United States

Barcode readability for DSCSA 2023 interoperability

Challenge
For the third consecutive year in 2019, AmerisourceBergen and McKesson conducted barcode assessments to gain an up-to-date view of industry's progress in implementing serialisation requirements of the 2013 Drug Supply Chain Security Act (DSCSA). Cardinal Health conducted its own barcode assessment of homogeneous cases from pharmaceutical manufacturers. All three assessments were supported by GS1 Healthcare US.

Approach
Taking a consistent, year-over-year approach, the teams from AmerisourceBergen and McKesson with collaboration from GS1 Healthcare US scanned 2D barcodes on product packages, capturing data to measure the percentage of readable 2D barcodes encoding an NDC, serial number, lot number and expiration date.

Readable 2D GS1 DataMatrix barcodes with all 4 DSCSA data elements

Specialty Products	Rx Products
71.9% scanned at AmerisoureBergen	**71%** scanned at McKesson

Homogeneous Cases	Homogeneous Cases
78.7% scanned at Cardinal Health with 2D (GS1 DataMatrix) barcodes	**73.3%** scanned at Cardinal Health with linear (GS1-128) barcodes

AmerisourceBergen
CardinalHealth
McKESSON

In the summer 2019 and for the third consecutive year, AmerisourceBergen Corporation (AmerisourceBergen) and McKesson Pharmaceutical (McKesson) in collaboration with GS1 Healthcare US®, assessed the barcodes of packages "lowest saleable unit" in their distribution facilities to obtain a view of industry's progress in implementing serialisation requirements of the 2013 DSCSA.[1] During this same timeframe, Cardinal Health conducted its own barcode assessment of homogeneous cases from pharmaceutical manufacturers, with support from GS1 Healthcare US.

Ameer Ali, Quentin Dittman & Scott Mooney

Conducting assessments

The DSCSA defines the requirements for an interoperable, electronic system to identify and trace pharmaceutical products throughout their distribution in the United States.[2] As part of the requirements, pharmaceutical products must be marked with a National Drug Code (NDC), serial number, lot number and expiration date.[3] (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).[4]

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

It is critical that barcodes are applied in a standardised way to facilitate accurate movement of product across the healthcare supply chain and to associate the physical product markings with the serialised electronic data exchange that will occur on or before 27 November 2023.

The 2019 barcode assessments expanded the scope of analysis to include the 27 November 2023 interoperable requirements and quantify impacts of readiness in these areas. GS1 Healthcare US and the Big 3 wholesalers are participating in the U.S. Food and Drug Administration (FDA) Pilot Project Program under the Drug Supply Chain Security Act, Docket No. FDA-2016-N-0407 for the scanning, data collection, analysis and reporting of the barcode testing pilot.

Previous barcode assessment studies were conducted by AmerisourceBergen and McKesson in 2017, and again in 2018 with the addition of Cardinal Health, each year facilitated by GS1 Healthcare US. These studies identified issues with lack of adherence to industry barcode standards and placement— problems that can result in serious consequences, such as improper identification of products, mis-shipments, reduced operational efficiency and product availability issues.

With results from the 2019 assessments, AmerisourceBergen, Cardinal Health and McKesson are now able to follow up and share results with their individual supplier manufacturers and repackagers so that they can continue to make any course corrections, as needed.

Data management

Taking a consistent, year-over-year approach, the teams from AmerisourceBergen and McKesson with collaboration from GS1 Healthcare US once again scanned 2D barcodes on product packages, capturing data to measure 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 centres, assessing the same types of products. AmerisourceBergen assessed specialty medications and McKesson focused on prescription pharmaceuticals.

The AmerisourceBergen team took a different scanning approach than in previous years by using a mobile application. "We created a mobile app that enables us to capture the data encoded in barcodes as well as note specific issues, analyse barcodes for specific criteria and take photos of the issues that we find—all within the same entry. We can then share the analysis and pictures with manufacturers, giving

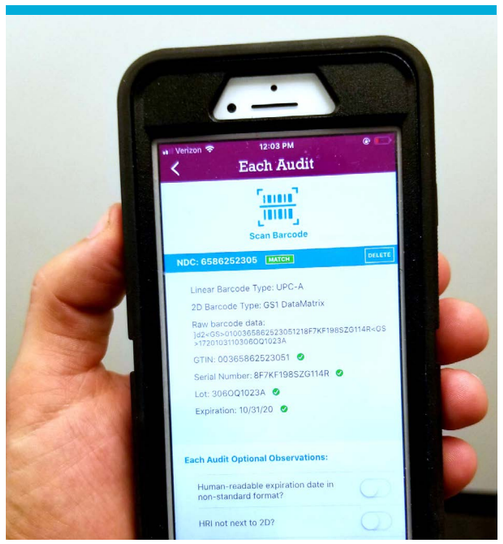

Photo courtesy of AmerisourceBergen. Mobile app displayed.

1 Drug Supply Chain Security Act, Pub. Law No. 113-54, 127 Stat 599 (2013).
2 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
3 Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(b)(2)(A), 127 Stat 599, 609 (2013).
4 Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(a)(9)[A], 127 Stat 599, 608 (2013).

them constructive feedback," explains Ameer Ali, Senior Manager of Secure Supply Chain & Manufacturer Operations, AmerisourceBergen.

In 2019, the sample sizes for both AmerisourceBergen and McKesson included:

- AmerisourceBergen scanned 1,545 packages representing 270 manufacturers and 100% of on-hand specialty products. The new mobile application enabled AmerisourceBergen team members to work individually and capture all information in one place—a significant boost to productivity.
- McKesson scanned 16,314 packages representing 477 manufacturers. A team comprised of McKesson personnel scanned barcodes using production scanners, and captured scanned information in McKesson's own production system.
- At both AmerisourceBergen and McKesson distribution centres, the GS1 Healthcare US team scanned more than 3,700 packages to provide an independent audit of the results. The analysis from the packages scanned by AmerisourceBergen, McKesson and GS1 Healthcare US teams revealed a 99.9% accuracy of the audited items.

Ali with AmerisourceBergen says, "Conducting the audit in conjunction with the GS1 US assessment ensures that the information is reflective of the entire industry and measured against agreed upon standards."

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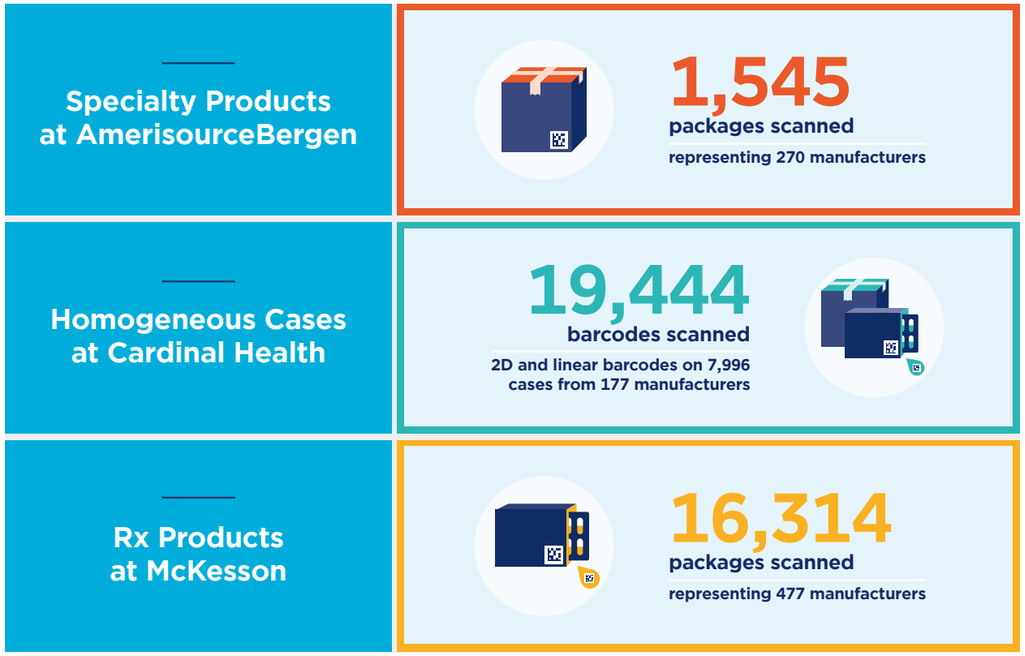

Cardinal Health focused on homogeneous case-level barcodes on pharmaceutical products in its Groveport, Ohio National Logistics Centre.

"This year, we wanted to see if there was an improvement year-over-year," says Quentin Dittman, Director of Operations Technology at Cardinal Health. "After last year's assessment, we really dug into the data. We started talking with our suppliers, reaching out to understand any issues. This understanding was really crucial for us in order to push for the highest level of compliance. Bad barcodes mean bad problems for the supply chain."

The HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain recommend 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, or one 2D barcode encoding all four data elements.[5] The Cardinal Health assessment encompassed both approaches.

A new addition to Cardinal Health's scanning process was its own internal tool to conduct the analysis and validation of product data. "We call it the 'barcode validator' and it's going to be used for our production going forward when we're evaluating all of our suppliers' barcodes," says Mr. Dittman. "We thought it was really important for us to have an in-house tool and system."

- Cardinal Health scanned 19,444 2D and linear barcodes on 7,996 cases from 177 manufacturers. This included both faster- and slower-moving ambient products from their racks, plus cold chain products stored in the refrigerator.
- At Cardinal Health, the GS1 Healthcare US team scanned 4,120 2D and linear barcodes on 1,548 cases.

> *"In my opinion, having GS1 US be part of the assessment by auditing the data was critical since they provide a third-party perspective on the quality of the data and process. They ensured that any data captured was verified, lending an extra layer of credibility to the results."*
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> **Quentin Dittman**
> Director of Operations Technology
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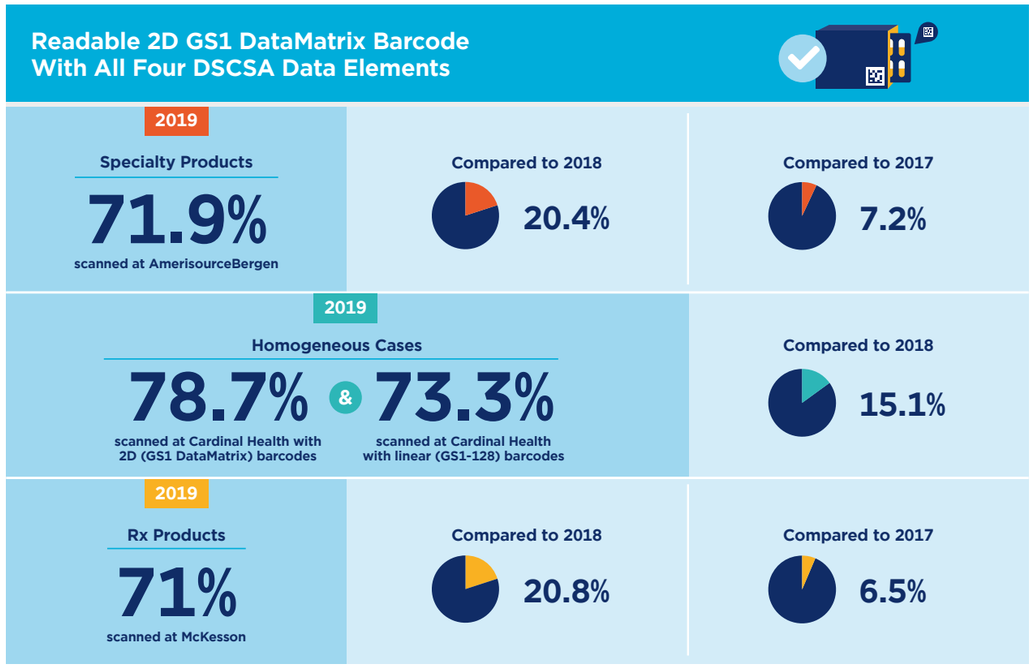

5 HDA (2017). HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain. Retrieved September 14, 2018 from https://www.healthcaredistribution.org/resources/hda-guidelines-for-bar-coding-in-the-pharmaceutical-supply-chain

Exceeding expectations

The results from the AmerisourceBergen and McKesson assessments showed a significantly higher year-over-year increase of nearly 52 percentage points when compared to the 2018 assessment, and 66 percentage points when compared to 2017.

In fact, all wholesalers were very pleased that suppliers exceeded their expectations of 50 percent to 60 percent.

- Of the specialty products at AmerisourceBergen, 71.9% of all packages had a readable 2D GS1 DataMatrix barcode with all four DSCSA-required data elements (compared to 20.4% in 2018, and 7.2% in 2017).
- Similarly, the prescription products at McKesson, 71% had a readable 2D GS1 DataMatrix barcode with all four DSCSA-required data elements (compared to 20.8% in 2018, and 6.5% in 2017).
- At Cardinal Health, 78.7% of homogeneous cases with 2D (GS1 DataMatrix) barcodes and 73.3% with linear barcodes had all four data elements (compared to 15.1% in 2018).

"The results just blew me away," says Scott Mooney, Vice President of Distribution Operations, Supply Chain Assurance, McKesson. "It was fantastic to see the percentage increase so high. Now, we just have to fill the gap to get to 100 percent."

Mr. Dittman agrees, "The results are very exciting; they exceeded my expectations. And as we process more and more inventory, I expect to see the compliance reach up to 90 percent or even 100 percent."

"The grandfathering allowance from the FDA was helpful to assure that supply chains remained stocked with inventory, and patients could get the proper medications that they needed, when they needed them. I think that there were far fewer manufacturers selling grandfathered product than might have been expected—given that we also saw such a high percentage of product with the 2D barcode."

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

An additional year-over-year significant change was experienced with the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. This could be a reflection of an industry build of inventory last year with lot-only based products, and in 2019, older inventory was consumed prior to the conversion of serialised packages.

Top observations

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

High levels of serialised inventory

US FDA issued a draft guidance, informing industry that it was delaying enforcement of the DSCSA requirements until November 2018, to provide manufacturers additional time and avoid supply disruptions.[6]

The AmerisourceBergen and McKesson assessments were conducted in May and July, respectively—at least six months after the November 2018 deadline.

"Of course, the compliance deadline really drove suppliers' actions toward serialisation," says Mr. Ali. "We recently started seeing significantly more serialised products in our warehouse distribution network. So, the serialised inventory in the supply chain is steadily increasing as expected, with grandfathered inventory expected to continue to decrease over the next several months."

Mr. Dittman adds, "Our manufacturing partners are burning through the backlog of inventory that they had produced when preparing to meet their 2018 serialisation requirements. We're getting to a point where all the products will soon be serialised as we're seeing the expiration dates slide."

Mr. Mooney from McKesson says, "The grandfathering allowance from the FDA was helpful to assure that supply chains remained stocked with inventory, and patients could get the proper medications that they needed, when they needed them. I think that there were far fewer manufacturers selling grandfathered product than might have been expected—given that we also saw such a high percentage of product with the 2D barcode."

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

Mr. Mooney points to the impressive effort by suppliers when making this change. While many of the suppliers may have a small number of products, many of them have 100-150 products that are manufactured in 10-12 different product facilities. “Our experience is that suppliers are not lagging behind,” explains Mr. Mooney. “A supplier that is not 100% may just have a facility that is delayed in getting the conversion completed to handle the 2D barcodes.”

Mr. Ali confirms that AmerisourceBergen saw that some manufacturers had a mixture of good and bad labels, most likely due to a variation of packaging locations and contract manufacturers.

Improved expiration date

AmerisourceBergen and McKesson also note the significant improvement of properly encoding the barcode with the expiration date—previously an issue in 2017 and 2018.

In previous assessment years, the wholesalers saw suppliers use “00” as the day in the expiration date. 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.

“Out of the 16,300 packages that we scanned, only 183 of these had expiration date issues,” advises Mr. Mooney from McKesson. “This was a huge, positive change and will be especially important when we start exchanging data as trading partners.”

Mr. Mooney suspects that guidelines like the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability*, helped suppliers make this shift.

Mr. Ali with AmerisourceBergen still warns about the impact on the supply chain when expiration dates are not encoded accurately, or human readable information is not labelled according to the guidelines. “Pharmacies, for example, that rely on human readable expiration dates may have difficulty accurately reading the information when dispensing pharmaceuticals to patients,” says Mr. Ali.

“This could have a real impact on patient health, in addition to the supply chain.”

An additional year-over-year significant change was experienced with the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. This could be a reflection of an industry build of inventory last year with lot-only based products, and in 2019, older inventory was consumed prior to the conversion of serialised packages.

Better barcode quality

Another area of improvement was the legibility of barcodes.

In 2017 and 2018, AmerisourceBergen and McKesson could not scan certain barcodes since they were applied on shiny surfaces or were printed in inappropriate colours.

“These kinds of problems were nearly absent this year,” says Mr. Mooney. “To the best of my knowledge, we had only two instances where we experienced barcodes in difficult-to-read colors or surfaces. With the quality barcodes, we were able to scan noticeably quicker.”

Mr. Dittman with Cardinal Health agrees that barcode quality improved, considering the amount of time required to make those changes. At the same time, he advises it’s not quite where it needs to be. “I’d like to see everybody following the standard. Although there is a marked improvement, it’s not where it should be from a supply chain or downstream perspective.”

Cardinal Health, McKesson and AmerisourceBergen are all reaching out to their suppliers, providing one-on-one feedback on areas where improvements can be made.

“As we move more towards the data exchange of 2023, I think our ability to leverage the information available today becomes more acute. It’s making sure that we have the right pieces in place until we get to 2023 when we can then all unlock the complete value that’s promised today.”

Quentin Dittman
Director of Operations Technology
Cardinal Health

“When all products have readable 2D barcodes, we can begin truly looking at the exchange of data and the incorporation of that data into our processes. We will be ‘marrying’ the physical product with its digital twin. In other words, every product will have a dual state—a digital version and physical version—that we will be able to match between our respective platforms. That’s what we are required to do in 2023.”

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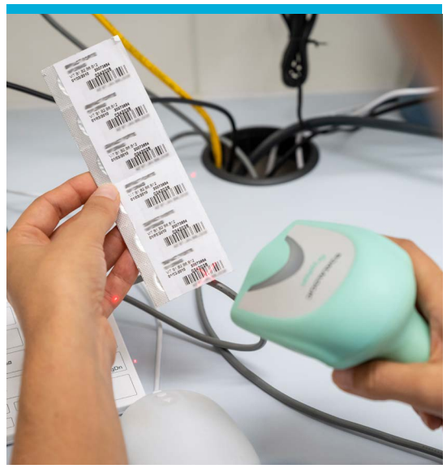

Business benefits

As suppliers “close the gap” for 100% readability, the next big step for wholesalers and suppliers alike will be using the data for more efficient processes.

“We begin using the data this November (2019) when we start doing saleable returns verification, confirming what’s encoded in the barcode against the data that manufacturers have kept on file,” says Mr. Mooney. “Many suppliers in the industry are working on getting the data organised and presentable for their verification returns program.”

Other process benefits for wholesalers include scanning barcodes to determine if a product’s expiration date is within acceptable limits, providing healthcare providers with the “go/no go” when dispensing of the product. “Today, we check for recalls manually by referring to the human readable on the package,” explains Mr. Mooney. “Now, with readable barcodes, we can harvest the data for increased efficiencies inside our distribution centre.”

Mr. Dittman from Cardinal Health also references the potential for increased efficiencies in Cardinal’s distribution centre as data is increasingly accessed from readable barcodes. “It starts at our front door when the product arrives in receiving. Barcodes help save us time, effort and ultimately, labour costs. There’s also a quality impact since we’re limiting (or eliminating altogether) manual intervention where there’s a propensity for error.”

“As we move from more than 70% to 100% readable barcodes, we will continue to lay the foundation for exchanging data as part of the 2023 requirement.”

Industry value

Perhaps the most exciting results will be realised in 2023—just three short years away. “When all products have readable 2D barcodes, we can begin truly looking at the exchange of data and the incorporation of that data into our processes,” says Mr. Mooney. “We will be ‘marrying’ the physical product with its digital twin. In other words, every product will have a dual state—a digital version and physical version—that we will be able to match between our respective platforms. That’s what we are required to do in 2023.”

“I think the dilemma we will face is that there’s a strong appetite to quickly use this data,” continues Mr. Mooney. “But from a process perspective, we need to take the time required to move as an industry—one step at a time. We can start to test the exchange of serialised data, but ultimately, the entire industry will need to have data flowing back and forth between all trading partners. We’re looking at ‘how and when’ this becomes possible.”

Mr. Dittman says, “As we move more towards the data exchange of 2023, I think our ability to leverage the information available today becomes more acute. It’s making sure that we have the right pieces in place until we get to 2023 when we can then all unlock the complete value that’s promised today.”

Mr. Ali adds, “With full traceability planned for 2023, the ability to track and communicate across the supply chain will be down to the unique lowest saleable unit. This has never been available before and will unlock value and increase accuracy and specificity to new levels. Until then, the objective is to work to eliminate physical and data exceptions, and add the processes and equipment necessary to enable the capture, verification and exchange of this information between stakeholders.”

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About the authors

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Ameer Ali is Senior Manager, Manufacturer Operations at AmerisourceBergen, a Fortune 25 company and a leading pharmaceutical distributor. He brings 16 years of Supply Chain experience in various industries. He’s involved with DSCSA implementation at AmerisourceBergen as well as optimising data exchange processes and packaging compliance. Mr. Ali participates in many industry initiatives including the GS1 US assessment of DSCSA barcodes in the pharmaceutical supply chain, the GS1 US Rx Secure Supply Chain Workgroup and project advisory board of the Healthcare Distribution Alliance Research Foundation. He also co-chaired the GS1 US Healthcare GLN Advisory Workgroup.

Quentin Dittman
Director of Operations Technology
Cardinal Health

Quentin Dittman is a Director, Deployment Leader at Cardinal Health, a position he has held since November 2019. He is responsible for Lean Six Sigma activities in the Pharmaceutical Segment in the East Deployment Area. Prior to this role, Mr. Dittman was Director of Sustain and Track & Trace at Cardinal Health. In this role, he is responsible for transforming the Pharmaceutical segment by leveraging technology and lean processes to deliver agility and flexibility in an ever changing environment. Quentin is also responsible for optimising the Pharmaceutical Distribution supply chain in response to the Federal Drug Supply Chain Security Act of 2013 (DSCSA).

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

Scott Mooney is Vice President of Distribution Operations, Supply Chain Assurance at McKesson Corporation. His primary responsibilities are assuring product integrity through regulatory compliance and traceability. Mr. Mooney leads McKesson’s Traceability Team working on Drug Supply Chain Security Act implementation across McKesson’s various business units.

He joined McKesson in 1987 and had previous roles in Finance, Distribution Center Management and as a Regional Vice President of Distribution Operations. Mr. Mooney is active in Healthcare Distribution Alliance’s (HDA) Traceability Workgroup in addition to serving on the HDA Industry Relations Council and participating in several committees including the Federal and State Government Affairs Councils and Regulatory Affairs Council.

He is a current Tri-Chair of the GS1 Global Healthcare Leadership Team having been on the team as a member for the past five years. Scott participates in the GS1 US Rx Secure Supply Chain Workgroup and was previously a member of the GSMP Process Oversight Committee.

About the organisations

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

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.

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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.

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