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SPECIFICATION **AmerisourceBergen Distribution Services** **SOP Title and Version**: SSC-SPEC-001 CMO Serialization Specification [r02]	23

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Author:

Name and Title	Signature	Date
Matt Sample Sr. Director Secure Supply Chain		

Revision History

Version	Date	Author	Description
1.0	23-FEB-2016	M. Sample	Initial Release
1.1	15-MAR-2016	M. Sample	Revised to cover all of ABC CMOs and updated for tertiary packaging GTINS where required.
2.0	16-MAR-2016	M. Sample	Added packaging prefix for vials
2.1	19-APR-2016	M. Sample	Corrected typo that indicated ABC shall manage serial numbers; correct statement is that CMOs shall manage…
6	21-APR-2106	M. Sample	- Revised requirements to address issues with India (DGFT) specific export requirements: packaging indicators on GTINs & SSCC on Partials - Added specific requirements about EPCIS exchange (AS2 & required events) - Differentiated between SSCC required for a pallet from the packaging line vs. logistics SSCC
r[02]	20-JUL-2018	M. Sample	Revised to remove requirement to permit YYMMDD format in the human readable format and explicitly recommend the use YYYY-MM, YYYY-MMM-DD, &, YYYY-MM, or YYYY-MMM.

Table of Contents

1. Purpose

The purpose of this document is to provide the minimum set of requirements to be used when designing compliant product labeling and packaging for the Drug Supply Chain and Security Act (DSCSA). Examples have been provided as guidance, however the final label design shall be approved by all required parties including Packaging, Regulatory, Quality, Engineering, and Marketing.

Requirements contained are the aggregation of requests from the wholesaler business, global standards organization, and current best practices. For each product, it is the assumption that AmerisourceBergen Business with will work the Contract Manufacturer to determine the optimal label layout, font size, and material. It is the goal to standardize upon layouts and proof sharing where possible.

2. Scope

This document contains labeling guidelines and examples for applying serialization markings to all applicable levels of product packaging, including case and pallet labels. At this time, the serialization barcode and labeling markings do not replace the current FDA required NDC and linear barcode.

This document applies to all contract manufacturers or packagers that are partnered with any AmerisourceBergen business, including BluePoint Laboratories, MWI Animal Health and American Health Packaging.

3. Roles & Responsibilities

Role	Responsibility
AmerisourceBergen product team	Own overall product and all approvals, such as artwork, are performed.
Contract Manufacturer	Contracted entity that manufacturers, or packages, products on behalf of AmerisourceBergen business units. Responsible for meeting the requirements for serializing AmerisourceBergen products.
Secure Supply Chain Operations	AmerisourceBergen's global serialization operations team. All integrations for serial number transactions for CMOs are managed by the SSC Operations Team.

4. Definitions, Acronyms and Abbreviations

ACRONYM/ ABBREVIATION	DEFINITION
SSCC	Serialized Shipping Container Code
GTIN	Global Trade Item Number
AI(00)	This is the GS1 Application Identifier for SSCC. The number that follows a (00) is the SSCC number.
AI(01)	This is the GS1 Application Identifier for GTIN. The number that follows a (01) is the products GTIN number.
AI(10)	This is the GS1 Application Identifier for batch / lot number. The number that follows a (10) is the products batch/lot number.
AI(17)	This is the GS1 Application Identifier for expiration date in YYMMDD format. The number that follows a (17) is the date.
AI(21)	This is the GS1 Application Identifier for the product's serial number. The number that follows a (21) is the serial number.
AI(30)	This is the GS1 Application Identifier for the quantity contained in a particular packaging unit. The number that follows a (30) is the quantity. This identifier is being retired by HDA and is not required in the 2D barcodes.
Serial Number Disposition	At the end of a batch run, this is the information associated with all commissioned serial numbers, including status and packaging aggregation hierarchy.
Primary Packaging	This is the lowest unit of packaging that requires serialization. Typically referred to as the lowest unit of sale. Examples of primary packaging are Bottles, Unit Cartons, and Wallets
Interpack Packaging	This is the level of packaging between the primary and case. Examples of Intermediate packaging are Inner Packs.
EPCIS	Electronic Product Code Information Services (EPCIS) is a global GS1 Standard for creating and sharing visibility event data, both within and across enterprises.
GS1 DataMatrix	A Data Matrix code is a two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern.
CMO	Contract Manufacturer producing product on AmerisourceBergen Business's behalf
Commissioning Event	The event that indicates that a serial number is born; typically contains lot, expiration, GTIN and serial number
Pack Event	The event that links a child serial number to a parent serial number. Eaches to Cases, Cases to Pallets, etc.
Ship event	The Event that provide shipping and purchasing information for all serial numbers physically shipped

5. References

Document	Location
HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain	http://www.hda.org/publications/hda-guidelines-for-bar-coding-in-the-pharmaceutical-supply-chain-quick-start-guide
GS1 AIDC Guideline	http://www.gs1.org/sites/default/files/docs/gsmp/healthcare/AIDC_Healthcare_Imp_Guide.pdf
GS1 DataMatrix	http://www.gs1.org/sites/default/files/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf
FDA SNI Guidance	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf
GS1 General Specifications Version 1.4	http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf
H.R. 3024; Drug Quality and Security Act (DQSA), Title II – Drug Supply Chain Security Act (DSCSA)	http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/
FDA Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors	https://www.fda.gov/downloads/drugs/guidances/ucm349009.pdf

6. Requirements

6.1 General Requirements

These are the general requirements for all products manufactured and packaged on behalf of AmerisourceBergen

Rqmt ID	Requirement	Mand/Recom
GEN_010	Contract Manufacturers shall follow GS1 standards for encoding information in a 2D DataMatrix	Mandatory
GEN_020	Contract Manufacturer shall manage the generation and allocation of all serial numbers.	Mandatory
GEN_021	Contract Manufacturers shall manage their OWN SSCC 18 codes aligning to GS1 Standards	Mandatory
GEN_025	Contract Manufacturers shall generate serial numbers that are a minimum length of 8 digits.	Mandatory
GEN_026	If no prior serialization strategy defined, contract manufacturers shall generate NUMERIC serial numbers. (non-alpha numeric)	OPTIONAL → Will align to existing CMO SN Strategy
GEN_027	Contract Manufacturers shall not start a serial number with a 0.	Mandatory - To minimize risk of data truncation.
GEN_030	Contract manufacturers shall receive the primary, or lowest unit of sale, GTIN, from the AmerisourceBergen Business team.	Mandatory
GEN_031	If no prior serialization strategy defined, it is preferred that contract manufacturers use the ABC preferred packaging indicators, see table 1, for higher levels of packaging above the each.	OPTIONAL → Will align to existing CMO SN Strategy
GEN_032	In the event that a contract manufacturer will not use the ABC preferred packaging indicators, they shall communicate those different indicators to the ABC team.	Optional
GEN_040	Contract Manufacturers may implement product aggregation for all packaged product if their strategy is to aggregate. This includes from the each, to the interpack (if applicable), and pallet.	OPTIONAL → this is only if a CMO has plans to aggregate.

GTIN Prefix	Packaging Level
0	Each – Bottle / Unit Carton / Vial Multi-Pack Carton / Wallet
2	Interpack – Pack Bundle (Bottle or Vial Cartons)
3	Interpack – Pack Carton (HUD, Wallet)
6	Shipper Case
8	Pallet (where required by local country regulations)

Table 1 – Packaging Level & GTIN packaging digit

6.2 Each and Interpack Labeling Requirements

The following requirements are applicable to all less than case packaging down to the lowest unit of sale and Interpack packaging: Bottles, Inner Packs, Cartons, etc. It is recommended to implement those optional requirements when label real estate permits.

Rqmt ID	Requirement	Mand/Recom
LBL_010	Contract Manufacturers shall label their primary, lowest unit of sale, with a 2D GS1 DataMatrix ECC200	Mandatory
LBL_050	Contract Manufacturers shall encode the GTIN in the 2D GS1 DataMatrix AI(01) for the lowest saleable unit.	Mandatory
LBL_060	Contract Manufacturers shall encode the Serial Number in the 2D GS1 DataMatrix AI(21) for the lowest saleable unit.	Mandatory
LBL_070	Contract Manufacturers shall encode the Lot Number in the 2D GS1 DataMatrix AI(10) for the lowest saleable unit.	Mandatory
LBL_080	Contract Manufacturers shall encode the Expiration Date in the 2D GS1 DataMatrix AI(17) for the lowest saleable unit. This should be stored in YYMMDD format, per GS1 AIDC standards.	Mandatory
LBL_130	Contract Manufacturers shall label their lowest unit of sale with the GTIN in Human Readable format	Mandatory
LBL_140	Contract Manufacturers shall label their lowest unit of sale with the Serial Number in Human Readable format	Mandatory
LBL_150	Contract Manufacturers shall label their lowest unit of sale with the Lot Number in Human Readable format	Mandatory
LBL_160	Contract Manufacturers shall label their lowest unit of sale with the Expiration Date in Human Readable format; YYYY-MMM-DD, YYYY-MMM, YYYY-MM are the acceptable formats. Dates may be required with either hyphens, space or forward (\) or backslash (/) to separate the portions of the expiry date. The use of YYMMDD is not acceptable.	Mandatory
LBL_070	Contract Manufacturers shall label any Interpack packaging, if applicable, with a 2D GS1 DataMatrix ECC200	Mandatory (if required to enable aggregation)
LBL_075	Contract Manufacturers shall encode the GTIN in the 2D GS1 DataMatrix AI(01) for the interpack.	Mandatory (if required to enable aggregation
LBL_076	Contract Manufacturers shall encode the Serial Number in the 2D GS1 DataMatrix AI(21) for the interpack.	Mandatory (if required to enable aggregation
LBL_080	Contract Manufacturers shall encode the Lot Number in the 2D GS1 DataMatrix AI(10) for the interpack.	Mandatory (if required to enable aggregation

| Rqmt ID	Requirement	Mand/Recom
LBL_085	Contract Manufacturers shall encode the Expiration Date in the 2D GS1 DataMatrix AI(17) for the interpack. This should be stored in YYMMDD format, per GS1 AIDC standards.	Mandatory (if required to enable aggregation
LBL_090	Contract Manufacturers shall label any Interpack packaging, if applicable, with the GTIN in Human Readable format	Mandatory
LBL_100	Contract Manufacturers shall label any Interpack packaging, if applicable, with the Serial Number in Human Readable format	Mandatory
LBL_110	Contract Manufacturers shall label any Interpack packaging, if applicable, with the Lot Number in Human Readable format	Mandatory
LBL_120	Contract Manufacturers shall label any Interpack packaging, if applicable, with the Expiration Date in Human Readable format; YYYY-MMM-DD, YYYY-MMM, YYYY-MM are the acceptable formats. Dates may be required with either hyphens, space or forward (\) or backslash (/) to separate the portions of the expiry date. The use of YYMMDD is not acceptable.	Mandatory
LBL_170	Contract Manufacturers shall verify the readability of the 2D GS1 DataMatrix, containing serialization information, to a minimum of a ISO Grade C	Recommended, to be agreed upon with CMO

6.2.1 Primary / Interpack Label Example 1:

Below is an example of a 22x22 GS1 DataMatrix with GTIN, Batch, Expiration, and Serial Number all encoded in the DataMatrix. When space is not a limiting factor, such as on new labeling design, it may be preferred to keep the human readable information together as illustrated below.

GTIN 10534890157010
LOT 12345678
EXP 2012-OCT-23
SN123456789012

For expiration date formatting, YYYY-MMM-DD, YYYY-MMM, YYYY-MM are the acceptable formats. Dates may be required with either hyphens, space or forward (\) or backslash (/) to separate the portions of the expiry date.

The use of YYMMDD is not acceptable. The use of YYMMDD is confusing to the end prescriber and may lead to misinterpretation of the expiration date.

The below example is **NOT** acceptable:

(01)09099999543217
(17)180521
(10)ABC1234567890
(21)A1234567890
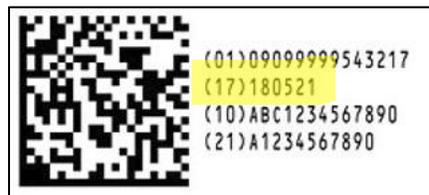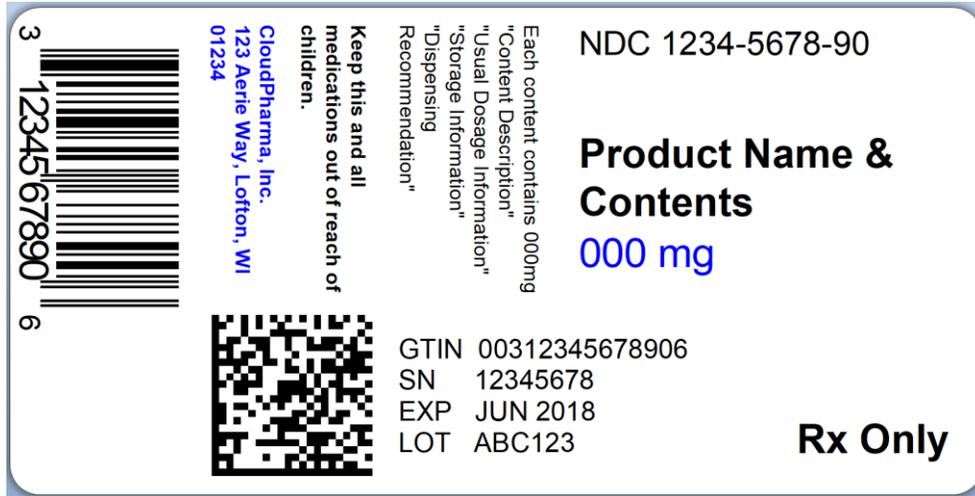
6.2.3 Primary Label Example #2:

Below is an example of a 22x22 DataMatrix with GTIN, Batch, Expiration, and Serial Number all encoded in the DataMatrix. However if space is a consideration, and GTIN, Lot, and Expiration date are already present on the primary packaging, only serial number was printed next to the DataMatrix:

It is recommended to use "SN", or "Ser No" to designate that the following information is the product serial number.

6.2.4 Primary Label Example #3:

Below is an example of a unit label including the required GS1 ECC 200 Data Matrix and Human Readable Information.

6.3 Homogenous Case Labeling Requirements

The following requirements are applicable to case labels and are aligned with the 2016 HDA DSCSA Barcode Guidelines.

Rqmt ID	Requirement	Mand/Recom
LBL_220	Contract Manufacturers shall label their cases with a 2D GS1 DataMatrix ECC200	Mandatory
LBL_230	Contract Manufacturers shall encode the GTIN in the 2D GS1 DataMatrix AI(01)	Mandatory
LBL_240	Contract Manufacturers shall encode the Serial Number in the 2D GS1 DataMatrix AI(21)	Mandatory
LBL_250	Contract Manufacturers shall encode the Lot Number in the 2D GS1 DataMatrix AI(10)	Mandatory
LBL_260	Contract Manufacturers shall encode the Expiration Date in the 2D GS1 DataMatrix AI(17) This should be stored in YYMMDD format, per GS1 AIDC standards.	Mandatory
LBL_280	Contract Manufacturers shall encode the GTIN in a 1D GS1-128 Linear Barcode AI(01) (See ABC Labeling Guidelines)	Mandatory
LBL_290	Contract Manufacturers shall encode the Serial Number in a 1D GS1-128 Linear Barcode AI(21) (See ABC Labeling Guidelines)	Mandatory
LBL_300	Contract Manufacturers shall encode the Lot Number in a 1D GS1-128 Linear Barcode AI(10) (See ABC Labeling Guidelines)	Mandatory
LBL_310	Contract Manufacturers shall encode the Expiration Date in a 1D GS1-128 Linear Barcode AI(17). This should be stored in YYMMDD format, per GS1 AIDC standards. (See ABC Labeling Guidelines)	Mandatory
LBL_320	Contract Manufacturers shall encode the Case Quantity in a 1D GS1-128 Linear Barcode AI(30) (See ABC Labeling Guidelines)	Mandatory
LBL_330	Contract Manufacturers shall label their product case with the GTIN in Human Readable format	Mandatory
LBL_340	Contract Manufacturers shall label their product case with the Serial Number in Human Readable format	Mandatory
LBL_350	Contract Manufacturers shall label their product case with the Lot Number in Human Readable format	Mandatory
LBL_360	Contract Manufacturers shall label their product case with the Expiration Date in Human Readable format; YYYY-MMM-DD, YYYY-MMM, YYYY-MM are the acceptable formats. Dates may be required with either hyphens, space or forward (\) or backslash (/) to separate the portions of the expiry date.	Mandatory

Rqmt ID	Requirement	Mand/Recom
	The use of YYMMDD is not acceptable.	
LBL_370	Contract Manufacturers shall label their product case with the Quantity in Human Readable format	Mandatory
LBL_371	Contract Manufacturers shall verify the readability of the 2D GS1 DataMatrix containing serialized information to a minimum of a ISO Grade C	Mandatory
LBL_372	Contract Manufacturers shall verify the readability of the GS1-128 barcodes containing serialized information to a minimum of a ISO Grade C	Mandatory
LBL_375	Contract Manufacturers shall verify human readable information via manual inspection, or OCV	Mandatory
LBL_377	Contract Manufacturers shall apply the case label to two adjacent sides; **preferable** using a corner wrap label.	Mandatory

### 6.3.1 Serialized Case label - Example of Corner Wrap

It is standard and best practice that case labels, utilize a 4" x 10" corner wrap label.

6.3.2 Serialized Case Label – Non-Corner Wrap Case Label Placement Example

Although not preferred, in the event that a corner wrap label is not feasible, two like labels shall be 1.00" from the shared corner and 1.25" from the bottom of the case.
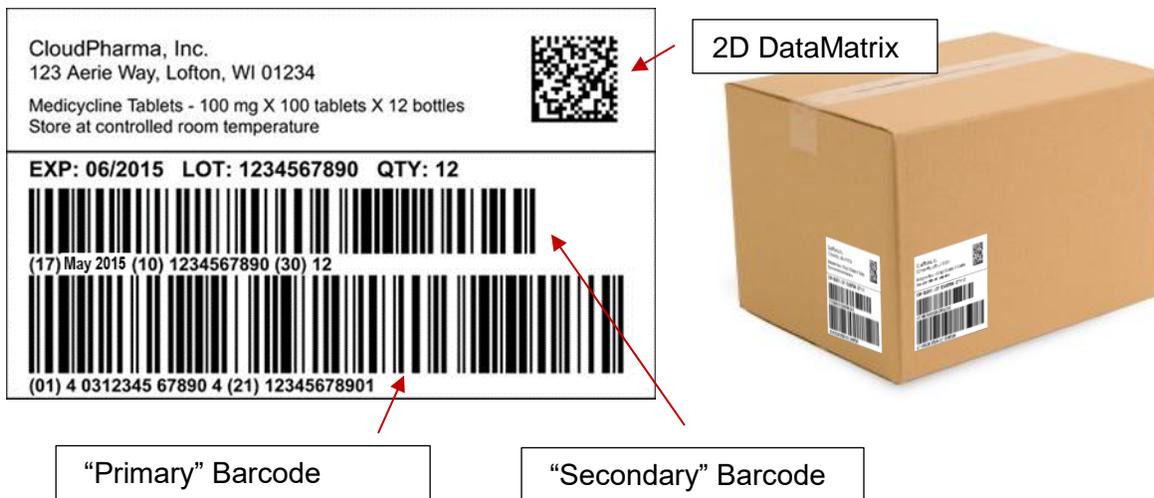
6.4 Non-Homogenous/Partial Cases & Pallet Labeling Requirements

The following requirements are applicable to those labels applied to all non-homogenous cases, partial cases, and shipper pallets.

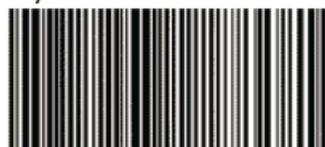| Rqmt ID	Requirement	Mand/Recom
LBL_380	Contract Manufacturers shall label their non-homogenous (mixed) and partial (not full) cases with an 18 digit SSCC in a GS1-128 Barcode using AI(00)	Mandatory **Optional** IF required to follow DGFT GTIN application on all cases
LBL_400	Contract Manufacturers shall label their non-homogenous (mixed) and partial (not full) cases with the SSCC in Human Readable format	Mandatory **Optional** IF required to follow DGFT GTIN application on all cases
LBL_380	Contract Manufacturers shall label their product pallets cases with an 18 digit SSCC in a GS1-128 Barcode using AI(00)	Mandatory
LBL_400	Contract Manufacturers shall label their full product pallets with the SSCC in Human Readable format	Mandatory
LBL_410	Contract Manufacturers shall label their partial product pallets cases with an 18 digit SSCC in a GS1-128 Barcode using AI(00)	Mandatory
LBL_430	Contract Manufacturers shall label their partial product pallets with the SSCC in Human Readable format	Mandatory
LBL_440	Contract Manufacturers shall verify the readability of the SSCC GS1-128 barcode to a minimum of a ISO Grade C	Mandatory
LBL_450	Contract Manufacturers shall verify SSCC human readable information via manual inspection, or OCV, on the Pallet Label	Mandatory

6.4.1 Packaging Serialized Shipping Container Codes Label Example

Below is an example of an SSCC-18 Label that would be used on all homogenous pallets coming from packaging facilities.

6.4.2 Logistics Serialized Shipper Container Code Label Example

Below is an example of an SSCC-18 Label that would be used on all logistic pallets coming from a 3PL or manufacturer distribution center:

1. **Ship-From Information**
Enter the origin address
Rec'd Font Size 10-12pt; Area 1" x 1 ¾"

2. **Ship-To Information**
Enter the customer warehouse address
Rec'd Font Size 10-12pt; Area 1" x 2 ¼"

3. **Ship-To Postal Code**
Enter as shown, with bar code of zip code below
Rec'd Font Size 10-12pt; Area 1" x 2"

4. **Shipper Information**
Include four-digit SCAC code of carrier, route (opt), bill of lading or carrier/PRO number
Rec'd Font Size 10-12pt; Area 1" x 2"

5. **PO Number**
Enter the customer PO number with bar code of the number below
Rec'd Font Size 20-24pt; Area 1"x 4"

6. **Expanded Supplier Name**
Enter the first seven characters of the supplier's name
Rec'd Font Size 36-40pt; Area 1" x 2 ¾"

7. **Customer Warehouse ID**
Enter the four-digit Customer warehouse number (first four digits from PO number)
Rec'd Font Size 36-40pt; Area 1" x 1 ¼"

8. **SSCC**
Enter the SSCC Identifier with large bar code below
Rec'd Font Size 18-22pt; Area 2" x 4"

SSCC 18 Product Code Break Down:

6.5 Contract Manufacturing Process, Data and Technical Requirements

The following are requirements for interfacing with AmerisourceBergen Business's serial number management repository. Note that specifics around integration with the serial number management repository will be provided in a separate interface specification document.

Rqmt ID	Requirement	Mand/Recom
SN_080	Contract Manufacturers shall be able to integrate with AmerisourceBergen Business's serial number management system via an automated interface via sFTP or AS2	Mandatory*
SN_085	Contract Manufacturers shall support sending serial number events via GS1 EPCIS 1.0 or higher.	Mandatory*
SN_090	Contract Manufacturers shall send serial number information (commissioning, pack (if aggregating), and ship events) for completed lots of product only.	Mandatory*
SN_100	Contract Manufacturers shall send serial number information to AmerisourceBergen Business's serial number management system after a lot has been completed and shipped; after CMO QA has signed off	Mandatory*
SN_110	Contract Manufacturers shall include, in the ship event, the related purchase order number.	Mandatory*
SN_160	If repackaging product, the contract manufacturer shall also communicate a list of consumed serial numbers (decommissioned) back to the ABC product owner as part of the batch record.	Mandatory*

*AmerisourceBergen Business recognizes that not all Contract Manufacturers have varying levels of technical capabilities. This will be evaluated on a case by case bases and it will be determined how much and to what level of data exchange will occur.

When a contract manufacturer is ready for data exchange, the SSC operations team will engage with the CMO and begin the onboarding process.
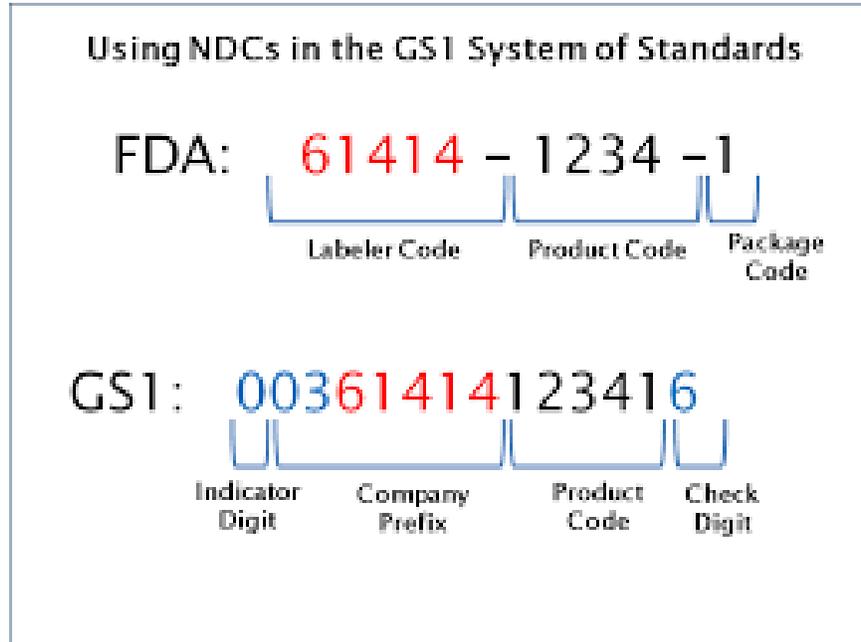
6.5.2 Process for Exchanging Data

The following is a typical process and data flow for exchanging POs & serialized data between CMOs.
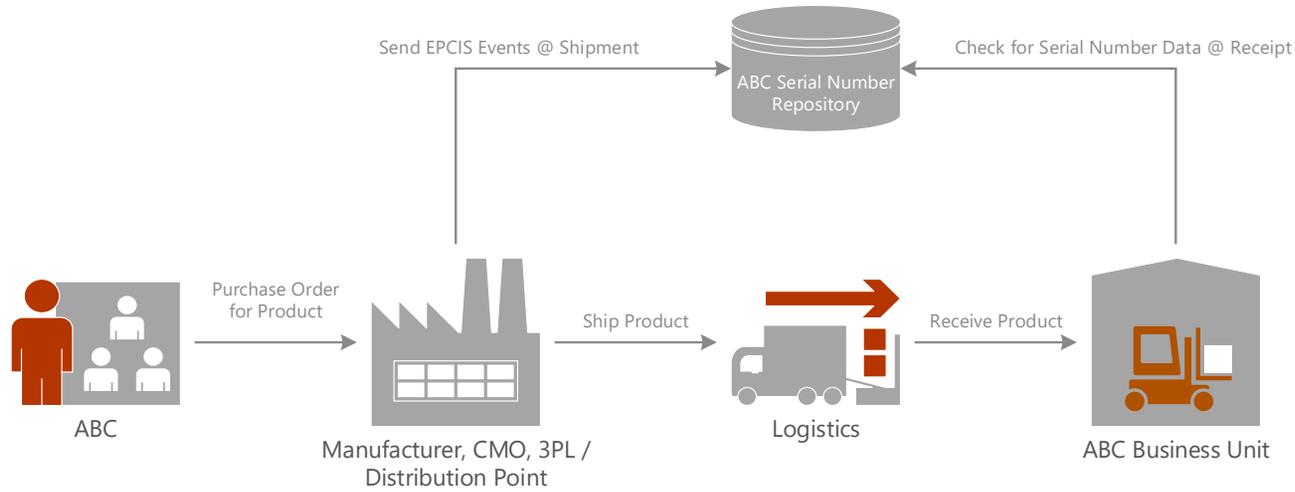
7. **Appendix**

7.1 Converting NDC to a GTIN

7.2 HDA Case Specification

See homogenous case labeling examples.

HDMA Shipping Case Product Identification Label – Summary Specifications
Bar Code Symbology, Encoded Data Element, Human-Readable Interpretation (HRI) & Print Quality

Important Parameters		Format #1 – GTIN+SERIAL NUMBER
Symbology (see Note 1)	Primary:	GS1-128 (incl. FNC1 where req'd)
	Secondary:	GS1-128 (incl. FNC1 where req'd)
	2D Prim+Sec.:	GS1 DataMatrix (incl. FNC1 where req'd)
Encoded Data Elements (see Note 2)	Primary:	GTIN-14 + SN: AI(01)+AI(21)
	Secondary:	EXP + LOT + QTY: AI(17)+AI(10)+AI(30)
	2D Prim.+Sec. COMBINED:	GTIN-14 + SN + EXP + LOT + QTY: AI(01)+AI(21)+AI(17)+AI(10)+AI(30)
GS1-128 Bar Code Symbol X-dimension Primary & Secondary	Preferred:	16.7-20.0 mils (0.0167-0.0200 in.)
	Minimum:	13.3 mils (0.0133 in.)* *Use largest X-dim that will fit on the label
GS1-128 Bar Code Symbol Height Primary & Secondary (Increased height can improve scannability)	PRIMARY	GTIN-14 + SN: AI(01)+AI(21)
	Preferred:	0.75 inches
	Minimum:	0.5 inches
	SECONDARY	EXP + LOT + QTY: AI(17)+AI(10)+AI(30)
	Preferred:	0.5 inches
	Minimum:	0.4 inches
GS1 DataMatrix (2D) Bar Code X-dimension	Preferred:	30.0 mils (0.0300 in.)
	Minimum:	30.0 mils (0.0300 in.)
Bar Code Quiet Zones - MINIMUM Width	GS1-128	10X (10 times X-dim; 0.20" recommended)
	GS1 DataMatrix	3X (3 times X-dim; 0.10" recommended)
Bar Code Quality - MINIMUM Grade	GS1-128	1.5/10/660 (per GS1 & ISO/IEC 15416)
	GS1 DataMatrix	1.5/20/660 (per HDMA & ISO/IEC 15415)
Position of Bar Code Symbols on Label	2D Prim.+Sec.:	GS1 DataMatrix, Upper Right Corner
	Secondary:	GS1-128, Directly Above Primary Symbol
	Primary:	GS1-128, Bottom of Label
Bar Code Human-Readable Interpretation (HRI) Position & Size	2D Prim.+Sec.:	None (Data is IDENTICAL to Prim. & Sec.)
	Secondary:	Below GS1-128, 10 Point (8 pt. min.)
	Primary:	Below GS1-128, 10 Point (8 pt. min.)
Secondary Data DESC.	Secondary:	Above GS1-128, 12 Point (10 pt. min.)
Printing Process and Substrate	All Labels	Thermal Transfer Pressure-sensitive Label
Label Skew	All Labels	+/- 2 Degrees from Horizontal** **Approx. 0.15 inch Across a 4" Wide Label

2D GS1 DataMatrix Specifications

Note 1: Primary and secondary data in separate GS1-128 bar codes and GS1 DataMatrix are required.
Note 2: GS1-128 & GS1 DataMatrix symbols encode FNC1 at the beginning of the symbol and as a variable-length field delimiter, as required.

GTIN:	FNC1+AI(01)+GTIN
GTIN+SN:	FNC1+AI(01)+GTIN+AI(21)+SN
EXP+LOT+QTY:	FNC1+AI(17)+EXP+AI(10)+LOT+FNC1+AI(30)+QTY
GTIN+SN+EXP+LOT+QTY:	FNC1+AI(01)+GTIN+AI(21)+SN+FNC1+AI(17)+EXP+AI(10)+LOT+FNC1+AI(30)+QTY