

# United States

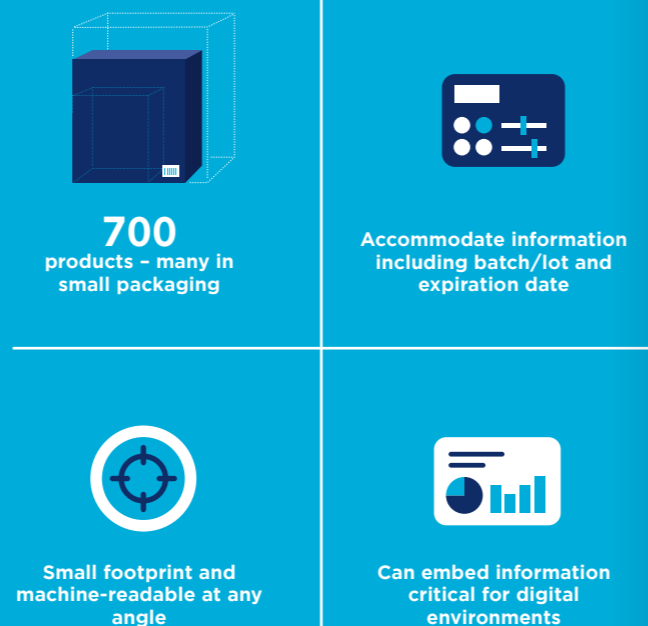
## Infusing Safety from Production to Patient with Unit-of-Use 2D Barcodes

### Challenge

With more than 700 products – many in small packaging – Fresenius Kabi had to find appropriate labelling protocols to accommodate a globally unique product code, batch/lot number, and expiration date.

### Approach

Fresenius Kabi decided to utilise the GS1 DataMatrix – a two-dimensional barcode able to carry the most crucial drug information in a small footprint that can be machine-read at any angle. It also allows Fresenius Kabi to embed a GS1 Global Trade Item Number® (GTIN®, which contains the US FDA National Drug Code), a lot number, and expiration date – information that is needed to identify drugs efficiently and accurately in today's digital environment.



### Leading 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 ground-breaking 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. The firm sees using GS1 standards to identify its products, for example, as being 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 National Drug Code (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 carried out extensive research and planning before im-

plementing 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 with this team 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 would be able to read and interpret the GS1 DataMatrix barcode.

GS1 recommends the GS1 DataMatrix for healthcare, 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.

*“We are embarking on this global project to provide clinicians the data they need to improve efficiency, accuracy – and for patient safety.”*



**Gwen Volpe**  
Registered Pharmacist and senior director of Medication Technology and Analytics, Fresenius Kabi.

### Pencil and paper to keyboard

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 centres supplying the European Union started to see customer requests for 2D barcodes. As a global company, standardising its labelling 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

*“How can we help? By allowing automatic identification of information within a GS1 DataMatrix barcode at the unit-of-use. You simply scan for accurate information.”*



**Gwen Volpe**  
Registered Pharmacist and senior director of Medication Technology and Analytics, Fresenius Kabi.



are used. You are asking clinicians, nurses, anaesthesiologists, pharmacists, other healthcare professionals to be perfect,” says Gwen Volpe.

### Let the labelling begin

The Fresenius Kabi sites in the US and Europe are now working on labelling products with the GS1 DataMatrix barcode, troubleshooting equipment, labelling 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 scanners read a linear barcode more readily than a 2D barcode. Most scanners are equipped to read either barcode, however, 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 the barcode. Some label papers 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 millilitre 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 labelling equipment,” says Jeanne Sirovatka, senior director of Packaging Design and Technical Projects for Fresenius Kabi.

The labelling 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, Jeanne understandably says the labelling of 100 percent of its products has "really broadened the work effort".

*"Because labelling at unit-of-use provides value to our customers, it's of value to us. These technologies are attractive to us in the generics business: it allows us to differentiate ourselves. We derive business value by meeting customer need."*

**Jeanne Sirovatka**  
Senior Director of Packaging Design and Technical Projects, Fresenius Kabi

### 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 labelling at unit-of-use provides value to our customers - it's of value to us," says Jeanne. "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 labelling delivers what its customers have been asking for: more data available digitally when and where it is needed. "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," says Jeanne Sirovatka.

In addition to productivity and safety improvements, hospitals and pharmacies 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.

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.



### GS1 DataMatrix barcode GTIN (NDC) + Lot + Expiry

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

*"In healthcare, it's vitally important to continually innovate to improve patient safety. Providing the means to improve accuracy and efficiency to our healthcare providers allows us all to focus on what matters most, and that's the patient."*

**Gwen Volpe**  
Registered Pharmacist and senior director of Medication Technology and Analytics, Fresenius Kabi.

### Path to adoption

Staff at Fresenius Kabi say entry costs to implementing the GS1 DataMatrix are not prohibitive and were pleasantly surprised by the number of hospitals and EHR vendors whose equipment was already capable of reading barcodes. There are no shortcuts in the 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 labellers based on printing technology," Jeanne 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."

### Conclusion

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," Gwen says. "Standards for medications matter. It is why GS1 standards are important to accurately identify medication for safer patient care."



### About the author



**Gwen Volpe**  
Senior Director of Medication Technology and Analytics, Fresenius Kabi US

Gwen Volpe is a licensed pharmacist, Fellow of ASHP (American Society of Hospital Pharmacists), and Lean Six Sigma Black Belt. She has worked in hospital, community, and long-term care pharmacy, healthcare technology, and the pharmaceutical industry in a career that has spanned more than 25 years. As a pharmacist she understands and advocates for the use of standards in healthcare for patient safety, interoperability, and clinician efficiency.

### About the organisations



**Fresenius Kabi** is a global healthcare company that specialises in medicines and technologies for infusion, transfusion, and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. Fresenius Kabi's US headquarters are in Lake Zurich, Illinois. Fresenius Kabi employs more than 40,500 people worldwide driven by a common purpose: to put lifesaving medicines and technologies in the hands of people who care for patients, and to find answers to the challenges they face.

[www.fresenius-kabi.com](http://www.fresenius-kabi.com)