Identification of medical devices containing an HCT/P in the United States.
Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014

Introduction

This recommendation applies specifically to the identification of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated as medical devices using a Unique Device Identifier (UDI) as required under the US Food and Drug Administration's (FDA's) Unique Device Identification System Final Rule (78 FR 58785; September 24, 2013).
GS1 and ICCBBA, working within the terms of an existing Memorandum of Understanding, have developed this recommendation to clarify the appropriate use of the GS1 and ISBT 128 unique device identifiers, and the interfaces between the standards.

The GS1 – ICCBBA collaboration

GS1 and ICCBBA established a Memorandum of Understanding in Aug 2007 to set out a framework of cooperation between the two organizations in areas of mutual interest. In particular it was recognized both standards play an important role in their respective spheres, there would be areas of interface between the two standards, and these should be well defined with logical transition. By developing this collaboration, the two organizations intend to provide their coordinated contribution to patient safety.

Collaborative actions have resulted in:

1. A guidance document on labeling of plasma derivatives;
2. A harmonized approach to the use of both GS1 and ISBT 128 in the identification of blood collection sets; and,
3. The development of an ISO Standard on patient identification.

In each case the organizations have worked together to ensure the solution presented is based on the standard best suited to the business process.

Understanding traceability

Traceability by unit / by lot (batch)

The hierarchy model for traditional supply chain goods can be represented as a sequence of one to many relationships with the product manufacturer as the highest element in the chain. Thus, a manufacturer will make multiple products, each uniquely identified within the organization by a product number (catalogue number, identifying a product class) and Global Trade Item Number (GS1 GTIN). Each product will typically be produced in batches identified by a batch or lot number. In situations where serialization is required, each item will carry its own serial number, which together with the GTIN identifies that item uniquely (product instance).

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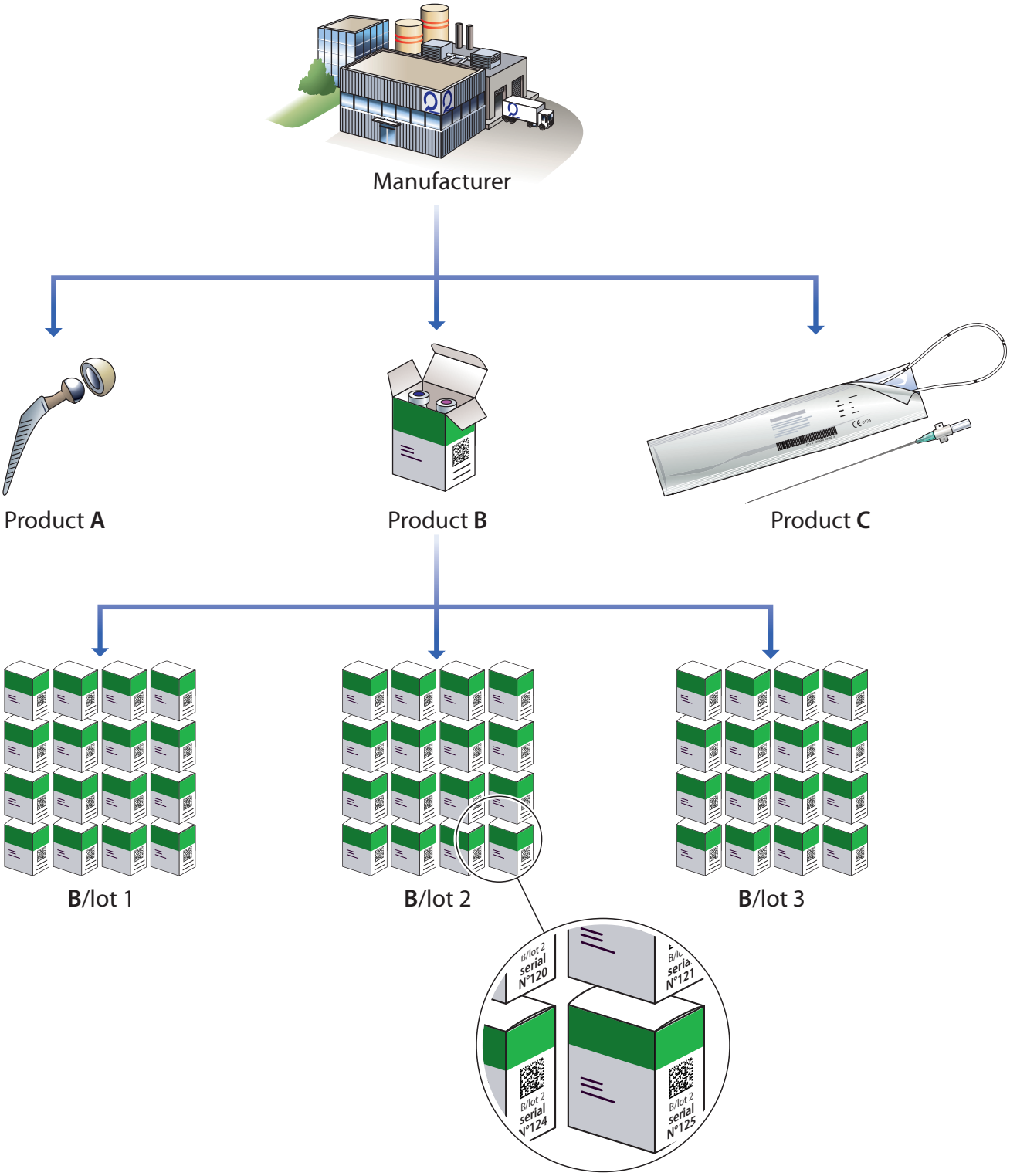

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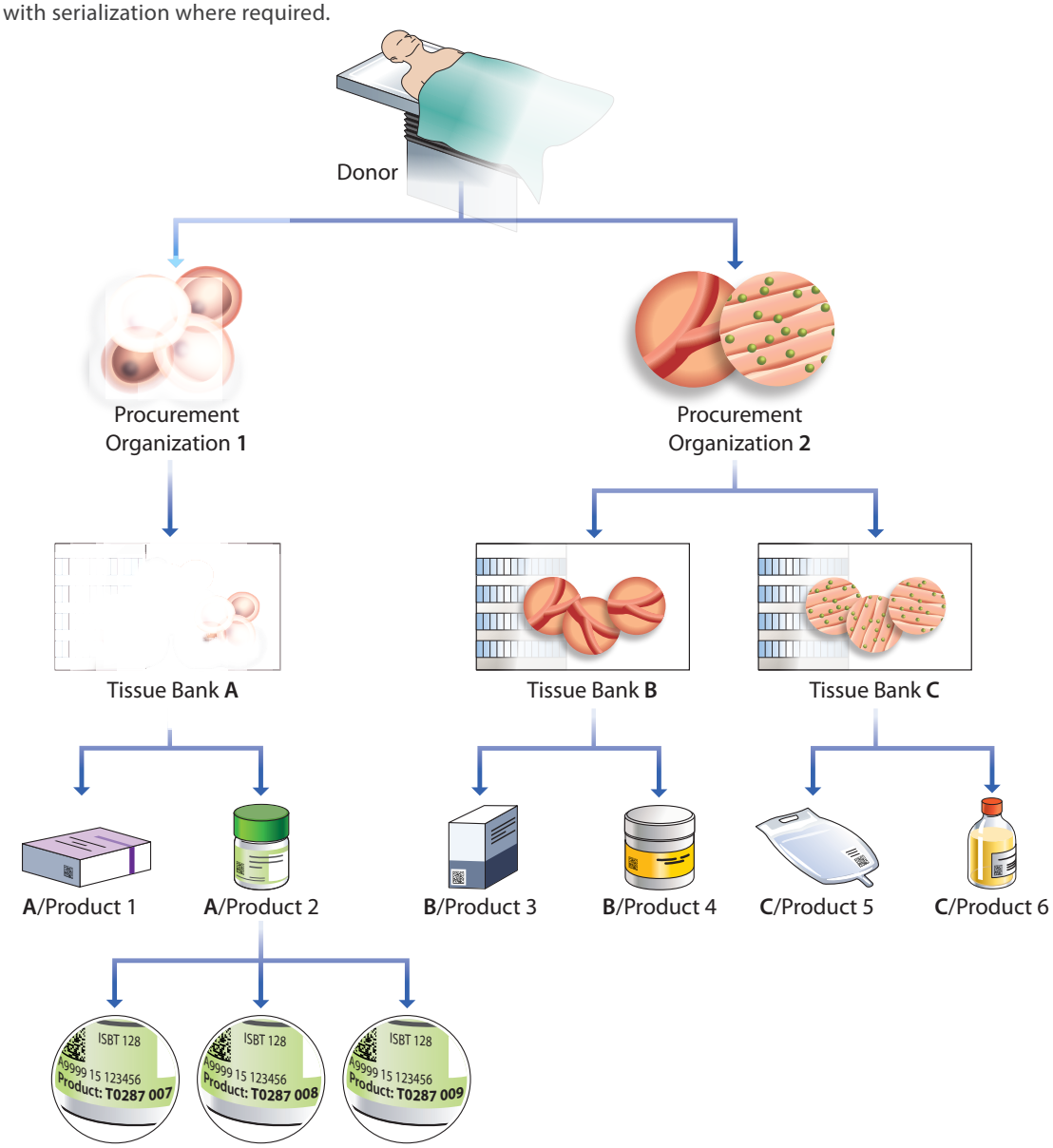
Good manufacturing practice, supported by effective regulation, controls the manufacturing process and ensures segregation between product classes and their respective batches. Therefore when product recall or follow up is required, it is almost exclusively contained within one of the grouping levels of the model. Most commonly this occurs at the batch/lot level or the product level.

Traceability to the donation

In the case of human tissue, the hierarchy model is different because most recall/follow up events have been associated with a specific donor. A single donor's tissues may be recovered and sent to more than one tissue bank processor, and this tissue can be distributed across multiple product lines.

The highest element in the hierarchy in this scenario is therefore the tissue donor. Subsequent levels include the identification of the donation event, the tissue processor, and the product/catalogue number of the individual products prepared together with serialization where required.



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Recall and follow up activities are generally associated with a specific tissue donor. A donor-related recall requires identification of all the tissue and organs associated with the single donor. This will often comprise specific items under a wide range of product lines from different organizations (an organ procurement organization, an eye bank and tissue processors). For example, one donor may donate solid organs (kidney, liver), corneas, skin, heart valves and vessels, bone (further processed to a range of products including shaped grafts and demineralized bone matrix), and soft tissue such as tendons, ligaments, amniotic membrane, pericardium, fascia, and nerves. This range of products spans multiple regulatory paradigms (organs, medical devices, biologics) and there can be a need for product tracing/tracking for immediate quarantine, withdrawal or recall with an expectation this will occur in an efficient and seamless manner.

A second scenario in tissue banking occurs when a problem has been identified by a single processor and involvement included a particular product line or many product lines. The latter scenario can include many lots, multiple products, and several donors.

The special nature of HCT/Ps

HCT/Ps are a precious resource most often provided by deceased donors and/or acutely grieving family members. Living donors also provide HCT/Ps that can improve and save lives of recipients in need. Tissue banks handle these medical products of human origin with care and respect, understanding the special gift of donation. It is important this care and respect is followed from the time of donation and recovery to the moment of implant, transplant, infusion, or transfer to a human recipient.

HCT/Ps have unique characteristics that impact their handling through the supply chain. In particular:

- HCT/Ps are regulated under 21 CFR Parts 1270 and 1271 by the FDA's Center for Biologics Evaluation and Research (CBER);
- HCT/Ps must carry a distinct identification code that relates each HCT/P to the donor and all records pertaining to the donor, and that labeling include information to facilitate effective tracking (using the distinct identification code) from the donor to the recipient and from the recipient to the donor;
- The ability to track all HCT/Ps from the donor to the consignee or final disposition, and from the consignee or final disposition to the donor, is expected;
- HCT/P management in healthcare facilities is subject to stringent standards (e.g., standards and elements of performance in The Joint Commission's Transplant Safety Chapter; AABB's Standards for Blood Banks and Transfusion Services);
- HCT/Ps can transmit disease. Enhanced traceability, with specific reference to traceability to the donor (or donors), is essential in the investigation and prevention of disease transmission; and
- There is a recognized need for standard product terminology and coding to support biovigilance as identified by World Health Assembly resolution WHA63.22.

The standard employed for medical devices containing an HCT/P, and supply chain procedures, should explicitly support these characteristics.

GS1 labeling: for the general supply chain

The FDA requirement for UDI applies to all medical devices distributed in the USA. The vast majority of these devices follow a standard manufacturing process model and can be effectively traced using traceability by lot/batch number. These should be labeled using the GS1 UDI that meets users' requirements in North America and across the world.
Through its normal standards management process GS1 and its users ensure that the GS1 system of standards continuously accommodates regulatory requirements.

ICCBBA labeling: for medical products of human origin

ISBT 128 is designed specifically to meet the special needs of HCT/P traceability. The use of a globally unique donation identification number, and the maintenance of international standard terminology and coding, ensures effective traceability to the donor and supports biovigilance activity.

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ICCBBA was established, and continues to operate, specifically to address the identification and traceability needs of medical products derived from human donors. To this end the organization has established links with over 300 professional experts in the field of transfusion and transplantation who participate in technical advisory groups responsible for ensuring the ongoing suitability of the standard.
At the international level, ICCBBA is a nongovernmental organization in official relations with the World Health Organization and ISBT 128 is recognized by WHO as the sole global standard for the identification and coding of Medical Products of Human Origin (which includes HCT/Ps)
ISBT 128 product terminology is incorporated into the European Union (EU) Product Compendium making it fully compatible with the Single European Code (SEC). The SEC will be required on tissues and cells distributed in the EU, including imports from third countries, in accordance with forthcoming EU legislation.

Characteristics Specific to ISBT 128

The following characteristics are specific to ISBT 128 and address the special supply chain needs for HCT/Ps as described above:

1. The ISBT 128 Standard Terminology and associated Product Code Database meet the need for standardized product coding across multiple providers in order to support biovigilance activity as recognized in World Health Assembly Resolution WHA63.22;
2. The device identifier combines a standard product description code with a tissue bank specified code element allowing tissue banks to assign distinct product type identifiers within a structured framework;
3. The standardized globally unique donation identification number (distinct identification code) is presented in a consistent, electronically readable format that supports rapid recall;
4. The scope and focus of ISBT 128 provides a specific and consistent identification system that spans all medical products derived from a human donor (including blood, cells, tissues, organs, milk); and is
5. Accepted by the European Commission for use in the Single European Code being introduced for use on all tissues and cells distributed in the European Union.

Summary

GS1 & ICCBBA collaborate to enhance patient safety, by recommending the use of the standard meeting specific business requirements.

Following a review of the business requirements of various supply chain parties, GS1 and ICCBBA recommend that medical devices that contain an HCT/P should be identified using the ISBT 128 Standard. Other medical devices should be identified using the GS1 system of standards.