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# Implementation of *ISBT 128* in a Cellular Therapy Facility

## Cellular Therapy Coding and Labeling Advisory Group (CTCLAG)







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# The Goal...

- Standardization of terminology
- Standardization of labeling
- Transcending language barriers
- Clear, unambiguous transfer of information about cellular therapy products

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# Plan Assumes:

- Decision to implement *ISBT 128* has already been made
- Key managers (technical, medical, Information Services) were involved in the decision

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# Appoint a Project Manager

Select someone knowledgeable about

- The operation
- The computer system
- Labeling

*And who is resourceful, persistent, persuasive,  
and committed to the project*





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# Resources—Gather information

- [www.aabb.org](http://www.aabb.org)
- [www.iccbba.org](http://www.iccbba.org)
  - ❑ *An Introduction to ISBT 128*
  - ❑ *ISBT 128 for Cellular Therapy*
  - ❑ *ISBT 128 Standard Technical Specification*
  - ❑ *ISBT 128 Standard Bounded Lists and Definitions*
  - ❑ *ISBT Standard Product Code Structure and Labeling (Cellular Therapy)*
  - ❑ *ISBT 128 Standard Cellular Therapy Product Coding Transition*
- Your software vendor
- Label vendors



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# Early Communication Phase



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# Obtain Executive Management Support

- The project will involve commitment of human and financial resources
- If anyone in executive management was not a part of the decision-making process to implement *ISBT 128*, now is the time to involve them

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# Inform Administration and Laboratory Supervisors

*It's not just a different label!*

- Identify which other departments are involved
  - ☐ Testing services?
  - ☐ Infusion staff?
  - ☐ Billing staff?
- Bring key staff into planning process

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# Planning/Information Gathering Phase



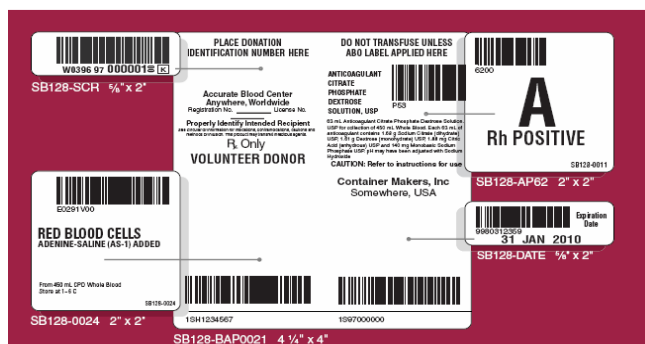
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# Follow Internal Change Control Policies

- Implementation plan
- Quality plan update
- Validation SOPs (software, equipment, processes)
- Training plan

# Determine Level of Involvement (organization impact)

- Manual system (use preprinted labels, but don't scan bar codes)
- Limited automation (will use pre-printed labels and will scan bar codes)
- Full electronic (read and print bar coded labels)
- Electronic data transfer?





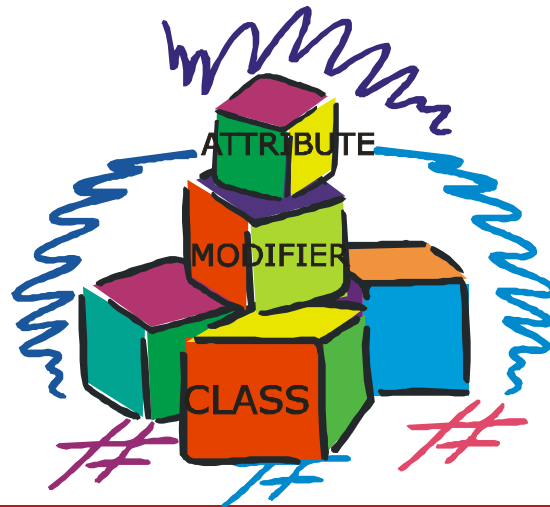
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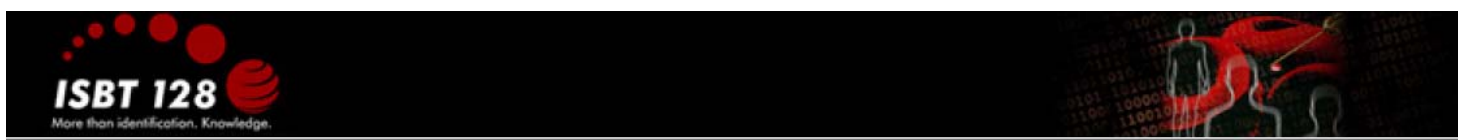
# Understand Product Codes

- *ISBT 128* Standard Bounded Lists and Definitions
- Cellular Therapy Product Coding Transition
- *ISBT 128 Standard Product Code Structure and Labeling (Cellular Therapy)*
- Access database for Product Code Descriptions

# Product Code Descriptions

- Rules Based
- Built by combining Classes, Modifiers, and Attributes
- Select from existing codes or request new ones





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*Product Code Request Form (Cellular Therapy)*

<b>Facility Identification Number</b> <input type="text"/>	<b>Contact Name</b> <input type="text"/>	<b>E-mail address</b> <input type="text"/>
<b>Component Class</b> -Select Class- HPC, Apheresis HPC, Cord Blood HPC, Marrow HPC, Whole Blood Concurrent Plasma, Apheresis TC, Apheresis TC, Marrow TC, Whole Blood TC, Cord Blood TC-T Cells TC-CTL TC-T Reg Cells TC-DC TC-NK Cells TC-Tumor Derived TC-MSD TC-APC TC-INV	<b>Modifier</b> -Select Modifier- <input type="text"/>	<b>Storage Temperature</b> -Select Option- <input type="text"/>
<b>Anticoagulant Type</b> -Select Option- <input type="text"/>	<b>Cryoprotectant</b> -Select Option- <input type="text"/>	<b>Manipulation</b> Default: no manipulation <input type="text"/>
<b>Intended use</b> Default: For administration <input type="text"/>	<b>Other Additives</b> -Select Option- <input type="text"/>	<b>Genetically Modified</b> Default: N/S <input type="text"/>
<b>Preparation: Blood Component third party donor</b> Default: N/S <input type="text"/>	<input type="button" value="ICCBBA, Inc"/> <input type="button" value="Reset"/>	

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# Compile your list of product codes

- Populate computer tables
- Set up billing mechanisms
- If collection/processing facility, share with your customers



# Your Product Code tables




Code	English	Swedish
E5395	POOLED PLATELETS PASII /XX/20- 24C ResLeu:<1log 6 Buffy coat plts prep Bacterial monitoring	Trombocyter, poolad PASII/XX/20-24C  Leukocytinnehåll < 1x10 <sup>6</sup>   Trombocyter från lättcellskonc Ev. Bakterie tillväxt kontrolleras





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# Understand Label Design

- *ISBT 128 Standard Technical Specification*
- *ISBT 128 Standard Product Code Structure and Labeling*
- Regulatory Documents for national requirements



 W0000 07 123456 8 	
Store at <-150C  Expiry Date: 10 OCT 2021	 Directed Collection
CRYOPRESERVED HPC, CORD BLOOD Patient, John Q      Date of Birth ID# 123V123456      10 OCT 2007	

 W0000 06 523457 8  Collection Center or Registry Anywhere, Worldwide	 5100 RhD Positive
Collection Date/Time 29 JAN 2006 15:15 (29 JAN 2006 20:15 GMT)	FOR INTENDED RECIPIENT ONLY
Properly Identify Intended Recipient. May transmit infectious agents.	Matched Unrelated Donor Donor # 123654987
 S0000D00      DIRECTED	Laboratory Testing Information Additional Laboratory Testing Information
HPC, APHERESIS	Expiration Date/Time: 31 JAN 2006 15:15 (31 JAN 2006 20:15 GMT)
Approx ____ mL in approx ____ mL Citrate DO NOT IRRADIATE DO NOT USE LEUKOREDUCTION FILTER Store at 1 to 10 C  Processing Laboratory Elsewhere, Worldwide	Recipient: John Q Patient ID#: 123456789 Date of Birth: 31 DEC 1984 Hospital Name City, Province, Country

 W0000 07 123456 8 	Collection Center or Registry Anywhere, Worldwide	Recipient: John Q Patient ID#: 123456789 Date of Birth: 31 DEC 1984 Hospital Name City, Province, Country
 S0000D00      Directed CRYOPRESERVED HPC, APHERESIS Date of collection: 12 MAY 2007		

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# Determine Equipment, Software, and Supply Needs

- Scanners
  - ☐ Linear
  - ☐ Imaging
- Printers
- Software
- Labels

[www.iccbba.org](http://www.iccbba.org) for vendors licensed with ICCBBA

# 2-D vs. Linear Bar Codes

Data Matrix



Code 128



Donation ID number



ABO/Rh



Product Code



Expiration Date/Time



Special Testing results

# Costs/Budgeting Process Considerations

- Software purchase or upgrade
- Linear vs. imaging bar code scanners
- Preprinted vs. on-demand labels
- Printing of new forms, etc.
- Labor



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# Plan for the Transition Phase

- If you receive *ISBT 128* labeled products before you've implemented
  - ☐ Will your computer be able to scan labels?
  - ☐ Update SOPs to be able to deal with products received
- If you implement first
  - ☐ Shared label examples with facilities that will receive your products in advance of shipping the first product

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# Execution Phase



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# Execution Phase

- Purchase equipment
- Write/perform equipment validations
- Write/validate SOPs

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# Develop Training Materials and Train Staff

- Identify who will need training
  - ☐ Nursing and Medical staff
  - ☐ Information Technology
  - ☐ Billing personnel



# Audit Quality System Procedures

- Quality Plan
- Emergency Response Plan
- Contingency Plan
- Computer down/Back-up Plans



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# Go Live!



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# Assess Progress

- What has gone well
- What has not gone well
- Workarounds
- Errors and accidents

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# Seek Assistance When Needed

- Those who have implemented *ISBT 128* already
- ICCBBA ([iccbba@iccbba.org](mailto:iccbba@iccbba.org))
- Other sponsoring organizations







# ISBT 128. One World. One Standard.

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