The Global Language of Business

Case Study

Fresenius Kabi

First to provide healthcare providers with GS1 EPC-enabled RFID tagging at the dosage level

Challenge

Fresenius Kabi, a global healthcare company, launched an ambitious program to support healthcare providers and become the first in its industry to tag vials of medication using Electronic Product Code-enabled radio frequency identification (EPC/RFID) technology.

The company's goals: Each container of medication would have an encoded EPC that carries the globally unique product code, unique serial number, expiration date and batch/lot number. The product code would consist of the Global Trade Item Number® (GTIN®) with an embedded National Drug Code (NDC), which identifies the manufacturer. The RFID tags would have to comport with the dielectric properties of the drugs, not impede manufacturing speed, and eventually be brought to scale across the company's extensive portfolio of pharmaceuticals.

Solution

Fresenius Kabi chose an EPC/RFID tagging system based on GS1 Standards. Using no proprietary software or rules, GS1 Standards enable any supply chain participant across the globe to read data with the proper RFID equipment, including hospitals and pharmacies that comprise Fresenius Kabi's primary customer base. By tagging each dose of medication, the healthcare provider and patient have an additional serialized measure of unique product identification.

Anticipated Benefits

- Hospitals that are applying their own RFID tags to pharmaceuticals no longer need to expend that time-consuming effort (and avoid potential process-quality or security issues) when using drugs from manufacturers that supply their products with RFID tags embedded in the label of each dose.
- Supplying the combination of the GTIN, serial number and tag ID, the RFID-tagged drug is virtually impossible to counterfeit, strengthening serialization already in place in compliance with the U.S. Food and Drug Administration (FDA) Drug Supply Chain Security Act[1] (DSCSA).
- In the event of a recall, the identity of target items can be pinpointed, with the item date, batch/lot, serial number or other related manufacturing details.
- Hospitals can achieve more precise inventory management, with the ability to read many RFID tags in one scan. This could lead to better drug management overall, and improved charge capture in hospital settings where barcode scanning is not conducive to the workflow.

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

From the Customer's Perspective

Fresenius Kabi specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. As a leading manufacturer of sterile injectable medications in the U.S., Fresenius Kabi believes that the company's values of collaboration and creativity are a strategic advantage, and using GS1 Standards for traceability exemplify these values.

As Angie Lindsey, vice president of marketing, puts it, "Our responsibility as a healthcare company does not end at the hospital's loading dock. By including RFID technology in the label of our medications, we are helping our customers manage their drug inventory with more precision and accuracy, tracking the medication all the way to the patient."

A few years ago, a senior executive from Fresenius Kabi was visiting a hospital customer in Chicago when a pharmacist showed him how they were using the hospital's RFID system and manually tagging drug vials, associating the information for the medication with the tag, including its name, manufacturer and expiration date. It was clear that this very labor-intensive tagging process was something Fresenius Kabi could help with.

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Angie Lindsey
Vice President of Marketing, Fresenius Kabi

After seeing firsthand the importance of RFID technology from a hospital's perspective, the executive asked, "What if we provided the vial with all the information already in the RFID tag?" The pharmacist's response was immediate and enthusiastic.

"Following this customer interaction, our team developed and presented the business case to our executive leadership to receive approval," says Lindsey. "It was apparent how adding RFID smart labels to products would serve a very important purpose for our customers."

"Throughout the implementation process, there was an opportunity to gain a variety of perspectives on RFID technology for medication tagging and educate our internal stakeholders," says Gwen Volpe, director of medication technology and analytics, serving as one of the project leads for implementing RFID tagging. "The teamwork within our organization is exemplary. We are a global company of more than 35,000 people and share a common purpose of working together to serve our customers and communities in 150 countries around the world. It was great to see our cross-functional team converge on a common vision, and then make it a reality."

Jeanne Sirovatka who leads the operational excellence/continuous improvement team for all three of Fresenius Kabi's U.S. manufacturing sites, was the logical choice to partner with Volpe.

"RFID certainly falls into the innovation category," Sirovatka says. "We completed our serialization equipment installation prior to the DSCSA deadline; it was important to us to continue as a leader. And we were able to leverage our packaging engineering expertise on the RFID project."

Coming Together to Innovate

With over 600 unique NDCs in its product line of generics, leading on a groundbreaking technology is no small matter—or undertaking. "In our RFID project, having input from both the commercial and manufacturing sides of Fresenius Kabi was very important. Many people were involved," says Volpe, a trained pharmacist.

Sirovatka with her military background and training as an analytical chemist echoes and expands on Volpe's point: "We use a classic scientific method; can we disprove something as a way to challenge it? This project team required experts from regulatory affairs, marketing, engineering, project management and quality control. Everybody came together to make this project work."

"A generic manufacturer leading the way is maybe counterintuitive, in some ways. We usually follow the innovators. But in this case, we're the one innovating from a technology perspective," says Matt Farley, senior manager of medication technology and analytics who serves on Volpe's team and like her is a pharmacist by training.

Voice of the Customer

Before launching the RFID tagging project, Volpe's team's market research looked at both customers' and vendor partners' needs: pharmacies, hospitals, healthcare automation and wholesalers—with the patient always in mind. The marketing team even assembled advisory boards to inform its decision-making.

"We talked to many hospital customers to gain their insights and understand their experiences with RFID technology for medication tracking. Safety and efficiency were the words we heard most often," recalls Farley.

"We looked at technologies that customers use every day," Volpe says. "We learned that standards were exceedingly important—in particular they specified GS1 Standards. They wanted the products they use to be RFID-enabled with the tag embedded and the drug identification data locally encoded like a barcode. Once you scan an RFID-tagged product, all the information you need is there: GTIN/NDC, lot, expiration and a unique serial number."

Going Beyond DSCSA

From the moment of its very passage by the U.S. FDA in 2013, it was easy to see how the DSCSA would improve patient safety.

The regulation enables traceability by specifying that pharmaceutical products must be marked with four data elements—an NDC (e.g., GTIN), serial number, lot number and expiration date. It also requires that packages 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).

Throughout the DSCSA implementation, GS1 US, the neutral not-for-profit membership-based organization, has been positioned to provide each participant in the pharmaceutical supply chain with the guidance needed to apply global GS1 Standards in support of DSCSA.

Driven by DSCSA implementations, pharmaceuticals in packages or homogeneous cases can be tracked and traced from manufacturers to the receiving docks of healthcare providers. Yet, the management of medicines throughout hospitals—from receipt to administration—is not within the scope of DSCSA.

With its initial implementation of EPC/RFID tagging of Diprivan, Fresenius Kabi is going beyond DSCSA requirements by encoding an RFID tag with the four, DSCSA-required data elements at the unit-of-use level. The company is adding another layer of protection to pharmaceutical integrity for the sake of patients, while saving healthcare providers time and providing precise inventory control throughout hospitals.

"Every barcode a customer scans is based on a GS1 Standard, so it really informed our decisions. It was quite easy once our research bore that out," Volpe continues.

As a member of the GS1 community, Fresenius Kabi is very familiar with the solutions, standards and resources the organization provides.

With the advent of the implementation, a Fresenius Kabi drug manufactured in Sweden would be the first in the industry to carry GS1 EPC/RFID tags.

Fresenius Kabi chose the drug Diprivan, a sedative used intravenously, as the first medication to be RFID tagged, primarily because, as the most utilized drug in its portfolio, hospitals were manually tagging it for the tightest possible inventory control.

"EPC-enabled RFID is an initiative focused on primary use within the hospital or pharmacy," Sirovatka continues. "And because it's so valuable at that level, it's truly a 'voice of the customer' solution."

Source: Fresenius Kabi

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Director of Continuous Improvement, Fresenius Kabi

Open and Interoperable

For its tag design, Fresenius Kabi steered away from vendors whose products relied on proprietary software for encoding. Fresenius Kabi chose a GS1 US Solution Partner—eAgile—to help them with tag and equipment design. "eAgile offered a custom design through a framework of experiments. With Diprivan as our product pilot, the RFID technology would have to adapt to the dielectric properties of the medication," Sirovatka says. "Essentially eAgile helped us create a new technology."

"All of our solutions are based upon open, interoperable standards," says Gary Burns, eAgile CEO. "It allows our solutions to be deployed globally at what we believe is a lower cost, because there aren't a lot of proprietary components to develop."

"eAgile was able to show us the process of RFID from end-to-end. It allowed us to see the process of creating an RFID tag, applying the tag, storing prior to shipping and so on. There was an emphasis on quality, which is really important to us," Volpe says.

Sirovatka agrees. "Quality and safety are always our top priorities. The fact that we're enabling quality and safety at the hospital is the fundamental driver for us to do this."

Disproving Myths

With eAgile's help, Fresenius Kabi also upended some misconceptions along the way to reach its solution, such as encoding all of the product data within the EPC-enabled RFID tag rather than merely linking to a cloud-based database.

"It's possible to embed all of the critical information directly into the data carried on the RFID tag, which makes the product vendor-independent, cloud-independent; it's GS1 open source," Sirovatka says. "Making the RFID tag like a barcode, with open, readable information is the way to make this an accepted technology."

The company was cautioned that its proposed tagging protocols would not work at manufacturing speed, something else Fresenius Kabi disproved. Some revelations came as nice surprises; others as interesting curiosities.

"We thought you could only write to a tag at about 150 units a minute maximum, which is not sufficient for our manufacturing lines. That turns out to be false. It's much higher; we're approaching up to 600 units now," Sirovatka says.

"Finding out that every medicine can have a different RFID reflective transmission capability was unexpected. It's important to have an upfront understanding of how your medication affects the RFID environment. I thought we could make one tag per size of vial and we'd be good. That's not necessarily true."

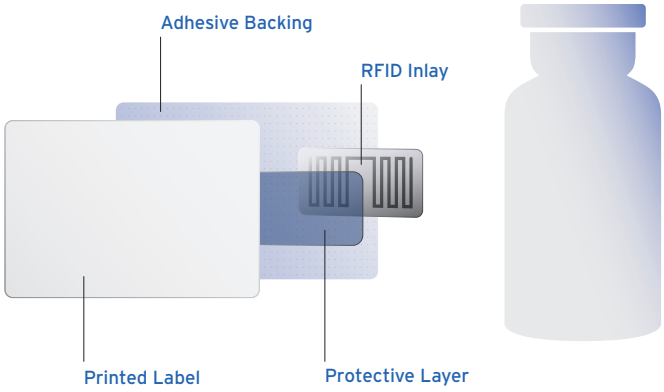

Image created by Fresenius Kabi

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Standard project challenges were also addressed as part of the mix: equipment integration, managing an implementation team, readying the plant team when the equipment was ready, developing a change management process and obtaining buy-in of participants all along the line who may be reluctant for new technology to change their way of doing things.

"It's not just Fresenius Kabi that needs to provide medicines with RFID, it's all manufacturers," says Sirovatka. "This is a proven use case with more opportunities beyond operating room usage to become a global inventory management system."

"As a leader in sterile injectable medications, we have a responsibility to tag our products so that they can be read easily and accurately by our customers in the U.S. and abroad, and use standards that any pharmaceutical manufacturer can adopt for consistency. We are all in this together for patient care," says Volpe.

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Director of Medication Technology and Analytics, Fresenius Kabi

Time and Safety

RFID tracking tags are most often found in hospitals' operating rooms and procedural rooms where firm control over medication trays and carts is most needed. Applying individual tags to drugs, inputting relevant product data into the system, double checking and validating the data can be extremely time-consuming.

"Many hospitals use what's called a kit-and-tray system. Prior to the procedure, the anesthesiologist retrieves a tray with many drugs that may be needed for the case," explains Farley.

Under pressure in an emergency or operating room setting, selecting the right medication for the right patient has very real life-and-death implications. If the tray has not been precisely maintained, an expired drug could be used or absent entirely. Following a surgery, the tray is returned to the pharmacy for replenishment.

"Manually maintaining the tray can become cumbersome for the pharmacy," Farley says. "With RFID tags identifying products, the pharmacist can scan all the tags and identify what's missing and what's about to expire. What once took a significant amount of time can now be done in a matter of seconds."

"Having the ability to track a product down to individual-use level is valuable. With RFID tagging, the pharmacy can close the loop on medication use, safety and inventory management with the ability to scan products at the point-of-care," Lindsey adds.

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Efficiency and Authenticity

Fresenius Kabi has made that scenario a reality with Diprivan, a widely used medication, and anticipates other manufacturers will be doing the same in the near future.

"There are huge efficiency gains with RFID. Increased control is one of the biggest factors for hospitals, along with the entire medication management process. Having a pharmaceutical company that follows cGMP[2] processes helps with that," Volpe says. "Having items that are serialized check all the boxes for innovation and traceability."

And Fresenius Kabi is afforded 100 percent verification that the label is applied correctly and secondary quality verification of its core data—a correct batch/lot number, expiry date, serial number, GTIN—is pre-encoded during manufacturing, not having to rely on external parties to record attributes correctly.

Although Fresenius Kabi has not had a counterfeiting problem in the U.S., implementing DSCSA requirements was the first step in combatting counterfeiting. In addition, RFID adds an invisible anticounterfeit device, in that not only is there a serial number embedded in the tag, there is a tag ID embedded by the chip manufacturer that is very difficult to duplicate. A combination of the GTIN, serial number and tag ID makes a tagged drug virtually impossible to counterfeit.

"We are working shoulder-to-shoulder with hospitals today, supporting them through the pandemic. Precise inventory management is even more important today than ever before," Lindsey says. "We specialize in 'ready-to-administer' products—prefilled syringes and premixed bags—with a goal to significantly reduce drug preparation at the point-of-care."

[2] FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (cGMP) regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

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A Pilot's Guide:
Advice From RFID Pioneers

Leadership Support

It's critical to have C-suite support for any project that is as far-reaching as this technology.

Research

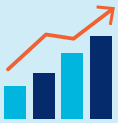
Talk to experts both inside and outside the organization, especially customers, to examine all perspectives and make well-informed decisions.

Neutrality

Base your solutions on open standards so your technology is inclusive rather than exclusionary. GS1 Standards enable interoperability among trading partners worldwide.

Breadth and Depth of Expertise

Everyone that touches the product should be involved in implementation. Regulatory affairs, marketing, engineers, project managers, quality control officers, and manufacturing need to buy into the ultimate goal.



Leverage the Investment

While the initial decision to pilot RFID technology may foster better customer service, do not ignore the potential for significant operational paybacks such as improved efficiencies and inventory control.

Looking Forward

The success of the project is reflected in the future plans for EPC-enabled RFID. Three Fresenius Kabi facilities in the U.S. across multiple product lines are being readied for the technology, with 21 medications planned for RFID in 2021, building out the technology to include more of its drugs in subsequent years.

"We'll be supporting our customers both from a sales and customer service standpoint, ensuring that they get the product properly and are able to start using it immediately. We're also working with RFID vendors to ensure that their systems properly interpret GS1 data standards.

"We are creating a lot of resources for support, including a website, information going out to customers, supporting education at conferences," Lindsey says. "It's a very important step to ensure customer satisfaction. All of these things are important to supporting the adoption of RFID in general."

EPC-enabled RFID tags on the Fresenius Kabi unit-of-use can ultimately eliminate inadvertent entry error changes to a medication's product data at the hospital and in the future along the supply chain.

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 eAgile

Established in 2009, eAgile sets the industry standard for RFID based IoT solutions for the healthcare, pharmaceutical and nutraceutical markets. From a vertically integrated headquarters in Grand Rapids, Michigan and supporting sales office in Zurich, Switzerland, eAgile designs, tests, manufactures and distributes an expanding portfolio of customized RFID products. Shipping to over 40 countries across 5 continents, eAgile's clients range from emerging healthcare tech start-ups to established industry leaders whose brands have become household names. www.eagile.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 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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www.gs1us.org/tools/solution-provider-finder

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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

Connect With Us

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