. To explore the realm of analytical capabilities that will be needed, we will build on the data and techniques that have been established for recombinant proteins and antibodies, but then extrapolate these means as we attempt to define what can work in the most difficult applications.





Characterization and Comparability for Complex Biological Products

Establishing Methods to Better Define Products and Demonstrate Comparability

THURSDAY, NOVEMBER 1, 2007

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

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

Keith L. Carson - WilBio and
John Hennessey, Jr. - Merck & Company, Inc. - Conference Chairmen

8:30-9:15 am **Monitoring Varicella Manufacturing Process Using a Flow Symmetry Assay**

Jorge Vázquez - Merck & Co. Inc.

9:15-10:00 am **Characterization of Autologous Cell Therapy Products for Cartilage Repair**

Stephen Duguay, Ph.D. - Genzyme Corporation

10:00-10:30 am **Break - Meeting Room Foyer**

10:30-11:15 am **Product Comparability Testing: Current Methods and Future Concerns**

Jeanne Novak, Ph.D. - CBR International Corp.

11:15-Noon **Characterizations of Whole Cell Cancer Immunotherapy in Late Stage Development**

Guatam Banik, Ph.D. - Cell Genesys, Inc.

Noon-1:30 pm **Lunch and Poster Session - Meeting Room Foyer**

1:30-2:15 pm **Designer Displacers for the Purification and Trace Substance Enrichment by RP Displacement Chromatography: A Case Study of Early, Late, and Co-displacing Peptide Impurities**

Barry Haymore - Sachem, Inc.

2:15-3:00 pm **Using SPR Sensor Technology to Improve Bio-Therapeutic Development and Quality Control**

Fredrik Sundberg - GE Healthcare BioSciences AB

3:00-3:30 pm **Break - Meeting Room Foyer**

3:30-4:15 pm **Engineered Drug Therapies Using Fabrication Technologies From the Electronics Industry: Targeted, Multi-plexed Delivery Agents**

Joseph DeSimone - Liquidia Technologies, Inc.

4:15-5:00 pm **Characterization & Comparability of a Recombinant HPV Vaccine**

Michael Washabaugh, Ph.D. - Merck & Company, Inc.

FRIDAY, NOVEMBER 2, 2007

7:30-8:30 am **Breakfast - Meeting Room Foyer**

8:30-9:15 am **Presentation Title Pending**

Dale Hunt, Ph.D. - Sonnenschein Nath & Rosenthal LLP

9:15-10:00 am **Development of a Surrogate Assay System for Bispecific Therapeutic Antibodies**

Irena Kirman, Ph.D. - Elusys Therapeutics, Inc.

10:00-10:30 am **Break - Meeting Room Foyer**

10:30-11:15 am **Advanced Analytical Tools for Characterizing and Comparing Biopharmaceutical Proteins**

Steven Cohen, Ph.D. - Waters Corporation

11:15-Noon **Panel Discussion**

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

