



2018 Update: Implementation of DSCSA Serialization Requirements

Three Pharmaceutical Wholesalers Assess Progress Since 2017

In May 2017, AmerisourceBergen and McKesson Pharmaceutical (McKesson), in collaboration with GS1 Healthcare US[®], assessed lowest sellable unit barcodes in their distribution facilities to obtain a “snapshot” of industry’s progress implementing serialization requirements of the 2013 Drug Supply Chain Security Act (DSCSA).¹ AmerisourceBergen and McKesson shared their results, impressions, and recommendations in a joint report² published by GS1 US in early 2018.

To follow up, AmerisourceBergen and McKesson conducted a second series of barcode assessments in May 2018 to gain an up-to-date view of suppliers’ progress. Cardinal Health joined the effort, conducting its own barcode assessment of homogeneous cases from pharmaceutical manufacturers, with support from GS1 Healthcare US.

“Our goal was to refresh the 2017 assessment results and gauge the 12-month progress,” says Ameer Ali, senior manager of Secure Supply Chain & Manufacturer Operations at AmerisourceBergen.

The DSCSA defines the requirements for an interoperable, electronic system to identify and trace pharmaceutical products throughout their distribution in the United States.³ As part of the requirements, pharmaceutical products must be marked with a National Drug Code (NDC), serial number, lot number, and expiration date.⁴ (When using GS1 Standards, the NDC is represented by a GS1 Global Trade Item Number[®] or GTIN[®].)

The DSCSA also specifies that packages (known as “lowest saleable units” in industry) must be marked with a two-dimensional (2D) barcode (e.g., GS1 DataMatrix barcode), and homogeneous cases with either a 2D barcode or linear barcode (e.g., GS1-128 barcode).⁵

AmerisourceBergen and McKesson conducted a second series of barcode assessments in May 2018 to gain an up-to-date view of suppliers’ progress. Cardinal Health joined the effort, conducting its own barcode assessment of homogeneous cases from pharmaceutical manufacturers, with support from GS1 Healthcare US.

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

2 GS1 US (February 2018). Assessing Current Implementation of DSCSA Serialization Requirements: Two pharmaceutical wholesalers take a snapshot of where industry stands on Phase 2 implementation. Retrieved September 14, 2018 from https://www.gs1us.org/documents?Command=Core_Download&EntryId=1210

3 United States. Department of Health and Human Services. Food and Drug Administration (FDA) (n.d.). “Drug Supply Chain Security Act.” Accessed September 14, 2018 at: <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

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

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



Photo courtesy of AmerisourceBergen

Although the statute provides that these requirements must be implemented by November 27, 2017, the U.S. FDA issued a [draft guidance](#) on June 30, 2017, informing industry that it was delaying enforcement until November 2018, to provide manufacturers additional time and avoid supply disruptions.⁶

“The one big change this time around, of course, was the U.S. FDA’s decision to delay enforcing requirements until November 2018,” says Scott Mooney, vice president of Distribution Operations, Supply Chain Assurance at McKesson. “With the expiration of the U.S. FDA enforcement discretion six months away, we were especially interested in any improvements in issues we identified in 2017, like barcode quality.”

Michael Rowe, manager of Operations Technology (Track & Trace), Cardinal Health, adds, “It was important for us to give our suppliers actionable ‘intelligence’ based on conducting an assessment. And for us, it provided an opportunity to drive standardization and increase efficiency for the entire supply chain.”

Assessment results offer an indicator of how many packages and cases in the market today are marked with a readable barcode containing the four DSCSA-required data elements.

With results from the May 2018 assessments, AmerisourceBergen, Cardinal Health, and McKesson are now able to follow up and share results with individual manufacturers so that they can make any course corrections—or accelerate implementation—as needed before the November deadline.

“The one big change this time around was the U.S. FDA’s decision to delay enforcing requirements until November 2018. With the expiration of the U.S. FDA enforcement discretion six months away, we were especially interested in any improvements in issues we identified in 2017, like barcode quality.”

Scott Mooney
Vice President of Distribution Operations, Supply Chain Assurance,
McKesson Pharmaceutical

⁶ United States. Department of Health and Human Services. FDA (June 2017). “FDA Issues Draft Guidance: Product Identifier Requirements Under the Drug Supply Chain Security Act - Compliance Policy.” Accessed September 14, 2018 at: <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm>

Consistent, Yet New Approach

Taking a consistent, year-over year approach, AmerisourceBergen and McKesson once again scanned 2D barcodes on product packages, tracking the percentage of readable 2D barcodes encoding an NDC, serial number, lot number, and expiration date.

Both wholesalers scanned package barcodes in the same distribution centers, assessing the same types of products. AmerisourceBergen assessed specialty medications and McKesson focused on prescription pharmaceuticals.

Yet, in 2018, the sample sizes were larger for both AmerisourceBergen and McKesson, and the scanning approach was different at McKesson:

- AmerisourceBergen scanned 5,009 packages (compared to 3,047 in 2017), representing 100 percent of on-hand products. Teams of two people (one from AmerisourceBergen and one from GS1 US) removed products from the shelves and scanned any available barcode. Information from the barcode scans was entered into a GS1 US database for compilation.
- McKesson scanned 16,200 packages (compared to 13,571 in 2017), representing 100 percent of on-hand products. A team comprised of only McKesson personnel scanned barcodes using production scanners, and captured scanned information in McKesson's own production system.

- At McKesson, a second sample of 1,482 packages was scanned by another team comprised of McKesson and GS1 US personnel. "GS1 US audited our results with their sample of scans, providing us with a 'quality check,'" explains Mooney. "We selected a diverse sampling of products throughout our building and then compared the results from the GS1 US sample scans with our McKesson-gathered data to make sure they were aligned and correlated."

Cardinal Health focused on homogeneous case-level barcodes on pharmaceutical products in its Ohio National Logistics Center. The [HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain](#) recommends that manufacturers use two linear barcodes with the NDC (GTIN) and serial number in one, and the lot number and expiration date in the other, and one 2D barcode encoding all four data elements.⁷ The Cardinal Health assessment encompassed both approaches.

- Cardinal Health scanned 15,708 barcodes on 6,481 cases. Teams comprised of both Cardinal Health and GS1 US members scanned barcodes on cases in the racks, including many located in high bays requiring forklifts. They scanned every available barcode, and information from the barcode scans was entered into a GS1 US database for compilation.

"While using linear barcodes is aligned with the DSCSA, in our supplier letters we recommend the use of two linear barcodes as a first step in the transition to ultimately using 2D barcodes," advises Rowe.

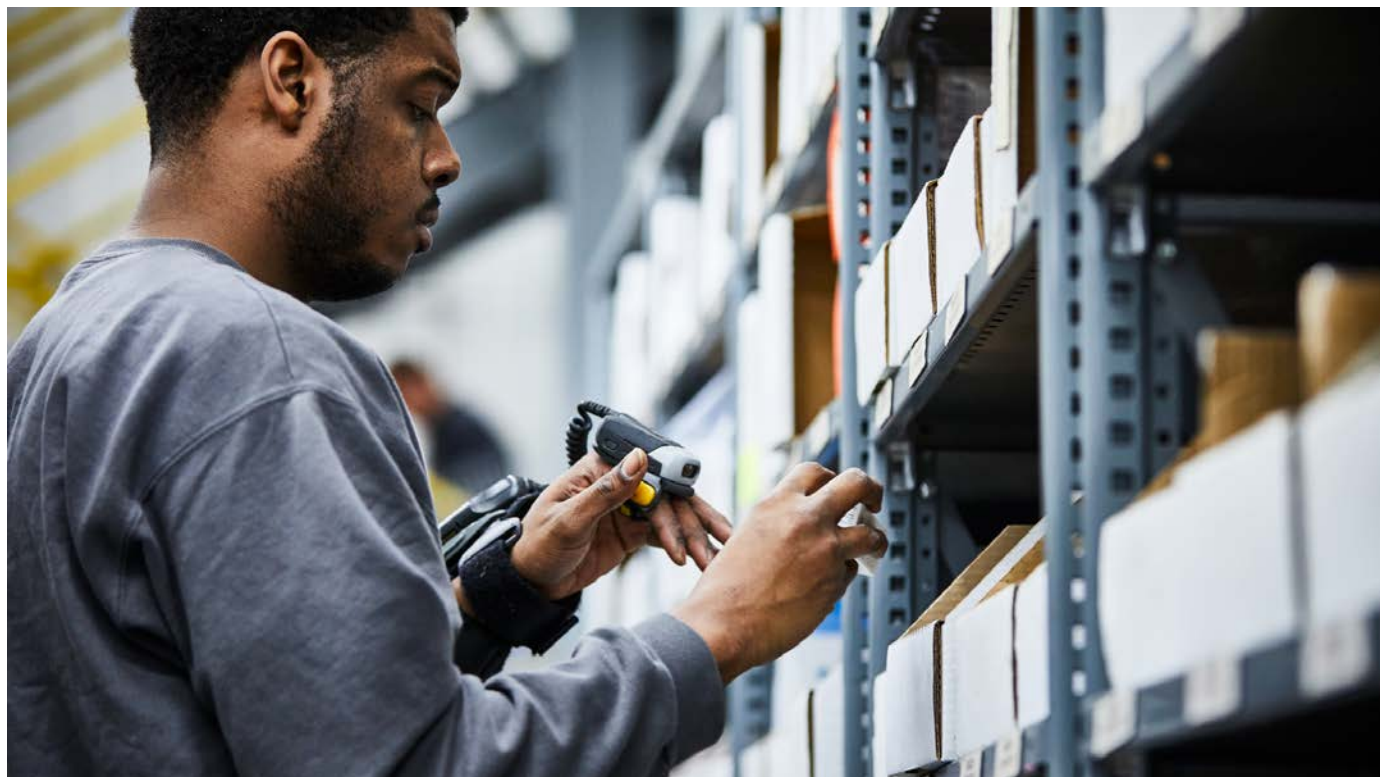
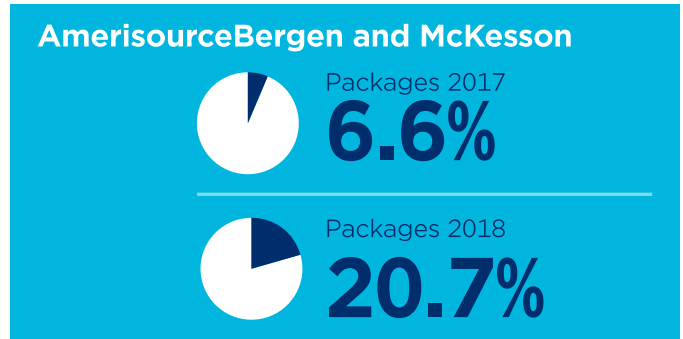
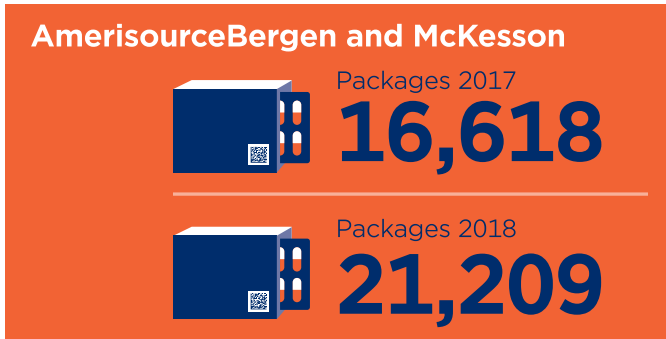
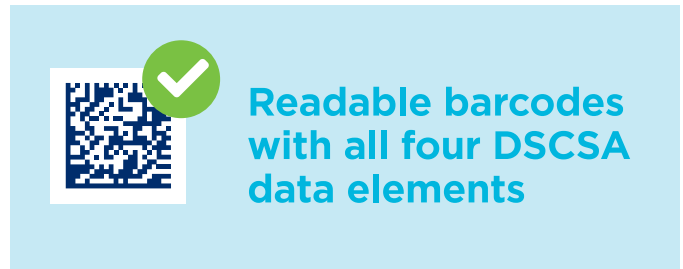


Photo courtesy of AmerisourceBergen

⁷ HDA (2017). HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain. Retrieved September 14, 2018 from <https://www.healthcaredistribution.org/resources/hda-guidelines-for-bar-coding-in-the-pharmaceutical-supply-chain>

Progress in 2D Barcode Adoption with DSCSA Requirements



Sources: AmerisourceBergen, McKesson Pharmaceutical, and Cardinal Health barcode assessments

Letters to suppliers from AmerisourceBergen and McKesson also include similar recommendations. For example, AmerisourceBergen plans to only scan the 2D GS1 DataMatrix barcode come 2023 for all its operations and is working with manufacturers to drive toward consistent adoption.

“While using linear barcodes is aligned with the DSCSA, in our supplier letters we recommend the use of two linear barcodes as a first step in the transition to ultimately using 2D barcodes.”

Michael Rowe
Manager of Operations Technology (Track & Trace), Cardinal Health

Making Progress

The results from the AmerisourceBergen and McKesson assessments showed a year-over-year increase of approximately 14 percentage points when compared to the 2017 assessment.

All wholesalers quickly admit that suppliers are making progress, but fell short of their expectations of 30 to 40 percent in 2018.

- At AmerisourceBergen, **20.4 percent** (1,025 packages) had a readable barcode with all four DSCSA-required data elements (compared to 7.2 percent in 2017).
- Similarly, at McKesson, **20.8 percent** (3,365 packages) had a readable barcode with all four DSCSA-required data elements (compared to 6.5 percent in 2017). Results from the GS1 US-scanned sample at McKesson were similar at 19.8 percent.
- At Cardinal Health, **15.1 percent** of homogeneous cases had readable 2D (GS1 DataMatrix) barcodes with all four data elements.

Top Observations

As part of the assessments, AmerisourceBergen, McKesson, and Cardinal Health noted the following observations:

Placement

In 2018, barcode color did not surface as an issue as much as it did in 2017. However, the three wholesalers agreed that the placement of barcodes on packages and cases remains an issue. “We noticed that many barcodes are too close to each other—something that is happening more frequently on cases than on packages,” says Ali of AmerisourceBergen.

“Having enough white space between barcodes is really critical,” agrees Rowe with Cardinal Health. “We have many manufacturers that are placing their labels too close to the edge of cases. So, the barcodes are wrapping around the case, making them unreadable. Two labels are also needed on each case since it may get scuffed up a bit going through the supply chain, damaging the label and barcode, but not the case or product within.”

GS1 Standards about barcode placement should be followed and can be found in section 6 of the [GS1 General Specifications](#).

UPC-A and GS1 DataMatrix

An issue observed by McKesson was the lack of alignment when suppliers need to use two barcodes: a UPC-A barcode to satisfy U.S. retail point-of-sale requirements and/or the [U.S. FDA Barcode Rule](#),⁸ and a 2D barcode for [DSCSA](#)⁹ requirements. The key to successfully using this marking strategy is that the GTIN in the UPC-A must be the same as the GTIN in the 2D barcode.

“We noticed that some suppliers had issues with this practice, including improperly formed GTINs,” explains Mooney. “This can cause confusion and problems for downstream trading partner scanning systems and transactional databases.”

GS1 Healthcare US prepared the document, [Guidance for Pharmaceutical Products Marked with Both UPC-A and GS1 DataMatrix](#) to assist U.S. manufacturers with the use of UPC-A and GS1 DataMatrix barcodes together.

“Serialization requires additional technology to generate, capture, and send serial numbers. We expect to see a large number of barcodes serialized over the next six months. That’s why we’re reaching out to help test these new labels, ensuring that they are done correctly without issues.”

Ameer Ali

Senior Manager of Secure Supply Chain & Manufacturer Operations, AmerisourceBergen

⁸ FDA Bar Code Label Requirement for Human Drug and Biological Products, 21 CFR §201.25 (2004).

⁹ DSCSA, Sec. 582(a)(9)[A][i].

Serialization

When analyzing the results, all wholesalers noted that the percentage of packages and cases with serial numbers in barcodes was lower than the other three data elements (i.e., NDC, lot number and expiration date).

For example, AmerisourceBergen found that only 77 percent of the 2D barcodes had serial numbers. “We weren’t surprised to see that,” says Ali of AmerisourceBergen. “Serialization requires additional technology to generate, capture, and send serial numbers. We expect to see a large number of barcodes serialized over the next six months. That’s why we’re reaching out to help test these new labels, ensuring that they are done correctly without issues.”

Rowe with Cardinal Health agreed. “We didn’t see as much serialized product as we had hoped for. My assumption is that some manufacturers are waiting to ‘turn on’ the serialization function and equipment since it can impact the productivity of their packaging line. As the deadline gets closer, barcodes with serial numbers should significantly accelerate.”

“Conducting the assessment has given us very specific data about each of our suppliers’ DSCSA barcode implementations . . . We have had conversations with about 50 manufacturers, to date, providing specific feedback on the barcode data we captured.”

Scott Mooney

Vice President of Distribution Operations, Supply Chain Assurance, McKesson Pharmaceutical

Expiration Date

One issue that continues to linger is the use of “zero-zero” as the day in the expiration date when encoding the barcode. “In 2017, we pointed out this issue and the problems it will cause when manufacturers, distributors, and dispensers share digital files (a requirement of DSCSA in 2023),” says McKesson’s Mooney.

A secondary problem was that the day in the expiration date was not being included in the human readable even when it was encoded in the barcode. “If a supplier correctly uses December 3 as the expiration date in the barcode, yet the human readable next to the barcode only shows the month and year (December 2018), the distributor could assume that the expiration date is December 30 rather than December 3,” explains Mooney.

GS1 Healthcare US, in its [GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#), recommends that manufacturers input an actual day to avoid confusion and ambiguity, and support transmission of the date through the inventory systems later on.

Detailed Feedback

AmerisourceBergen, McKesson and Cardinal Health are taking steps to provide an overview of the assessment results via supplier letters, webinars, and presentations. Feedback also includes detailed discussions with individual suppliers and recommendations for improvements.

Ali with AmerisourceBergen explains, “We have built a center of excellence for barcodes in logistics. We want to use this knowledge to help manufacturers, because if we don’t work together now to fix these barcodes and ensure compliance with standards, it will impact the entire supply chain in the upcoming years.”

“For some products, the 2D GS1 DataMatrix barcode is perfect and other products haven’t gotten there yet. For these manufacturers, we anticipate that their barcodes will be perfect at some point soon since they obviously understand how to create quality barcodes.”

Michael Rowe

Manager of Operations Technology (Track & Trace), Cardinal Health

“We’re seeing mixed results from some of our larger manufacturers that have multiple products and multiple packaging lines,” says Cardinal Health’s Rowe. “For some products, the 2D GS1 DataMatrix barcode is perfect and other products haven’t gotten there yet. For these manufacturers, we anticipate that their barcodes will be perfect at some point soon since they obviously understand how to create quality barcodes.”

“Conducting the assessment has given us very specific data about each of our suppliers’ DSCSA barcode implementations,” says Mooney with McKesson. “For example, we were able to compare the NDC to the actual GTIN that was in a supplier’s barcode. We identified the suppliers that had not properly generated their GTINs because they had not encoded the NDC number in the right way. We have had conversations with about 50 manufacturers, to date, providing specific feedback on the barcode data we captured.”

To represent an NDC using a GTIN, a company must ensure the NDC Labeler Code is integrated into the GS1 Company Prefix segment of the GTIN (or UPC Company Prefix segment, as applicable), and the NDC Product/Package Code is used to populate the Item Reference segment of the GTIN.

GS1 Healthcare US provides detailed guidance about how to integrate NDCs into GTINs in the [GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#).¹⁰

Looking Forward

“With improvements in our results this year, DSCSA implementations are going in the right direction,” says Mooney of McKesson. “I expect to see the percentage gradually growing and growing. One thing is certain: All new packages after November 27, 2018, should have 2D barcodes on them.”

“The big difference this year (versus last year) is that the U.S. FDA has provided [guidance](#) about ‘grandfathering’ product that has been already packaged and in inventory prior to the November 2018 deadline,” continues Mooney. “U.S. FDA guidance allows for un-serialized product without the 2D barcode to continue to be transacted in commerce until it expires. The grandfathering guidance now applies to both manufactured and repackaged product after the FDA Guidance issued in September 2018. This gives us the ability to move forward and not worry about shortages to patients or financial loss.”

Ali with AmerisourceBergen adds, “Since the majority of pharmaceutical products have a multi-year lifecycle, we don’t expect to realize the full impact of DSCSA serialization until the end of 2021. It will be a gradual process as we continue to work out issues and adjust processes to experience the benefits of complete, accurate product data. A case in point: Our specialty divisions are using the lot and expiration date information to control inventory. For our oncology supply business, interestingly enough, about 60 percent of products are serialized.”

“Since the majority of pharmaceutical products have a multi-year lifecycle, we don’t expect to realize the full impact of DSCSA serialization until the end of 2021. It will be a gradual process as we continue to work out issues and adjust processes to experience the benefits of complete, accurate product data.”

Ameer Ali

Senior Manager of Secure Supply Chain & Manufacturer Operations, AmerisourceBergen

“We’re taking this time to enhance our processes to ensure efficient receipt, pick, pack, and ship for grandfathered and new products,” explains Rowe with Cardinal Health. “We’re also training our associates about barcodes and their importance for our business, today and moving forward. The transition to 2D barcodes is huge for us operationally and will help take our business and our customers to the next level of delivering efficient and safer healthcare.”

¹⁰ See §5.1.1.1 for integrating NDCs into UPCs (GTIN-12s) and §5.1.1.2 for integrating NDCs into GTIN-14.



DSCSA Barcoding Recommendations

AmerisourceBergen, Cardinal Health, and McKesson provide the following recommendations for suppliers:

- **Pay particular attention to barcode placement** on cases and packages to avoid readability issues.
- **Refer to and implement GS1 Standards** for barcode size, placement, encoding, and more to improve barcode quality.
- **Take advantage of assistance** provided by all three wholesalers, including sample barcode testing, educational sessions, and individualized support.
- **Use the DSCSA education and implementation resources** available from GS1 Healthcare US.
- **Accelerate the implementation of serialization** and work out the any issues now before the deadline.
- **Keep your eye on the “prize”** for all trading partners, as the promise of a standardized, highly efficient, global supply chain becomes a reality.

Learn More

Visit www.gs1us.org/dscsa.

GS1 US, Inc. is providing this paper, as is, as a service to interested parties. GS1 US MAKES NO REPRESENTATIONS IN THIS REGARD AND DISCLAIMS ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF ACCURACY OR RELIABILITY OF ANY CONTENT, NONINFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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 paper 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 is not a representative or agent of the U.S. FDA. The content herein has not been reviewed, approved or authorized by the U.S. FDA, and is not to be considered legal or regulatory advice.

All information contained in this paper, unless otherwise noted, has been provided by AmerisourceBergen, McKesson Pharmaceutical, and Cardinal Health.

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 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 more than 30 local GS1 Healthcare user groups around the world that support the adoption and implementation of global standards developed by GS1®. For more information, visit www.gs1us.org/healthcare.

GS1 US Corporate Headquarters

Princeton Pike Corporate Center, 1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648 USA
T +1 937.435.3870 | E info@gs1us.org
www.gs1us.org

Connect With Us



6 14141 02576 3