ISBT 128
For Cellular Therapy

More Than Labeling
ISBT 128 for Cellular Therapy

- What do you know about ISBT 128?
- What do you want to know about ISBT 128?

Overview to Address:
- What
- Who
- Why
- When
An Overview of ISBT 128

- What
  - What is ISBT 128?

- Who
  - Who designed ISBT 128?
  - Who manages ISBT 128?
  - Who will use ISBT 128?

- Why
  - Why do I want to use ISBT 128?

- When
  - When do I have to use ISBT 128?
What is ISBT 128?

- An international information standard for blood, cellular therapy and tissue products.

- The standard provides:
  - Globally unique donation (product) identification.
  - Internationally accepted terminology, definitions, product codes, and reference tables.
  - Support for the open movement of products around the world in such a way that critical information is rapidly, accurately, and unambiguously communicated.
Who Designed ISBT 128?

The International Society of Blood Transfusion originally designed the system. The standard was accepted by the ISBT Council in 1994.

- Gained international acceptance for transfusion and is now in widespread use.
- Being extended to cellular therapy and tissues.
Who Manages ISBT 128?

ICCBBA

- Non-profit organization ([www.iccbba.org](http://www.iccbba.org))
- Responsible for the development and maintenance of the ISBT128 standard
- Maintains ISBT128 databases for Facility Identification and Product Coding
  - Assigns new product codes
  - Maintains licensing requirements
- Provides technical support
Who Will Use ISBT 128?

- We “Cellular Therapy Programs” will use ISBT 128.

- Recognizing, the field of CT is very global and the need for accurate transfer of products and related information is critical:
  - FACT, JACIE, ISCT and ICCBBA held meetings in 2005 and agreed to standardize coding and labeling of CT products using ISBT 128.
Cellular Therapy Coding and Labeling Advisory Group
Member Organizations
Cellular Therapy Coding and Labeling Advisory Group

Initial Goals

- In accordance with existing regulations:
  - Standardize CT product terminology
  - Design product label templates
    - Employing Principles of Good Labeling
Cellular Therapy Coding and Labeling Advisory Group

Results

- Terminology and Labeling Standard:

- Implementation Guidance:

Ongoing

- Will continue to advise re: new product codes, definitions
- Educate, promote use of ISBT128 Standard
- Ensure continued consistency with professional standards
Why Do I Want To Use ISBT 128?

- Meets Primary Objective:
  - Improved Quality, Safety and Traceability of Cellular Therapy Products
Key Features of *ISBT 128*

- Provides a standard information environment for global application
  - Unique donation (product) numbering system
  - International product list, definitions and codes
  - Standard structures and formats for additional key information (e.g., ABO, Rh(D), HLA, type of donor, expiration date)
  - Flexible system for describing products, assigning product codes and adding new products
Key Features of ISBT 128

- Provides a standard information environment for global application (Continued)
  
  - Adaptable to various delivery mechanisms (currently, linear or 2-D bar codes common)
  - Mechanism for development and maintenance of the standard; version control
  - Satisfies regulatory requirements for traceability and for retention of information
ISBT 128: Information Elements

In order to understand the system operation, we need to review the specific elements.

- Standard terminology and definitions
- Reference tables
  - Consistent product codes
- Data structures
- Delivery mechanisms
- Labeling
ISBT 128 Information Hierarchy

- Labeling
- Delivery Mechanisms
- Data Structures
- Reference Tables
- Definitions

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Information Elements

- Standard terminology and definitions
  - Ensure understanding throughout CT community
  - Built and managed by international consensus to ensure consistency and level of detail
  - Adaptable to new products

- Reference tables
  - Consistent product codes

- Data structures

- Delivery mechanisms

- Labeling
Information Elements

- Standard terminology and definitions
- Reference tables
  - Provide means of mapping definitions to codes
  - Ensure consistent interpretation
  - Flexible, additions permitted, managed
    - Consistent product codes
- Data structures
- Delivery mechanisms
- Labeling
Information Elements

- Standard terminology and definitions
- Reference tables
  - Consistent product codes
    - Product codes assigned by ICCBBA, Inc.
    - New code built by specifying a combination of defined characteristics that becomes incorporated into the product database table, ensuring that product will be accurately identified worldwide
- Data structures
- Delivery mechanisms
- Labeling
Information Elements

- Standard terminology and definitions
- Reference tables
  - Consistent product codes
- Data structures
  - Technical definitions for data transfer
  - Allow independent systems to communicate
  - Developed and maintained to meet needs
- Delivery mechanisms
- Labeling
Information Elements

- Standard terminology and definitions
- Reference tables
  - Consistent product codes
- Data structures
- Delivery mechanisms
  - Transfer data to label using specific symbology
  - *ISBT128* is independent of delivery system
    - Linear bar code
    - 2D bar code
    - Reduced Space Symbology Codes
    - Radio frequency tags (RFID)
- Labeling
Delivery Mechanism

Linear Barcode – Code 128

- Industry Standard Symbology
  Code 128
- Ubiquitous
- Read by all bar code scanners
- ‘Space hungry’
- Not suitable for very small labels
Delivery Mechanisms

2-Dimensional Codes

- Newer technology
- Requires imaging scanner
- Higher density
- One code, several items of information
- Some modification to software systems
- Uses existing ISBT 128 data structures
Delivery Mechanisms
Size Comparison
Linear VS 2-D
Information Elements

- Standard terminology and definitions
- Reference tables
  - Consistent product codes
- Data structures
- Delivery mechanisms
- Labeling
  - Defines method of providing information in a consistent layout on the product label
  - Ensures consistency between electronic and eye-readable information
Label Example

Standard Bar Code Positions
Label Example: Cellular Therapy Product

Product
Why Do I Want To Use ISBT 128?

Hopefully, after this overview, you can see the merits of adopting ISBT 128 Labeling.

Refer to the ICCBBA, Inc., website: [http://www.iccbba.org](http://www.iccbba.org) for resource material
- ISBT 128 An Introduction to Bar Coding
- Product Code Structure and Labeling – Cellular Therapy Products
- Information regarding facility registration.
When Do I Have To Use ISBT 128?

- There is no currently defined implementation date for CT facilities.

- However, the accreditation / regulatory bodies (FACT, AABB and FDA) support the adoption and implementation of ISBT 128.
Acknowledgements

Cellular Therapy Coding & Labeling Advisory Group

www.iccbba.org