

# AHCTA

31 March 2009

EBMT 2009, Göteborg

# Agenda

- Welcome
- Apologies
- Review of activities to date
  - Import//export
  - Standards comparison & harmonisation
- Where next?
  - WBMT and global standards/accreditation?

# Mission Statement

The Alliance for Harmonisation of Cellular Therapy Accreditation (AHCTA) is formed by representatives of the following organisations:

- American Association of Blood Banks (AABB)
- American Society for Blood & Marrow Transplantation (ASBMT)
- European Group for Blood & Marrow Transplantation (EBMT)
- Foundation for the Accreditation of Cellular Therapy (FACT)
- International NETCORD Foundation
- International Society for Cellular Therapy (Europe) (ISCT)
- Joint Accreditation Committee ISCT-EBMT (JACIE)
- World Marrow Donor Association (WMDA)

# Mission Statement contd.

- The ... organisations commit themselves to the harmonisation of their respective standards with the objective of creating a single set of quality, safety and professional requirements for cellular therapy including haematopoietic stem cell (HSC) transplantation. These standards will comprehensively cover all aspects of the process from assessment of donor eligibility to transplantation and clinical outcome. This commitment will be supported by collaboration on the drafting of complementary standards and guidelines, promotion of the concept of a global set of standards among the cellular therapy professional community and regulatory authorities and regular communication on all relevant issues affecting cellular therapy guidelines.
- AHCTA regards regulatory authorities as partners in the application of these global standards, essential to their successful adoption and will endeavour to inform and support these authorities in the area of cellular therapy regulation.

# AHCTA

## Comparison of Standards

# Background & Definitions

- Equivalent scope and objectives
- Definitions:
  - SAE not defined in AABB
  - Allogeneic, procurement, quarantine not specifically defined in WMDA
  - Cell, donation, human application, preservation only defined in EU TCD
- Organisations responsible for activities vary – e.g. Tissue establishment, Transplant centre/programme, Facility
- ALL define Quality management, systems, the need for SOPs, traceability and validation

# Inspection and Regulation

- Inspection – arrangements for this described by all
- Intervals vary from 2 – 4 years
- Re-inspection in response to severe AE/AR report in EUTCD
- May be needed after complaints, AE or reports of non-compliance (others)

# Donor Standards

- All require voluntary, unpaid donation
- Equivalent requirements for age, anonymity/confidentiality, screening and evaluation, counselling and consent
- GA, central lines and G-CSF not stated in EU and WMDA; N/A in Netcord-FACT
- Medical history includes infectious, malignant and genetic disease
- HTLV testing under discussion by WMDA; other tests =

# Labelling and Coding

- Describe requirements for labels at completion of Collection, processing and at distribution for administration
- All except EU describe requirements for partial labels
- Outer container labelling required by all but inner container not by EUTCD; Netcord-FACT?
- Minor differences in e.g. -recommended storage time stated  
by FJ, FN and AABB
  - volume required by FJ and AABB
  - BHL differ