Cell therapy labelling

Workshop 12: May 7, 2006
EU Directive 2004/23/EC: Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

- Establishment of a register of entities operating in the field
- Designation of the competent authority (ies) in Member States
- Implementation of a quality system for tissue establishments (SOPs, guidelines, training & reference manuals, reporting forms, donor records etc.)
- Introduction of a system of accreditation of tissue establishments by Member States and a system for notification of adverse events and reactions
- Organisation of inspections and control measures within Member States
- Ensurance of data protection and confidentiality.
- Assurance of traceability of tissues and cells through laboratory identification procedures, record maintenance and an appropriate labelling system

- Design of a single European coding system
First meeting: Prague March 2005 at the EBMT annual meeting

**Present:**
- ICCBBA Inc.: Paul Ashford
- JACIE: Eoin McGrath, Diana Samson, Derwood Pamphilon and Ineke Slaper-Cortenbach (ISCT Europe);
- FACT/ISCT: Adrian Gee
- Experts: Alan Lankester and Stella Larson

**Decided to use ISBT 128 for all “cellular therapy” products to provide an uniform coding and labelling system worldwide**
International Cellular Therapy Coding and Labelling Advisory Group

- review existing regulation regarding labeling;
- design product label templates that satisfy regulatory requirements;
- provide a focus for the standardization of terminology and product naming;
- promote the adoption of the ISBT 128 standard in cellular therapy facilities around the world;
- provide advice and support to facilities introducing the standard;
- advise on the ongoing development of the ISBT 128 standard to support new developments in cellular therapy.
Members of the TAG group

Chair: Paul Ashford  ICCBBA representative  
(Pat Distler, ICCBBA office)
Secretary: Adrian Gee, Co-sponsored representative

Terminology:
Phyllis Warkentin, FACT representative
Alan Lankester, Technical expert
Leigh Poston, ISCT representative
Derwood Pamphilon, EBMT representative
Kathy Loper, AABB representative
Ineke Slaper-Cortenbach, JACIE/ISCT Europe representative

Label design:
Adrian Gee
Stella Larson, Technical expert
Evelyne Marry, WMDA representative
Fran Rabe, NMDP representative
Stephanie Lee, ASBMT representative

Ellen Lazarus, FDA representative

Dr. Zbigniew M. Szczepiorkowski: ASFA representative