

Participating
Organizations



Advancing Transfusion and
Cellular Therapies Worldwide



Cellular Therapy Coding and Labeling Advisory Group

The Boards of AABB, ASBMT, EBMT, FACT, ICCBBA Inc, ISBT, ISCT, ISCT Europe, JACIE, and NMDP:

recognising the significant benefits of international standardisation of coding and labelling in clinical practice;

taking into account the requirements of new regulation, in particular the European Tissue and Cells Directive (2004/23/EC) and the FDA interest in bar coding of biological products [Federal Register: February 26, 2004 (Volume 69, Number 38)];

acknowledging the widespread use of the international information standard *ISBT 128* in the fields of blood transfusion and transplantation;

recognising the need for international management and technical co-operation for the successful maintenance and development of such standards,

confirm their support for the international use of *ISBT 128* in the coding of haematopoietic progenitor cell and other therapeutic cell products and announce the establishment of a co-sponsored International Cellular Therapy Coding and Labeling Advisory Group to:

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

For further information on this initiative contact cellulartherapy@isbt128.org