



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