

Cell Therapies Liaison Meeting – 29 November 2011

Chairs:

William Janssen, Ph.D. – ISCT

Anita Szajek, Ph.D. - USP

This Years Topics

❖ Challenges to Development of Cellular Therapeutics

- » Ancillary Materials (e.g. collagenase source)
 - Selection
 - Qualification
 - Application / Testing
- » Pharmacovigilance
 - Paradigm for Therapeutic Related Adverse Events
 - Identification
 - Categorization
 - Reporting
 - Interpretation of AE data

Theme / Goal for This Meeting

Partnership

- » Seeking avenues for Cell Therapies Stakeholder Community to help FDA to help us
- » Identify challenges that stand between BOTH Stakeholder Community AND FDA in the development of cellular (and gene) therapeutics
 - Early phase development
 - Advanced phase development and commercialization
- » Recognition of unique and important role that FDA must maintain

Thank-you



- » To all attendees, stakeholder organizations
- » To all presenters
- » To Audrey Le (ISCT head office) and Kathy Loper (AABB)
 - » For extraordinary effort in organizing this meeting
- » Especially to our colleagues at FDA
 - » For continued participation in this series of Liaison Meetings
 - » For generous investment of time and treasure to be present at Cellular Therapies related conferences (ISCT, AABB, ASBMT, etc.)