



Case Study

Fresenius Kabi

Fresenius Kabi Infuses Safety from Production to Patient with Unit-of-Use 2D Barcodes

Challenge

Fresenius Kabi, a global healthcare company, is seeking to continue its tradition of innovation by enhancing its entire portfolio's product labels with a GS1 DataMatrix barcode, allowing clinicians to digitally access greater amounts of crucial data for patient care. With more than 700 products – many of them in small packaging – finding the appropriate labeling protocols would take thought and planning to accommodate a globally unique product code, batch/lot number, and expiration date.

Solution

Having already introduced electronic product code-enabled (EPC) radio frequency identification (RFID) to a subset of products based on GS1 Standards, Fresenius Kabi again chose GS1 Standards. This time, they decided to utilize the GS1 DataMatrix – a two-dimensional barcode able to carry the most crucial drug information in a small footprint – to identify its entire product portfolio worldwide.

The DataMatrix can be machine-read at any angle and is ideal for health care where more vital information must be captured on pharmaceutical products essential for critical hospital workflows. The GS1 DataMatrix allows Fresenius Kabi to embed a GS1 Global Trade Item Number® (GTIN®, which contains the FDA National Drug Code for U.S. products), a lot number, and expiration date – information that is needed to identify drugs efficiently and accurately in today's digital environment.

Anticipated Benefits

- **Patient Safety.** GS1 DataMatrix barcodes support safety checks during preparation, dispensing, and administration to support superior patient care. With each dose of medication carrying core lot and expiry data, along with other identifying information, clinicians are able to quickly and more precisely verify medications are in-date and not recalled during various medication-use processes.
- **Convenience.** Critical drug identification can be instantly read by medication management systems clinicians use every day, eliminating time-consuming manual data entry and human error. This also supports documentation, the logging of essential drug information, with a simple scan.
- **Brand Enhancement.** Enabling its customer base of healthcare customers to access enhanced information with a single product scan, the addition of a GS1 DataMatrix barcode reinforces Fresenius Kabi's reputation as an innovative leader and underscores its willingness to help ease the burdens of customers' day-to-day operations.
- **Global Identification.** GS1 Standards are global and ensure that, regardless of product destination, a pharmacy or hospital receiving the product can scan the GS1 Data Matrix barcode. The vital information gleaned from that scan of a single dose of medicine, IV solution, or biological preparation, is an important benefit for a global operation like Fresenius Kabi.

Fresenius Kabi Leads with Innovation

Fresenius Kabi is a global leader in the manufacture of generic sterile injectable medicines along with medical technologies for transfusion, infusion, and nutrition. The company consistently employs groundbreaking technology that keeps it leading the industry not just for internal expediency, but for the value it brings the entire ecosystem from production line to patient.

Using GS1 Standards to identify its products, for example, is as much a measure of corporate citizenship as it is an operational incentive. After witnessing the efficacy of radio frequency identification (RFID) tags in a hospital, the company launched an initiative to become the first manufacturer to tag specified products with RFID “smart” labels that are scanned to find not only the NDC number, but also a unique serial number, lot number, and expiration date.

Now, Fresenius Kabi is at the forefront by applying GS1 DataMatrix barcodes to its entire portfolio – all 700-plus products. Just as it did with its RFID initiative, Fresenius Kabi has done extensive research and planning before implementing this company-wide undertaking, involving a cross-functional team from both the manufacturing and the commercial business units. These professionals were assembled from supply chain, regulatory affairs, marketing, engineering, medical affairs, project management, and quality control. A core group of pharmacists and advisors drawn from customers and vendors also worked alongside Fresenius Kabi to verify results and validate assumptions.

Fresenius Kabi solicited feedback from customers, barcode experts from healthcare institutions, as well as many hospital medication vendors, to ensure they could read and interpret the GS1 DataMatrix barcode.

“We are embarking on this global project to provide clinicians the data they need to improve efficiency, accuracy – and for patient safety,” says Gwen Volpe, Registered Pharmacist and senior director of Medication Technology and Analytics, Fresenius Kabi.

GS1 recommends the GS1 DataMatrix for health care, because of its ability to encode a wealth of vital information in a small footprint ideal for vials, syringes, and other small packaging. With a scan of the GS1 DataMatrix barcode, hospital or pharmacy personnel can identify the name and code of the therapeutic, the manufacturer, the lot it came from, and its expiration date.

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GS1 Standards are fundamental to many industries worldwide, making them the natural choice for any manufacturer doing business globally. GS1 identifiers – including Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) – are the preferred and prevalent standards used by the healthcare community, pharmaceutical and medical device manufacturers, and their distributors. GS1 Standards also support the U.S. Food and Drug Administration (FDA) Drug Supply Chain Security Act (DSCSA) aimed at enhancing patient safety and security in the pharmaceutical supply chain.



Familiar Territory

Fresenius Kabi manufacturing centers supplying the European Union started to see customer requests for 2D barcodes. As a global company, standardizing its labeling procedures made sense for Fresenius Kabi, particularly as it was seen as a future-proof decision.

Fresenius Kabi has chosen the GS1 DataMatrix on its products to include a lot/batch number – and most critically – an expiration date, one of the most important factors in the lifecycle of a pharmaceutical product, which helps to prevent an expired product from being administered to a patient.

“These numbers are printed on all pharmaceutical products, but that is when the challenges for our customers begin – when manual entry into a hospital system and visual checks are used. You are asking clinicians, nurses, anesthesiologists, pharmacists, other healthcare professionals to be perfect,” says Volpe. “How can we help? By allowing automatic identification of information within a GS1 DataMatrix barcode at unit-of-use. You simply scan for accurate information.”

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Let the Labeling Begin

The Fresenius Kabi sites in the U.S. and Europe are now working on labeling products with the GS1 DataMatrix barcode, troubleshooting equipment, labeling design and application processes, and administering training that may be needed for pharmacists scanning GS1 DataMatrix barcodes for the first time.

Like any new process, the 2D barcode has presented some challenges. On the equipment side, it was known that the imaging equipment – the scanners – read the linear barcode more readily than the 2D barcode. Most scanners are equipped to read either barcode, so an adjustment to the programming of the machine typically solves the issue.

In the case of label design and application, Fresenius Kabi knew that sufficient white space must surround the GS1 DataMatrix to help the equipment isolate and read. Some label papers also presented an issue, with highly reflective paper impeding the accurate “reading” of a barcode. Not surprisingly, printing labels to fit on such tiny packaging – a two milliliter vial, for instance – takes careful consideration.

“From a technical perspective, printing a very small 2D barcode on a very small label is harder than it looks and has, in some cases, required completely new labeling equipment,” says Jeanne Sirovatka, senior director of Packaging Design and Technical Projects for Fresenius Kabi.

The labeling was designed so a barcode scanner would only be able to “see” one barcode at a time, eliminating the issue of a scanner’s “preference” for a linear barcode scanner over a GS1 DataMatrix.

While the previous RFID project involved only a small group of drugs, the labeling of 100 percent of its products has understandably “really broadened the work effort” in Sirovatka’s words.

Convenience and Clarity

The time savings and accuracy gains resulting from the scan of a GS1 DataMatrix barcode in place of manual processes are immense. But the improvement to patient safety is incalculable.

“Because labeling at unit-of-use provides value to our customers – it’s of value to us,” says Sirovatka. “These technologies are attractive to us in the generics business: it allows us to differentiate ourselves. We derive business value by meeting customer need.”

When Fresenius Kabi offered RFID tagging of its generics, it saw an anecdotal increase in uptake by customers equipped with radio frequency scanning equipment. It anticipates similar adoption because GS1 DataMatrix enhanced labeling delivers what its customers have been asking for: more data available digitally when and where it is needed.

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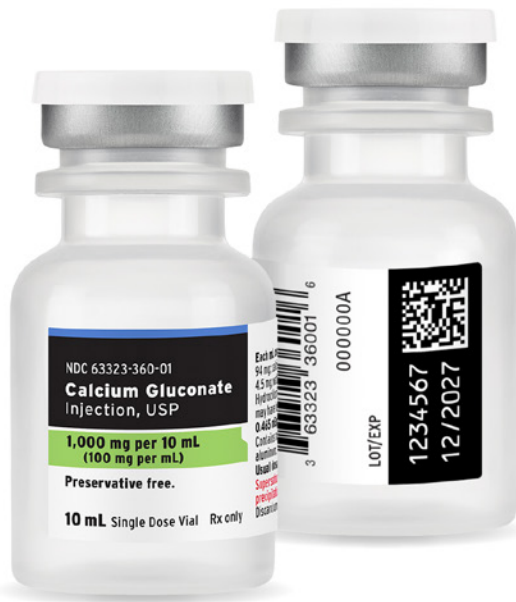
“If we receive a customer complaint indicating a problem with a product, the customer can easily provide much more information, making it easier to investigate, find a root cause, and correct the problem, if necessary.”

In addition to productivity and safety improvements, hospitals and pharmacies also conserve resources. Waste from the disposal of expired products is greatly reduced when looming expiration dates are clearly pinpointed. Streamlining in-hospital workflows through automatic identification and verification of products enhances compounding and inventory management of the medications. If one clinical practice cannot use a product about to expire, perhaps another within the same system can.

If a recall occurs, locating the medications is made easier and suitable alternatives can be identified and implemented more quickly. Removing expired drugs from hospital systems is much more efficient. Once a medication is scanned by a nurse prior to being given to a patient, the precise digital identity of the medication is automatically transmitted to the patient’s electronic health record (EHR). Should a subsequent recall occur, the patient who received the medication can be more easily identified and contacted.

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GS1 Data Matrix barcode GTIN (NDC) + Lot + Expiry

- Reduced manual data input
- Easy to scan at any position
- Improved clinician efficiency
- Increased patient safety

Whether a medication is found on a stockroom shelf, in an automated dispensing cabinet, in an IV compounding area, or on a cart in a procedure area, the GS1 DataMatrix can help to identify these drugs more accurately, quickly, and efficiently.

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Path to Adoption

Despite what some may think, entry costs are not prohibitive, and a one-time investment in a scanner may be less daunting in an environment where the habit of scanning barcodes is firmly established. During its own planning, Fresenius Kabi was pleasantly surprised by the number of hospitals and EHR vendors whose equipment was already capable of reading both types of barcodes. There are no shortcuts for the amount of planning needed for a successful transition, however.

“We knew what some of the issues would be: a preference for 1D versus 2D barcode scanners, size constraints, the need to upgrade or replace labelers based on printing technology,” Sirovatka says. “Issues of paper sheen and reflectivity, of truly understanding the spacing that would allow for a selective scan balanced with the mandated [human-readable] copy – those conceptual problems were more subtle.”

As the first pharmaceutical manufacturer to do this across its entire portfolio, the lessons learned by Fresenius Kabi will help others in the industry take the same path using GS1 Standards.

“Nearly all of us have been to the hospital; we trust that our caregivers are being given the tools and technologies that they need to provide care for our loved ones and for us,” Volpe says. “Standards for medications matter. It is why GS1 Standards are important to accurately identify medication for safer patient care.”

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About the Organizations



About Fresenius Kabi

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion, and clinical nutrition. Its products and services are used to help care for critically and chronically ill patients. www.fresenius-kabi.com/us



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 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

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IAPMO

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*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

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