IMPLEMENTATION GUIDE

ISBT 128 Implementation Toolbox

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Table of Contents

1 Introduction 4
1.1 Purpose 4
1.2 Scope 4
1.3 Intended Audience 4
1.4 Other References 4
1.5 Changes in this Version 5
2 ISBT 128 Implementation Toolbox 6
2.1 Toolbox Items: 6
3 Case Studies 9
3.1 US Implementation of ISBT 128 9
3.2 Scandinavian Case Study 9

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1 Introduction

1.1 Purpose

The purpose of this document is to provide a toolbox of commonly used items essential for implementing ISBT 128. It also provides guidance and recommended steps for consideration when planning out one's ISBT 128 implementation. Most of the items within this document exist individually on the isbt128.org website, and this document brings them together in a handy toolbox.

1.2 Scope

This document provides references to set up a comprehensive ISBT 128 implementation plan. The applicable steps and resources needed may vary due to different needs in facilities. Therefore, facilities should use this as a guide or checklist of things to consider rather than attempting to follow it precisely.

1.3 Intended Audience

This document is intended for staff (management, laboratory, quality, and information technology) of facilities using ISBT 128, software developers, manufacturers of labels for MPHO, and personnel looking to use and implement the ISBT 128 labeling standard.

1.4 Other References

ICCBBA Website (www.isbt128.org)

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1.5 Changes in this Version

The following table indicates the major changes between Version 1.0.0 and Version 1.0.1. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to the formatting or organization, or additional guidance, are in regular print. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 Implementation Toolbox Version Control: Version 1.0.0 vs. 1.0.1

	Version 1.0.0 Chapter, Section, Table, or Figure	Version 1.0.1 Chapter, Section, Table, or Figure	Change	Rationale
1.	Copyright	Copyright	Provided an updated copyright statement	Per legal recommendations
2.	Throughout	Throughout	Fixed capitalization formatting	For consistency
3.		2.1.15	Added IG-041 to the toolbox items	For completeness
4.		End of Document	Added a reference page for internal ICCBBA use only	To facilitate internal document control

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2 ISBT 128 Implementation Toolbox

2.1 Toolbox Items:

2.1.1 What is ISBT 128?
This provides a brief overview of the information environment and the ISBT 128 Standard. New users who are unfamiliar with ISBT 128 or the elements that contribute to standardization may find this useful.

2.1.2 IN-036 ISBT 128 Implementation Steps to Complete after Registration
This document provides a number of recommended actions to take after registering with ICCBBA. Users who are not sure what to do next can refer to this document for the next steps in their implementation process.

2.1.3 IN-037 ISBT 128 Implementation Plan
This is a comprehensive implementation plan, and the applicable steps may vary due to different needs in facilities. Therefore, facilities should use it as a guide or checklist of things to consider rather than attempting to follow it precisely.

2.1.4 IN-035 An Introduction to Common ISBT 128 Data Structures
This document provides a technical explanation (with citations/references) on common ISBT 128 Data Structures.

2.1.5 Facility Identification Number Database
The Facility Identification Number (FIN) Database contains all FINs and information from registered facilities. The database allows users to see where a product was collected or processed. **(Note: you must be logged-in to view this page.)**

2.1.6 ISBT 128 Product Description Code Database
The ISBT 128 Product Description Code Database contains the product description codes for all types of medical products of human origin (e.g., Blood Components, Cellular Therapy, Tissues, etc.). These codes are used in the ISBT 128 Product Code. **(Note: you must be logged-in to view this page.)**
Click here for more information about the product code.

2.1.7 ISBT 128 Product Lookup Program
This program contains all product description codes and allows users to search across all product types for the codes they need. The program may also be used to look up a code's product description. Instead of looking through the thousands of codes in the ISBT 128 Product Description Code

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Database, the program makes it easier to search for codes you need. **(Note: you must be logged-in to view this page.)**

2.1.8 Sample Bar Codes
Here are some label examples that were provided by ISBT 128 registered and licensed facilities from various places around the world.

2.1.9 Audit Tool for Cellular Therapy
This audit tool may be used for ensuring compliance with the ISBT 128 Standard. It contains interactive and printable checklists that can be used to verify that a facility has successfully implemented ISBT 128.

General Publications:

2.1.10 ST-001 ISBT 128 Standard Technical Specification
This document is a comprehensive description of the rules surrounding the ISBT 128 Standard, as well as guidance in the interpretation of these rules. Users can reference this document for help with regards to the coding and labeling of medical products of human origin (e.g., Blood Components, Cellular Therapy products, Tissues, etc.).

2.1.11 ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin
The Standard Terminology document provides definitions to all ISBT 128 terminology. This terminology is used to create the unique product description codes in the ISBT 128 Product Description Code Database. The document should be used in conjunction with the ISBT 128 Product Description Code Database.

2.1.12 ST-010 ISBT 128 Standard Product Description Code Database
This document provides specifications and guidance for the use of the ISBT 128 Product Description Code Database. Reference this document for help with understanding the structure of the ISBT 128 Product Description Code Database.

2.1.13 IG-033 Implementation Guide: Use of the Donation Identification Number [Data Structure 001]
This document provides guidance for the use of the Donation Identification Number (DIN) [Data Structure 001]. It goes into detail regarding each element that makes up the DIN.

2.1.14 IG-034 Implementation Guide: ISBT 128 Facility Identification Number
This document provides guidance for the use of Facility Identification Numbers (FINs) found in a number of ISBT 128 data structures. If you are also unsure if you need multiple FINs or a single FIN, this document provides

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some scenarios regarding the usefulness of multiple and single FINs in an organization.

2.1.15 IG-041 Implementation Guide: Use of ISBT 128 in Resource-Limited Countries

This document provides guidance for implementation of the ISBT 128 Standard for blood transfusion in resource-limited countries. It is intended to provide options allowing facilities to promote safety, traceability, and efficiency without needing to implement all features of the ISBT 128 Standard.

2.1.16 IG-043 Implementation Guide: A Validation Tool for ISBT 128 Data Structures

This document contains valid and invalid barcodes that may be used to validate software that reads and interprets ISBT 128 barcodes. Regulatory and compliance staff, as well as software developers, may find this guidance document helpful when developing certain validation test plans.

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3 Case Studies

3.1 US Implementation of ISBT 128

This case study (CS-001) looks at the methods and organizations involved in adopting the ISBT 128 international standard for blood transfusion in the United States.

3.2 Scandinavian Case Study

This case study (CS-002) looks at the collaborations that were utilized when adopting the ISBT 128 international standard for blood transfusion in Scandinavia.

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END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification
ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin
ST-010 ISBT 128 Standard Product Description Code Database

TB-004 ISBT 128 and Traceability

IG-033 Use of the Donation Identification Number [Data Structure 001]
IG-034 ISBT 128 Facility Identification Number
IG-041 Use of ISBT 128 in Resource-Limited Countries
IG-043 A Validation Tool for ISBT 128 Data Structures

IN-035 An Introduction to Common ISBT 128 Data Structures
IN-036 ISBT 128 Implementation Steps to Complete after Registration
IN-037 ISBT 128 Implementation Plan

CS-001 US Implementation of ISBT 128
CS-002 Case Study: Implementation of ISBT 128 in Scandinavia

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