

Cell Therapies Liaison Meeting

Welcome & Introductions

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FOUNDATION FOR THE
ACCREDITATION OF
CELLULAR THERAPY

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*THANK YOU
EVERYONE
FOR BEING HERE!*



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Ambitious Goals for Meeting

- **Cell Therapies Stakeholder Community**
 - Focus on autologous products
 - Questions:
 - Therapeutic product versus practice of medicine
 - Production environments and other CMC considerations
 - Concerns over Globalization
- **FDA**
 - ISBT128
 - Mesenchymal Stem Cells

Agenda

- **Section 1 – Cellular Therapies Current Topics**
 - ISBT128 labeling and product naming
 - The expanding range of cellular therapeutics
- **Section 2 – Mesenchymal Stem Cells**
 - The ISCT Survey on MSC Production Methods
 - MSC Chemistry, Manufacturing and Controls
- **Section 3 – Globalization of Cellular Therapies Science and Practice**
 - Regulatory guidances and trends, globalization
 - Patient care, advocacy and protection

To maximize time for discussion

- Speakers have been asked to aim for a 20 minute talk -10 minutes questions organization
- Between the three major sections 10 minute breaks have been scheduled – please continue discussion even as we move around for coffee, etc.
- There is a final 25 minute discussion period which may be used to absorb overtime issues from earlier in the afternoon
- PLEASE, DURING DISCUSSION, SPEAK CLEARLY SO THAT THOSE ON SPEAKERPHONE CAN HEAR

Hybridization of Themes

- **Globalization**
 - ISBT128
 - Autologous product translational studies
- **Chemistry, Manufacturing and Control**
 - Mesenchymal stem cell production
 - Manufacturing environments for any cell therapies product

The Biggest Cellular Therapies Story of the Year...

**Meningitis Outbreak 2012: Steroid-
Related Fungal Meningitis Cases
Rise To 47**

PATIENT SAFETY , PUBLIC HEALTH

Contamination found in 2 more New
England Compounding Center products

**Meningitis Outbreak: 338 Cases, 25
Deaths**

INTRODUCTIONS

- **PLEASE IDENTIFY YOURSELF**
 - NAME
 - ORGANIZATION YOU REPRESENT HERE TODAY