The Global Language of Business

2020 Update: Progress on 2023 DSCSA Interoperability

Pharmaceutical Industry on Steady March Toward Readiness

A History of the Assessments

In 2017, AmerisourceBergen Corporation and McKesson Pharmaceutical in collaboration with GS1 Healthcare US® launched a program to take "a snapshot of implementation progress" in meeting the requirements of the Drug Supply Chain Security Act (DSCSA)[1]. In 2018, Cardinal Health joined the effort, with each company taking a different slice of their wholesale operations to assess barcode readability: AmerisourceBergen would assess package (lowest saleable unit) barcoding of specialty pharmaceuticals, those prescribed by specialists and for unique therapeutic uses. To avoid duplication, McKesson would measure packages (lowest saleable units) of prescription (Rx) drugs, those in wide use sent to hospitals and retail pharmacies. Cardinal would evaluate compliance progress with the labeling of homogeneous cases.

Both AmerisourceBergen and McKesson – dealing with some items that could have small packaging profiles – would be gauging the use of a two-dimensional (2D) barcode (e.g., GS1 DataMatrix barcode), while Cardinal would be evaluating either 2D or linear barcodes (e.g., GS1-128 barcode)[2]. As part of the requirements, both methods of identification must be marked marked with a U.S. Food and Drug Administration (FDA) National Drug Code (NDC), serial number, lot number, and expiration date. (When using GS1 Standards, the NDC may be represented by a GS1 Global Trade Item Number® or GTIN®.)[3]

In keeping with recommended COVID-19 safety protocols, GS1 US did not conduct its side-by-side auditing at the wholesalers' facilities for the 2020 assessment.

2020 Improvements

The 2019 year-over-year assessment showed a steep rise in compliance; 2020 produced still more positive results with proper barcoding on packages coming in at double-digit (19%) gains, rising from 73 percent to 87 percent. Case level improvements rose from 78.7 percent to 93 percent, an 18 percent improvement.

Background

In 2013, the U.S. FDA enacted the DSCSA requiring the pharmaceutical industry to adopt a means of identifying and tracing certain pharmaceuticals distributed throughout the United States. Because of the complexity of the implementation, drug manufacturers were given a ten-year period to come into compliance with the traceability initiative using a phased approach.

Soon after the DSCSA was enacted, the pharmaceutical industry came together and agreed on using GS1 Standards as the platform for DSCSA compliance efforts, a practical decision based on the ubiquity of these standards used in supply chain and trading partner communications throughout the world.

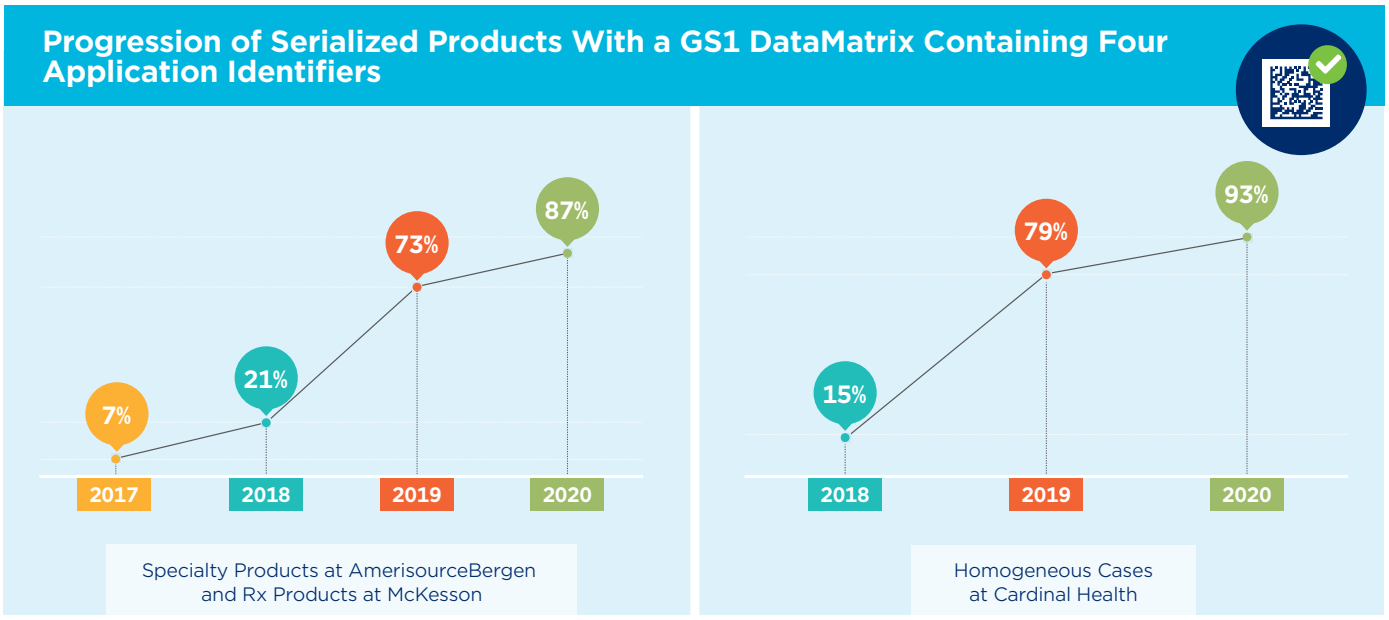
1 Drug Supply Chain Security Act, Pub. Law No. 113-54, 127 Stat 599 (2013).

2 Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(a)(9)[A], 127 Stat 599, 608 (2013).

3 Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(b)(2)(A), 127 Stat 599, 609 (2013).

Results from the 2020 Barcode Assessment with the 2D GS1 DataMatrix found that the products properly labeled with all four Application Identifiers (AIs) can be broken out as follows:

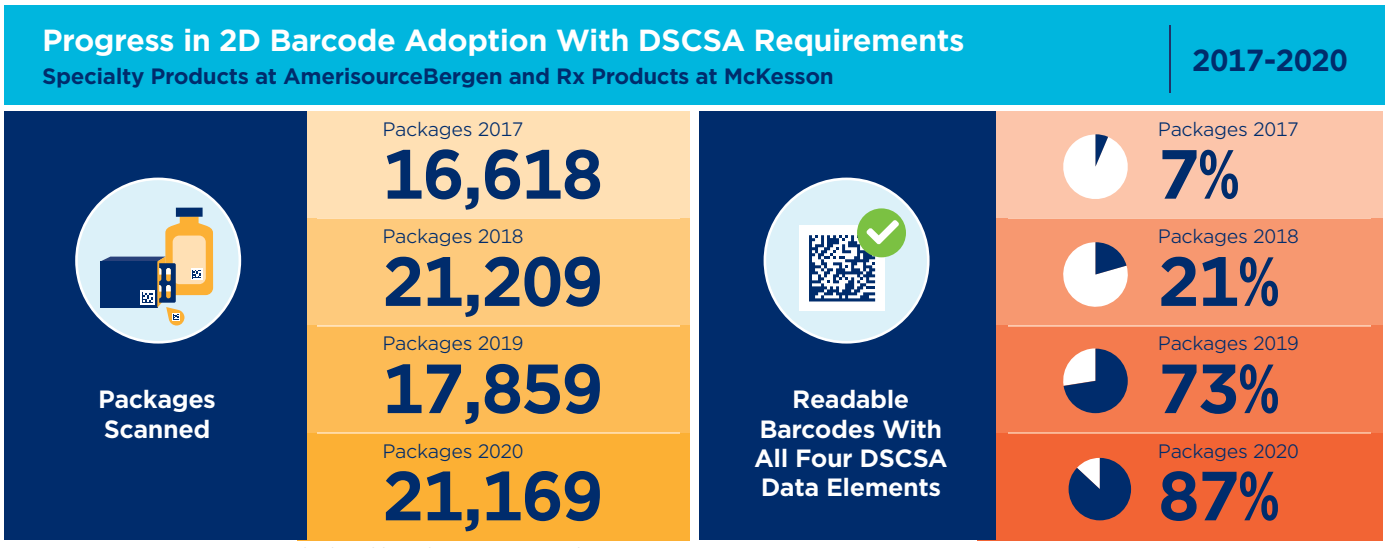
- Specialty packages tracked by AmerisourceBergen achieved a 90.1 percent rate of compliance
- Rx packaged drugs tracked by McKesson achieved an 86.6 percent rate of compliance, and
- Homogeneous cases tracked by Cardinal attained a level of 93.1 percent for compliance.



Source: 2020 GS1 US Barcode Assessment

Figure 1. Four Application Identifiers (AIs) were complete: GTIN (with embedded NDC), Serial Number, Lot Number and Expiration Date.

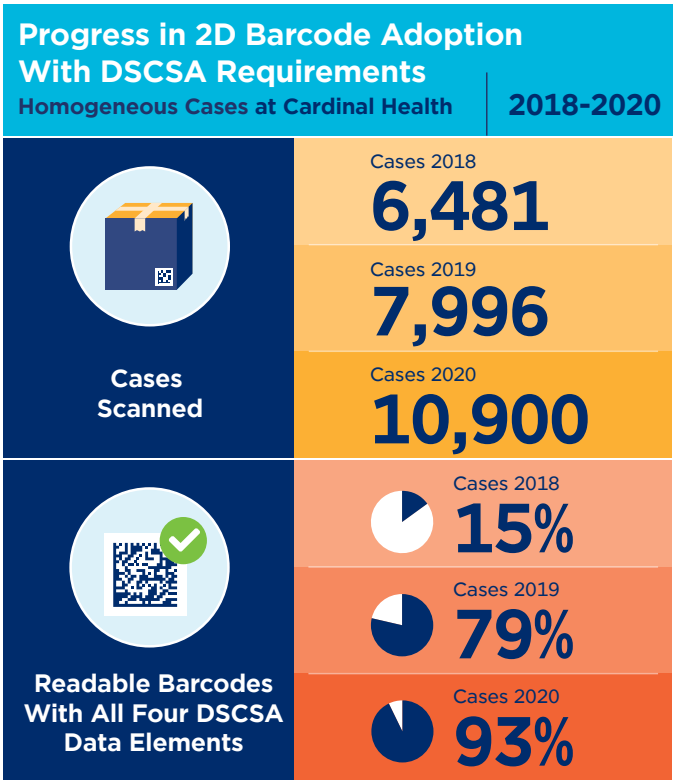
"In previous years we were trying to measure the adoption of the 2D barcode and the product identifier," says Scott Mooney, vice president of distribution operations for McKesson. "But 2020 was the last measurement point before the first required utilization of that barcode in DSCSA, so it was more critical because it presented the 'last view' before the interim deadline in November. I had expected the number to have moved up some, but I don't know that I had expected it to move up almost 20 percent from what we had seen last year. It had significance, because that increase now means that an appreciably higher number of products would be going through the salable returns verification, had that process not recently been deferred by the U.S. FDA."



Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

Figure 2. A steady climb in compliance has been seen on all "lowest saleable units."

"Every year our barcode assessment shows better and better results. Manufacturers have more time to understand the requirements, more time to get grandfathered products out of the supply chain, more time to act on feedback on what they may be doing wrong and how they can improve on it from all the different downstream partners, including us," says Trevaun Willey, Cardinal's senior consultant, Operations Technology.



Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

Figure 3. As the number of cases scanned for assessments has grown, so too has the percentage of cases with all data elements increased.

Expiration and Experience

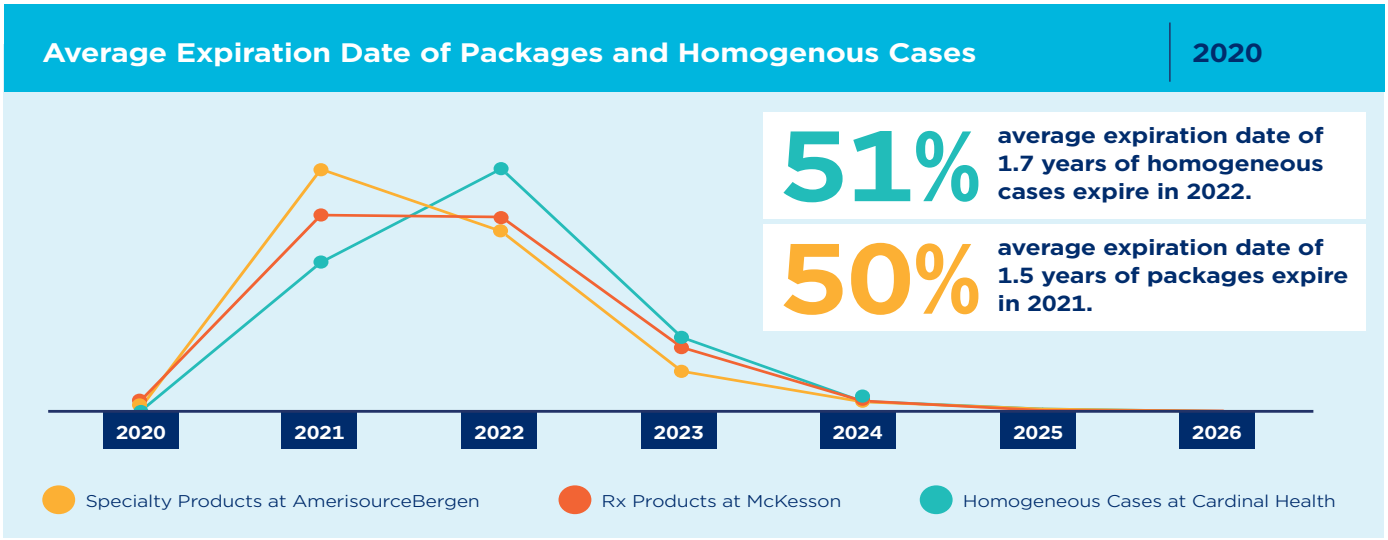
The double zero day remains a challenge because it does not fit the data format for the Electronic Product Code Information Services (EPCIS) standard used for exchanging product information. It is discouraged for use in the barcode itself. Again in 2020, the analysis showed that almost two percent of the serialized items had a "00" expiration date. Interestingly, this was four percent on specialty packages, and four percent on the homogeneous cases, while the Rx packages had no 00 expiration dates.

Last year, a significant year-over-year change was seen in the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. The average expiration date of products in the Big 3 wholesalers' distribution centers in 2020—1.6 years—is the exact same result as 2019.

A discrepancy between a Universal Product Code (U.P.C.) on a package and a 2D barcode can also cause downstream problems. "GS1 has a standard relating to how these two codes interrelate to each other," Mooney says, "and when two barcodes have differing GTINs, the opportunity for confusion becomes obvious."

As competitors, the three wholesalers cannot "compare notes," but can rely on GS1 US—as a neutral party—to take the lead in communicating data anomalies with the industry.

Aggregated, all 51,400 scans at the Big 3 resulted in a 90.1 percent rate of compliance with three years still remaining until the final DSCSA deadline. Because it is used in a number of commercial ways, not surprisingly the GTIN (with the NDC embedded) was the most consistently found identifier on every unit scanned, ranging from a low of 93.1 percent (Rx packages) to highs of 97.8 (homogeneous cases) and 99.7 percent (specialty). The second most frequent identifier captured varied.



Source: 2020 GS1 US Barcode Assessment

Figure 4. Product expiration dates at all three wholesalers remained consistent, following similar timelines.

Barcode Assessments Reveal Challenges for Industry to Address

Color and Size. Initially, barcode color combinations and sizes varied, causing scanning and data capture issues. When selecting colors and printing the barcode, a black symbol on a white background produced no-fault scanning. Other colors either would not scan at all or produced inconsistent results. Some symbols were too small, and those products that carried QR and other barcodes could cause confusion and issues. GS1 Standards address these issues.

Placement and Uniformity. Barcode placement ran the gamut: bottoms or tops of bottles or boxes, wrapping around cases, printed on shiny surfaces, attachments blocking easy access to codes. Some were printed too close together or print was smudged. These issues hinder scanning. On those that require a 2D code along with a retail point-of-sale code (UPC), both must carry the same GTIN.

00 Dates. 00 date designations, while technically correct in terms of the barcode, are problematic when that date is used later in digital data transfer. When shared between manufacturers, distributors and dispensers, the zero-zeroes in the date field will error out and not work for anything other than being printed in the barcode. GS1 Healthcare US recommends using an actual day to avoid confusion and ambiguity, and support transmission of the date through inventory systems.

Special Characters in Lot/Serial Numbers. The need for continued attention to scanning issues was demonstrated in 2020 when special characters – dots, dashes and slashes – used in the lot and serial number fields posed challenges when data is exchanged between trading partners. Although acceptable by GS1 Standards, computers sometimes interpret the characters as messaging protocols rather than data elements. GS1 is working alongside the industry to develop an acceptable solution to circumvent the issue going forward. Similarly, the use of leading zeros in lot and serial numbers should be avoided to eliminate risk of mismatches if they are dropped.

Still Just A Snapshot

Even with all the issues worked through to date, barcode assessments are just a snapshot of industry adoption and compliance with the DSCSA and will always be an ongoing process. New products coming onto the market, new packaging developed for existing products, third party manufacturers being contracted by pharmaceutical companies all present the potential for tweaks to serialization.

“The assessments are a good representation, but things can go awry,” says Liberty Dewey, senior consultant for Cardinal’s Operations Technology. “For example, a manufacturer proactively reached out to us to let us know their contract manufacturer had put quantity into the barcode and asked if it was going to cause problems with our receiving or our returns verification. The need to continually check compliance will be an ongoing endeavor.”

With more than a single recipient or destination for the serialized information, accuracy and consistency become vital. The need to address a data issue no matter its seeming significance – small or large, showstoppers or hiccups – is paramount to smooth interoperability downstream.

“There are a lot of different systems exchanging data. Data posted in one system and then extracted and sent to another system – even within the same company – has enormous implications for harmonizing data,” says Ameer Ali, senior director of Manufacturer Operations at AmerisourceBergen.

Photo courtesy of AmerisourceBergen

"There's the warehouse management system, the repository, the ERP, and the data exchange systems. There are some hard errors – showstoppers – while others are simply not in accordance with the guidelines or recommendations, like leading zeros in serial or lot numbers. These soft errors may cause a problem in the future if not addressed."

"The assessments are a good representation, but things can go awry … The need to continually check compliance will be an ongoing effort."

Liberty Dewey
Senior Consultant, Operations Technology, Cardinal Health

Digital Twins Close Loop

A wholesaler cannot receive serialized product from a manufacturer, until serialized data accompanies it. A "digital twin" allows the industry to move to the next step of capturing serialized sales to the entity dispensing the drug. An individual unit can only be identified when it carries a readable GS1 2D DataMatrix barcode. Until the loop is completed you cannot provide a purchaser with serialized DSCSA information.

"We are quickly approaching the point in time where the majority of the items have the barcode and it's accurate," Mooney says, "and it's repeatable from package to package. Now we can begin to move on to those data-capture, data-sharing events that are necessary to finish out the DSCSA."

For the Big 3, the DSCSA requirements can improve productivity. "If manufacturers are using 2D barcodes, it only requires one scan as opposed to two scans to get all four product identifiers from two linear barcodes. If they have all product identifiers encoded—especially in a 2D barcode—it can be a very easy receiving process." says Josh Dritz, director of operations technology at Cardinal.

"Get it done, get it tested, and have a high degree of confidence that when 2023 arrives, your products can continue to move."

Scott Mooney
Vice President, Distribution Operations, McKesson Pharmaceutical

Conversely, the lack of all four product identifiers means conducting extra steps to be able to verify that they are missing and then logging the information to go back to the manufacturer in question. "We currently have it set up to do two additional scans to be able to try to get all four. If the receiver is not able to do that then we need to perform a grandfather function, mark it as a bad barcode. Additional steps are needed, which adds more time to the receiving process," Dritz says.

"And it creates an exacerbated productivity issue and it also creates inventory issues because product is either quarantined or morgued, depending on the result of the return verification. This is an issue with individual products rather than at the case level," Dewey says.

Patient Safety and Beyond

GS1 Standards are one of the reasons for commonalities in successful serialization within the industry. With so many data points, so many application locations, and so much individualized inventory, the guidance provided by GS1 will eventually bring thousands of products through thousands of supply chain checkpoints with nearly complete visibility and traceability.

A mismatch or a failure to verify a product disrupts the supply chain operation whether at the wholesale distributor, at the receiving dock, at the drug dispensary or at the point of returns. One error causes a ripple effect, upstream and downstream.

"Compliance is a prerequisite to verification, to the accurate exchange of data and to achieve full traceability in 2023."

Ameer Ali
Senior Director of Manufacturer Operations at AmerisourceBergen

"The top priority is compliance – but barcode compliance is just part of a multi-phased plan. The proper physical labelling and barcoding is going to set up the next phase: data exchange and traceability from beginning to end of the supply chain," Ali says. "Compliance is a prerequisite to verification, to the accurate exchange of data and to achieve full traceability in 2023."

"If you're talking about the ability to apply serialized barcodes to products per DSCSA, I think there's a wider understanding than ever before. But if you're talking about the readiness to create interoperable systems inclusive of saleable returns verification … I think that we remain concerned about the amount of work that lies ahead of us. Thankfully the FDA's enforcement discretion allows the industry to focus more attention on 2023 interoperability."

Josh Dritz
Director, Operations Technology, Cardinal Health

Expert Advice: Communication and Focus

Communicate. All three wholesalers communicate with their manufacturer partners on the progress being made on DSCSA requirements. Each company communicates with manufacturers with specifics about their product data. AmericsourceBergen, for instance, developed a mobile application that enables it to photograph products with problematic barcodes, thereby attaching a visual representation of the precise concern to the appropriate supplier.

"I encourage manufacturers to review the information in our published reports. In each of the years to-date, the analytics have identified trends or patterns, which could be problematic. The information is very valuable for their understanding of the barcoding they're applying," Mooney says.

Focus. The Big 3 are unified in their advice to manufacturers to stay focused on serialization programs. While some may wish to defer compliance efforts because of accelerated costs, it's a risky decision.

Perhaps a character set is encoded incorrectly or a GTIN is not based on an U.S. FDA NDC number. When those issues arise, the manufacturer will get feedback to correct the errors before they become endemic to its entire portfolio.

"Get it done, get it tested, and have a high degree of confidence that when 2023 arrives, your products can continue to move," says Mooney.

"If you're talking about the ability to apply serialized barcodes to products per DSCSA, I think there's a wider understanding than ever before," Dritz says. "But if you talk about the readiness to create interoperable systems inclusive of saleable returns verification, inference between "eaches" (lowest saleable units) and cases, the ability to trade information electronically, I think that we remain concerned about the amount of work that lies ahead of us. Thankfully, the U.S. FDA's enforcement discretion allows the industry to focus more attention on 2023 interoperability."

Following standards faithfully is critical to success in any industry, but especially in such a global one that deals in life-saving products. "Manufacturers have different ways of doing things or different interpretations, which could result in variation and downstream exceptions that disrupt product flow. This was likely a driver behind DSCSA language requiring conformance to international standards, like the ones developed by GS1," Ali says.

Learn More

Visit **www.gs1us.org/dscsa**.

About the Companies

About AmerisourceBergen

AmerisourceBergen Corporation is one of the world's largest pharmaceutical services companies, serving global markets with a focus on the pharmaceutical supply chain. Servicing pharmacies, providers and pharmaceutical manufacturers, the company provides global product sourcing and distribution and related solutions designed to improve product access, increase supply chain efficiency and enhance patient care. www.amerisourcebergen.com

About Cardinal Health

Headquartered in Dublin, Ohio, Cardinal Health, Inc. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, health systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company provides clinically-proven medical products and pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Backed by nearly 100 years of experience, with approximately 50,000 employees in nearly 60 countries, Cardinal Health ranks among the top 25 on the Fortune 500. www.cardinalhealth.com

About McKesson Pharmaceutical

McKesson Corp. is a global health services and information technology company, which provides medicines, pharmaceutical and care management products. It operates through the McKesson Distribution Solutions and McKesson Technology Solutions segments. The McKesson Distribution Solutions, which includes McKesson US Pharmaceutical, distributes ethical and proprietary drugs, medical-surgical supplies and equipment and health and beauty care products throughout North America. This segment also provides specialty pharmaceutical solutions for biotech and pharmaceutical manufacturers, provides financial, operational and clinical solutions for pharmacies. www.mckesson.com

About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to help improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1. www.gs1us.org/healthcare

About GS1 US

GS1 US®, a member of GS1® global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). www.gs1us.org

Proprietary Statement

This document contains proprietary information of GS1 US. Such proprietary information may not be changed for use with any other parties for any other purpose without the expressed written permission of GS1 US.

Improvements

Improvements and changes are periodically made to publications by GS1 US. All material is subject to change without notice. Please refer to GS1 US website for the most current publication available.

Disclaimer

Except as may be otherwise indicated in specific documents within this publication, you are authorized to view documents within this publication, subject to the following:

1. You agree to retain all copyright and other proprietary notices on every copy you make.
2. Some documents may contain other proprietary notices and copyright information relating to that document. You agree that GS1 US has not conferred by implication, estoppels, or otherwise any license or right under any patent, trademark, or copyright (except as expressly provided above) of GS1 US or of any third party.

This publication is provided "as is" without warranty of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, or non-infringement. Any GS1 US publication may include technical inaccuracies or typographical errors. GS1 US assumes no responsibility for and disclaims all liability for any errors or omissions in this publication or in other documents which are referred to within or linked to this publication. Some jurisdictions do not allow the exclusion of implied warranties, so the above exclusion may not apply to you.

Several products and company names mentioned herein may be trademarks and/or registered trademarks of their respective companies. GS1 US does not, by promulgating this document on behalf of the parties involved in the creation of this document, represent that any methods, products, and/or systems discussed or recommended in the document do not violate the intellectual property rights of any third party. GS1 US has not performed a search to determine what intellectual property may be infringed by an implementation of any strategies or suggestions included in this document. GS1 US hereby disclaims any liability for any party's infringement of intellectual property rights that arise as a result of any implementation of strategies or suggestions included in this document.

This publication may be distributed internationally and may contain references to GS1 US products, programs, and services that have not been announced in your country. These references do not imply that GS1 US intends to announce such products, programs, or services in your country.

GS1 US shall not be liable for any consequential, special, indirect, incidental, liquidated, exemplary, or punitive damages of any kind or nature whatsoever, or any lost income or profits, under any theory of liability, arising out of the use of this publication or any content herein, even if advised of the possibility of such loss or damage or if such loss or damage could have been reasonably foreseen.

GS1 US HEREBY DISCLAIMS, AND YOU HEREBY EXPRESSLY RELEASE GS1 US FROM, ANY AND ALL LIABILITY RELATING TO YOUR COMPLIANCE WITH REGULATORY STANDARDS AND LAWS, INCLUDING ALL RULES AND REGULATIONS PROMULGATED THEREUNDER. GS1 US MAKES NO WARRANTIES OF ANY KIND RELATING TO THE SUITABILITY OF THE GS1 STANDARDS AND THE SPECIFIC DOCUMENTS WITHIN THIS PUBLICATION TO COMPLY WITH ANY REGULATORY STANDARDS, LAWS, RULES AND REGULATIONS. ALL INFORMATION AND SERVICES ARE PROVIDED "AS IS."

*GS1 US employees are not representatives or agents of the U.S. FDA, and the content of this publication has not been reviewed, approved, or authorized by the U.S. FDA. The following information contained herein is for informational purposes only as a convenience, and is not legal advice or a substitute for legal counsel. GS1 US Inc. assumes no liability for the use or interpretation of the information contained herein.

No Liability for Consequential Damage

In no event shall GS1 US or anyone else involved in the creation, production, or delivery of the accompanying documentation be liable for any damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, or other loss) arising out of the use of or the results of use of or inability to use such documentation, even if GS1 US has been advised of the possibility of such damages.

IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

*If applicable

GS1 US Corporate Headquarters

Princeton South Corporate Center, 300 Charles Ewing Boulevard
Ewing, NJ 08628 USA
T +609.620.0200 | **E** info@gs1us.org
www.gs1us.org

Connect With Us

6 14141 02828 3