

ISBT128 Coding/Labeling & Cellular Therapy Products

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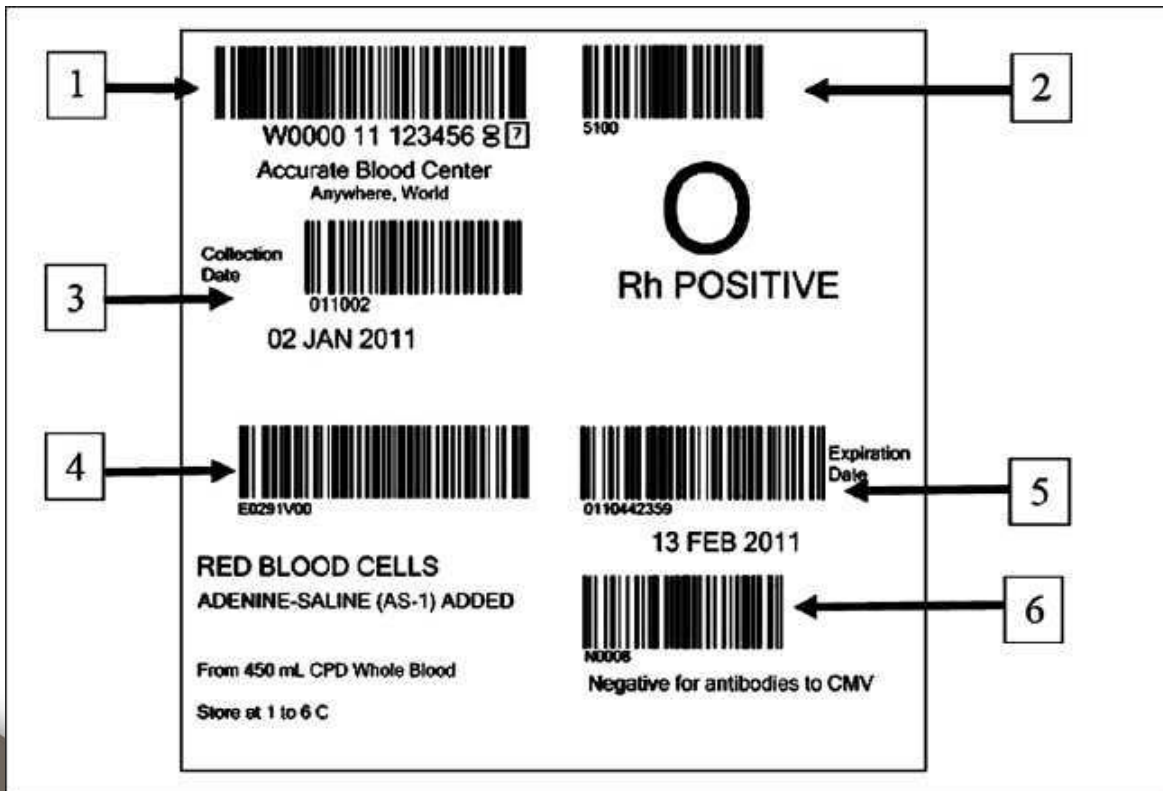


FOUNDATION FOR THE
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CELLULAR THERAPY

What is ISBT 128?

- Information standard for blood, cells, tissues and organs that provides:
 - Globally unique donation numbering system
 - Standard structures and formats for information
 - International product list, definitions and codes
 - Bar coding for secure information transfer
 - Mechanism for further development and maintenance of the standard

ISBT128 General Format



Standard ISBT 128 label:

- (1) Donor Identification Number
- (2) ABO/Rh groups
- (3) Collection date
- (4) Product code
- (5) Expiration date and time
- (6) Special testing (optional)

ISBT128 General Format



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Current Coding

Blood

Cellular
Therapy

Tissues

Plasma
Derivative
(ABO specific)

Human Milk

New Areas of Coding

Organs

Regenerative
Medicine
Products

Assisted
Reproductive
Technology

?

1989

ISBT Working Party on Automation and Data Processing begins work on a new coding system to replace Codabar.

1995

ICCBBA is formed as a not-for-profit organization.

1994

ISBT council approves ISBT 128 standard and agrees to form ICCBBA, an organization to manage the standard

ICCBBA

- Not for profit
- Based in the US (Executive Director in the UK)
- Manages the ISBT 128 Standard
 - Maintaining databases and supporting documentation
 - Supporting advisory groups of experts to continually advance the standard

1997

1st facility implements ISBT 128 for blood --Estonia

1st facility to use ISBT 128 for Cellular Therapy--US

2007

1st plasma derivative company labels solvent/detergent-treated plasma with ISBT 128 - Switzerland

2003

1st facility implements ISBT 128 for tissues –United Kingdom



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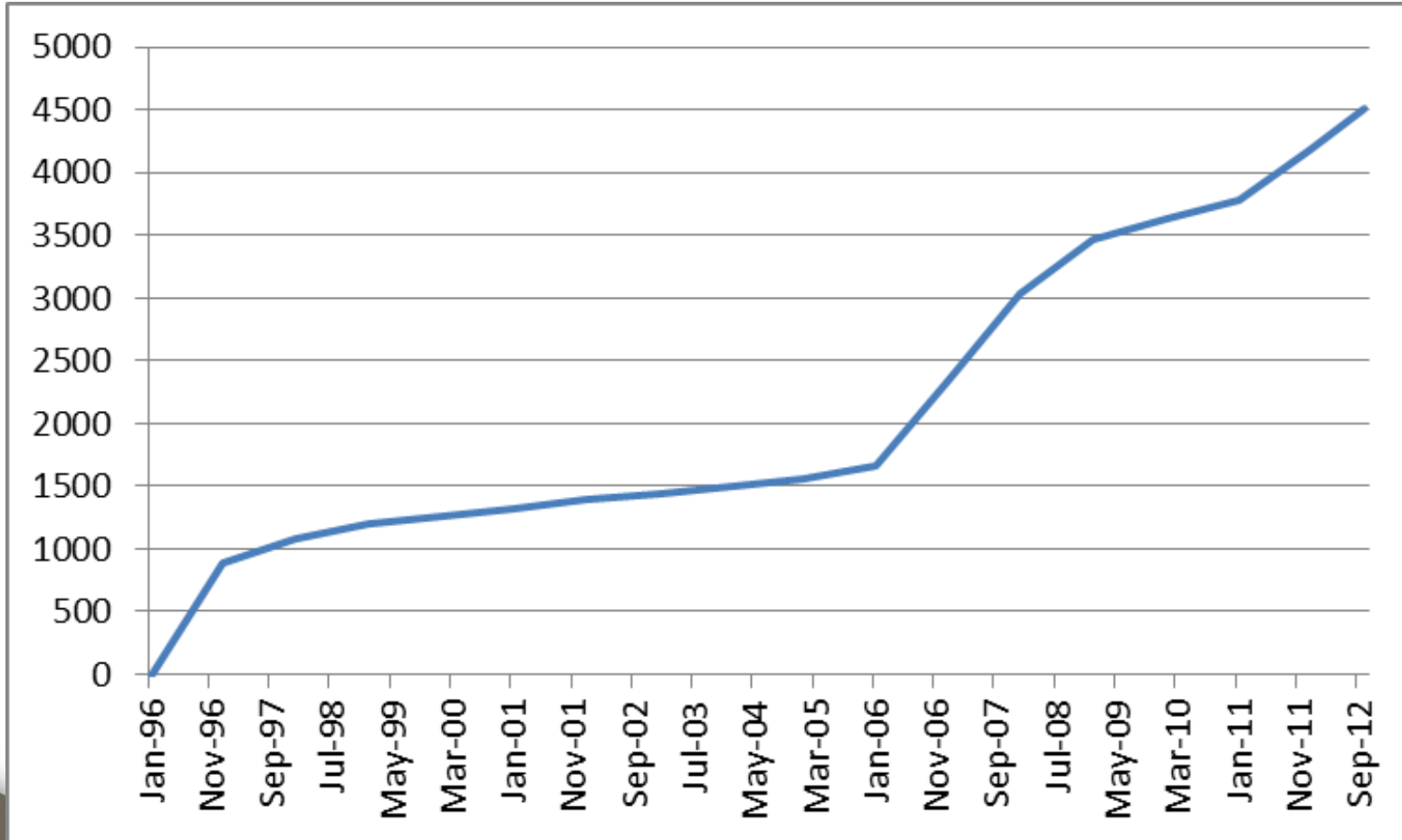
2010

ICCBBA enters into a work program with the World Health Organization (WHO) to develop organ transplant nomenclature through the standardized Organ Nomenclature Globally (SONG) group

2011

Pilot project in Scotland using ISBT 128 for human milk

Number of Registered Facilities



Who is Registered to use ISBT 128?



Facilities in 72 Countries are Currently Registered with ICCBBA

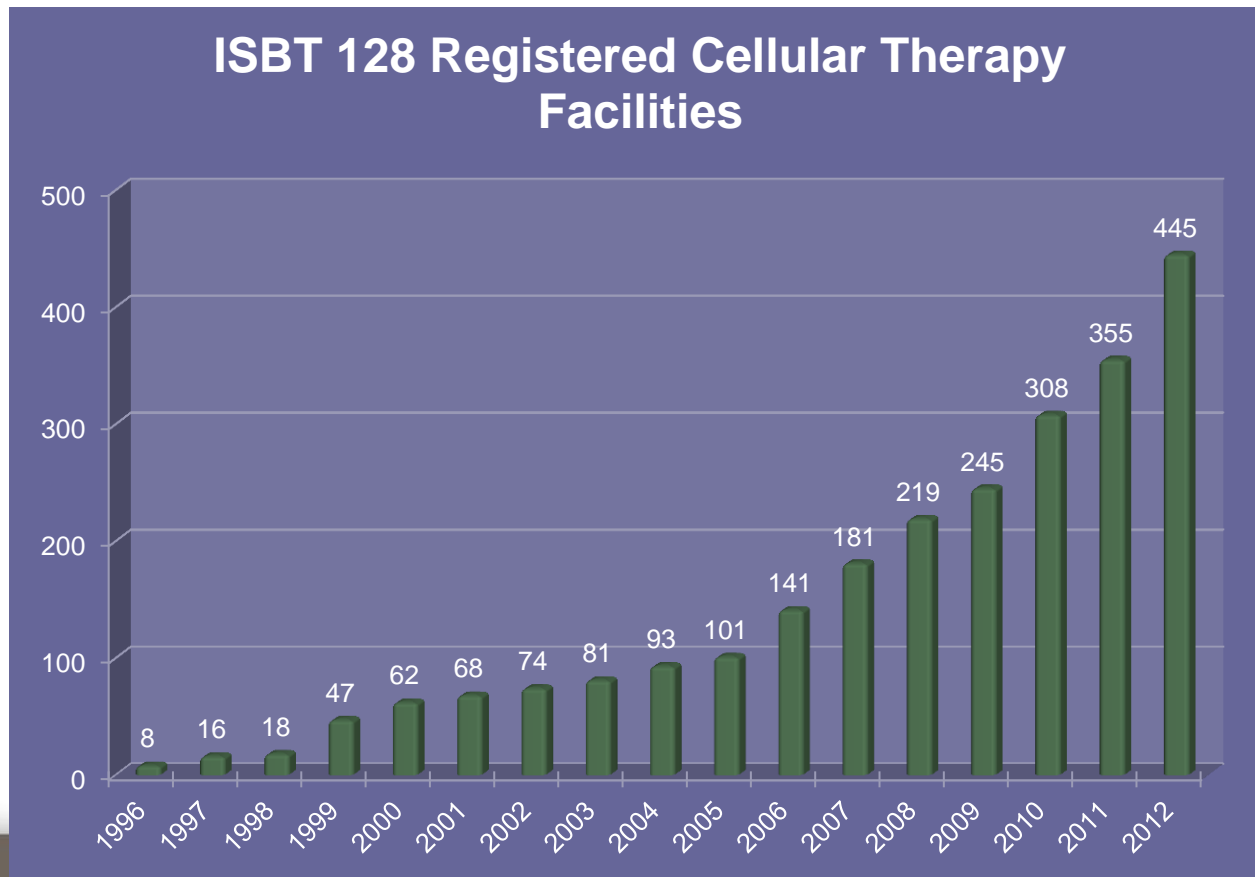
- Important – global scope of cellular therapy products (e.g. unrelated donor HPC-A)

- | | | | | | |
|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|--------------------------|
| Algeria | Columbia | Hungary | Lithuania | South Korea | The Netherlands |
| Argentina | Cyprus | Iceland | Malaysia | Saudi Arabia | Turkey |
| Australia | Czech Republic | India | Mexico | Serbia & Montenegro | United Arab Emirates |
| Austria | Denmark | Iran | Moldova | Singapore | United Kingdom |
| Bangladesh | Dominican Republic | Ireland | Nigeria | Slovenia | United States of America |
| Belarus | Egypt | Israel | Norway | South Africa | Thailand |
| Belgium | Estonia | Iceland | Pakistan | Saudi Arabia | Vietnam |
| Bosnia-Herzegovina | Finland | Italy | Panama | Spain | The Netherlands |
| Botswana | France | India | Poland | Serbia & Montenegro | Zimbabwe |
| Brazil | Germany | Ireland | Portugal | Sri Lanka | Turkey |
| Canada | Greece | Israel | Qatar | Sudan | United Arab Emirates |
| China | Honduras | Jordan | Romania | Sweden | United Kingdom |
| Croatia | Hungary | Kazakhstan | Russian Federation | Switzerland | United States of America |
| Czech Republic | Iceland | Kuwait | Saudi Arabia | Syria | Vietnam |
| Denmark | India | Latvia | Singapore | Taiwan (Republic Of China) | Zimbabwe |
| Dominican Republic | Ireland | Japan | Slovenia | Thailand | |
| Egypt | Israel | Jordan | South Africa | | |
| Estonia | Italy | Kazakhstan | Spain | | |
| Finland | Ivory Coast | Kuwait | Sri Lanka | | |
| France | Japan | Latvia | Sweden | | |
| Germany | Jordan | Lithuania | Switzerland | | |
| Greece | Kazakhstan | Malaysia | Syria | | |
| Honduras | Kuwait | Mexico | Taiwan (Republic Of China) | | |
| Hungary | Latvia | Moldova | | | |
| Iceland | Lithuania | Nigeria | | | |
| India | Malaysia | Norway | | | |
| Iran | Mexico | Pakistan | | | |
| Ireland | Moldova | Panama | | | |
| Israel | Nigeria | Poland | | | |
| Iceland | Norway | Portugal | | | |
| Italy | Pakistan | Qatar | | | |
| India | Panama | Romania | | | |
| Ivory Coast | Poland | Russian Federation | | | |
| Iran | Portugal | Saudi Arabia | | | |
| Israel | Qatar | Serbia & Montenegro | | | |
| Israel | Romania | Singapore | | | |
| Kazakhstan | Russian Federation | Slovenia | | | |
| Italy | Saudi Arabia | South Africa | | | |
| Ivory Coast | Serbia & Montenegro | Spain | | | |
| Japan | Sri Lanka | Sri Lanka | | | |
| Jordan | Sweden | Sudan | | | |
| Kazakhstan | Switzerland | Switzerland | | | |
| Kuwait | Syria | Taiwan (Republic Of China) | | | |
| Latvia | Taiwan (Republic Of China) | Thailand | | | |
| Lithuania | Thailand | Turkey | | | |
| Malaysia | Turkey | United Arab Emirates | | | |
| Mexico | United Arab Emirates | United Kingdom | | | |
| Moldova | United Kingdom | United States of America | | | |
| Nigeria | United States of America | Vietnam | | | |
| Norway | Vietnam | Zimbabwe | | | |
| Pakistan | Zimbabwe | | | | |
| Panama | | | | | |
| Poland | | | | | |
| Portugal | | | | | |
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| Russian Federation | | | | | |
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| Taiwan (Republic Of China) | | | | | |
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| United Arab Emirates | | | | | |
| United Kingdom | | | | | |
| United States of America | | | | | |
| Vietnam | | | | | |
| Zimbabwe | | | | | |



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ISBT128 & Cell Therapies



Status of ISBT 128

- >4,500 facilities have registered to use ISBT 128
- 68 countries on 6 continents have registered facilities
- 546 new facilities in 2012 as of October 31
- >100 vendors of equipment and supplies are licensed to use ISBT 128
- >40 million products are labeled with ISBT 128 each year

Tissue Organizations

- American Association of Tissue Banks
strategic plan: “Participate in and support
ISBT 128 coding for tissue labeling.”
- European Tissue Technical Advisory Group
very active in developing new tissue
terminology

Cellular Therapy

- 12 cellular therapy professional societies from around the world support ISBT 128
 - Notably includes FACT, JACIE, ISCT, AABB
- Some require the use of ISBT 128 terminology in their Standards
- Some require a plan for full implementation of ISBT 128

Cellular Therapy Coding & Labeling Advisory Group



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ISBT 128 and Licensed Cellular Therapy Products

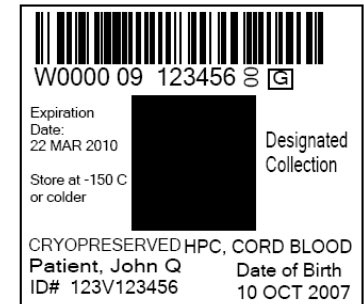
- **Limited/Mixed Experience**

- Umbilical cord blood for allogeneic transplantation

- Moved forward with ISBT standardized naming
 - Exception to normal regulatory requirements

- sipuleucel-T

- PROVENGE



Non-proprietary name

Proprietary name

NDC bar code

Moving Forward

- Are the two approaches mutually exclusive or can they be reconciled?
 - Naming: Standard product name *versus* Proprietary product name *versus* Non-proprietary product name (generic name?)
 - Bar codes: NDC versus code 128
 - Product identity
- More extensive conversation is needed

Cell Therapy Products vs. Other Part 351 products

- **Pharmaceuticals**
 - Main ingredient can be synthesized through defined chemical processes or in a defined bio-reactor system
 - Pharmaceuticals completely interchangeable as long as chemistry of final product identical – multiple producers may make same product
 - Products made independent of need and stored
- **Cell Therapy Products**
 - Main “ingredient” can only be obtained from a living or very recently deceased donor
 - Cell therapy product must come from limited donor and be administered to limited recipient
 - May not collect cells / produce final product until need exists

Additional Considerations Important for Labeling System to be Employed

- **Tracking / Tracing / Biovigilance**
 - As with blood products, cell therapy products are associated with donors.
 - Need to be able to track products in cases where post donation infectious agent discovered
- **Product identity**
 - Need, for non-autologous products to align donor and recipient qualifiers, e.g. HLA type (also similar to blood products)
 - Product itself must have specified potency indicators, e.g. CD34+ cell content
- **Suppression of human error and trans-lingual globalization – i.e. bar codes**
 - Product requires multiple elements to be coded, single bar code (such as NDC) likely not sufficient

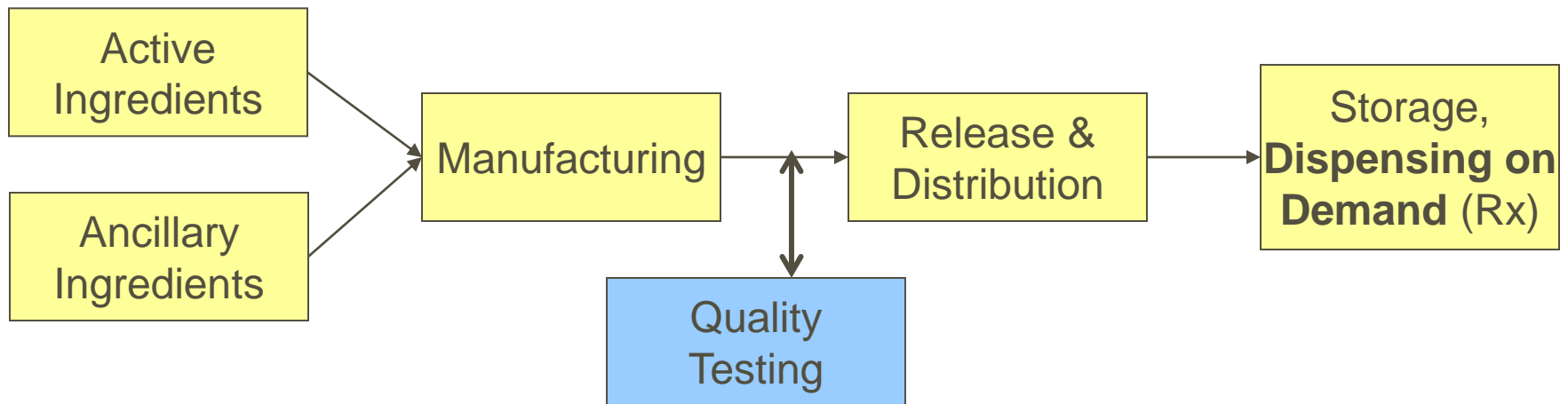
Proposal

- The cell therapies community wishes to engage the FDA (and other regulatory bodies around the world) in a larger conversation regarding naming and labeling paradigms for licensed cell therapy products
 - Generate a system for product naming and labeling that fits the unique characteristics and paradigm for manufacturing and distribution of cellular therapy products
 - Build sufficient scope into the system to accommodate not only near term transition of products to licensed status (e.g. HPC-Apheresis) but to also products that may be well down the road
 - Inclusive of both autologous and allogeneic products

Proposal

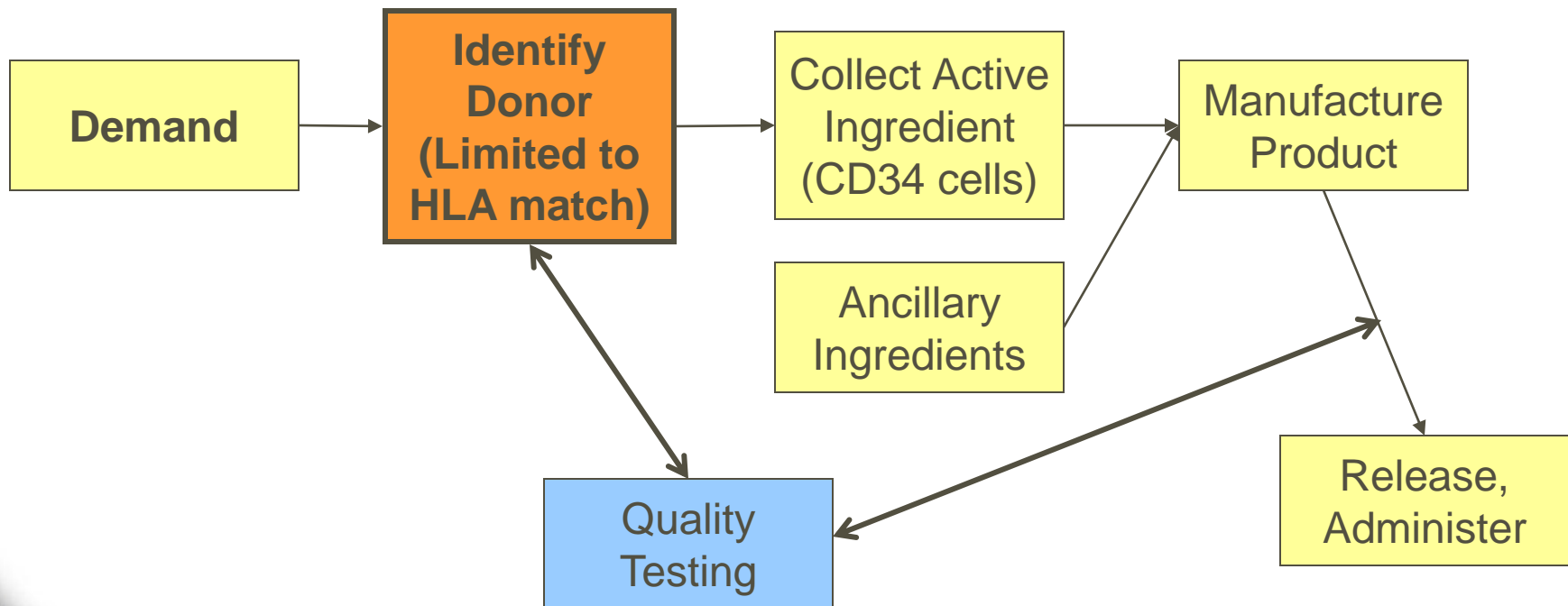
- We believe that ISBT128 forms an excellent foundation for coding / labeling / naming of cell therapy products
 - Already covers virtually all CT products in current use
 - CTCLAG process has input from all major cell therapy related organizations and from FDA
 - Strong international base

Traditional Pharmaceuticals



HPC, cord blood is one of the few cell therapy products that fit this paradigm.

HPC, Apheresis for Transplant



What is being adopted *NOW*

 W0000 10 123456 8 J	 4700	○ Rh Positive
Collection Center or Registry 2nd Line of Name City, State/Province, Postal Code		
Collection Date/Time 22 JAN 2010 13:59 CET (22 JAN 2010 14:59 GMT)		For Use by Intended Recipient Only
Do Not Irradiate Do Not Use Leukoreduction Filters		Unrelated Donor Donor # W0001 123654987
 S1134400	 0100241055	Expiration Date/Time: 24 JAN 2010 10:55 CET (24 JAN 2010 10:55 GMT)
HPC, APHERESIS Other Additives Present See Attached Documentation for Details		Intended Recipient: SMITH, ROGER R MRN: 123456789 Date of Birth: 07 JUL 1963
Approx _____ mL in approx ____ mL Citrate		Processing Laboratory Name 2nd Line of Name City, State/Province, Postal Code
Store at 1 to 10 C		

We strongly believe that as we enter the conversation on cell therapies naming and labeling that this, since it already contains elements that are critical to the safe management of these products, should serve as the point of departure.



Critical Issues Moving Forward

- Tracking / Tracing
- Donor-Recipient pairing
- Facilitation of product ordering
 - Some form of standard nomenclature
- Product standards
- Product interchangeability
- Expandability to multiple cell therapy products
- International usability and acceptance
 - Facilitation of product movement across boundaries
- Expandability to related products
 - Tissue engineered products
- Management of sub-optimal donations
- Relationship between licensed and pre-licensure products
- Relationship between 351 and 361 products
 - Almost universally produced in same facility