Creating a Strategic Foundation of Quality Data

Siemens Healthineers takes UDI implementation to next level for its digital transformation

Siemens Healthineers helps healthcare providers transform the delivery of care while improving the patient experience. Touching up to five billion patients worldwide every day, Siemens Healthineers relies on innovation and the beneficial design of its solutions, which in recent years have included digitalizing healthcare solutions to accommodate the large-scale transformation that today's healthcare industry demands. Using compliance with the U.S. Food and Drug Administration (FDA) Unique Device Identification (UDI) Rule[1] as the spark, Siemens Healthineers ignited systemic data governance, data quality, and data collaboration programs and processes that promise a future continuum of value.

Nothing could be more exemplary of a large organization's ability to foster widespread change than Siemens Healthineers' efforts to come into compliance with the U.S. FDA Unique Device Identification Rule. An early supporter of GS1 Standards in healthcare, Siemens Healthineers recognized the benefits and advantages that using GS1 Standards can offer companies and supply chains. With numerous internal and external manufacturing sites and thousands of products, the company was determined to use its implementation of GS1 Standards as a broader opportunity to propel the company forward.

A History of Traceable Healthcare

The partnership between Siemens Healthineers and GS1 US® spans nearly a decade, with Siemens becoming an early adopter in the GS1 US GTIN® Sunrise Initiative: the drive to encourage industry to apply the GS1 Global Trade Item Number® (GTIN) to products to standardize identification, increasing the ability to conduct e-commerce worldwide.

To derive maximum benefit across its supply chain, the Siemens Healthineers team took a straightforward and comprehensive approach by assigning a GTIN to every Siemens Healthineers' product and having processes in place to ensure product information is complete and accurate. This laid the foundation to leverage additional GS1 Standards, including the GS1 Global Data Synchronization Network™ (GDSN®).

The team took advantage of the GDSN as the opportunity to adopt proven product data standards and a highly efficient method for sharing standards-compliant data. Information on all of Siemens Healthineers' products is now available through the GDSN, and Siemens Healthineers uses GDSN to share product information with trading partners and to submit the required data set to the U.S. FDA Global UDI Database (GUDID).[2]

"We saw the potential of GS1 Standards for laying a firm foundation on which we could build," says Elisa Bowling, program director of Supply Chain Management Strategy and the UDI project lead.

What's most notable about Siemens Healthineers' embrace of GS1 Standards is not how extensively they have been applied for commerce and supply chain efficiencies, but that they have been used as a broader opportunity to advance the company's harmonization strategy. In fact, this is a recurring theme in the Siemens Healthineers standardization story: Use marketplace imperatives as a catalyst to improve business operations overall.

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Elisa Bowling *Program Director, Supply Chain Management Strategy and UDI Project Lead*

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1   For information about the rule, see the U.S. FDA Unique Device Identification System.

2   Hein, Dr. Dietmar. (2012/2013). *Siemens Healthcare Diagnostics: A holistic approach to global data standards.* Retrieved from https://www.gs1.org/docs/healthcare/GS1_Healthcare_Reference_Book_2012-2013.pdf

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GS1 Standards

Mounting an effort of the magnitude of UDI in a large corporation is no small undertaking, but Siemens Healthineers is no novice when it comes to managing challenges or complexity.

Siemens Healthineers' very existence resulted from merging three different businesses with three very different legacy systems and practices. The manufacturing practices varied among the more than 40 sites: some internal manufacturers and others original equipment manufacturers (OEMs).

Executive Sponsorship and Top-Level Vision

As more details underpinning the U.S. FDA UDI Rule became known and understood, Siemens Healthineers formed a global executive sponsorship group to provide oversight.

This team of key executive leaders thoroughly understood the importance of applying GS1 Standards to UDI. Moreover, they were eager to build upon the framework that GS1 Standards offered and led by example in encouraging project members to find even more applications for standards throughout the Siemens Healthineers supply chain. Leadership was bullish on transforming the delivery of healthcare for customers, patients, and for the company.

"We basically received a 'blank check'... and I'm not speaking financially; it was a blank check to abandon traditional thinking that sometimes occurs in organizations," says Bowling. "They provided 'air cover' that allowed for us to make sustainable decisions and apply innovative design—such as using the power of GTINs and barcodes to future-proof our ability to identify, track, and analyze the movement of products within the supply chain."

The executive sponsors also promoted an atmosphere for continuous education, allowing Siemens to build robust in-house expertise on GS1 Standards for product identification. Armed with the proper knowledge, the project team could make decisions such as transitioning all products to be identified with GTINs encoded in robust two-dimensional (2D) GS1 DataMatrix barcodes (from traditional GS1-128 barcodes) while appropriately educating customers.
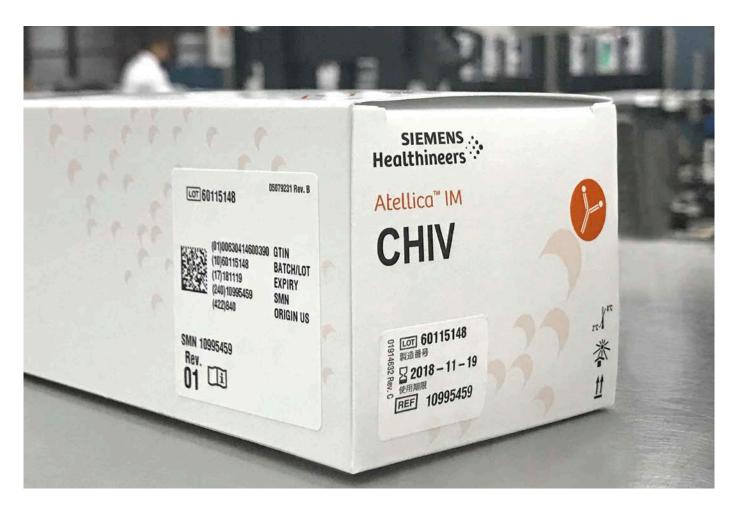
As a result, very early into the standards project, the Siemens Healthineers team found itself working toward compliance to the UDI regulation, but also contributing to something much bigger than this single initiative.

Bowling adds, "Dollars, ROI and productivity were never a focused requirement within the project. These were not required for the team to move forward. UDI compliance was a given, and once this was initiated, the fire was lit to embed standards fully into the organizational structure."

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We were expanding the deliverables from the [UDI] project. We were putting a GS1 DataMatrix barcode on everything [other than what is required by the regulation], because we recognized the improvement it makes; not just for us and our product tracking, but throughout the supply chain, ease-of-clearance through customs and utilization by our customers. That's successful!"

Chuck Fives *Vice President, Manufacturing and UDI Project Executive Sponsor*

A Tall Order for a Small Item

Seeking a barcode that can be applied to a CT scanner weighing more than two tons that can also fit on single patient's blood analysis card narrowed the possibilities significantly. Evaluating options against the product portfolio and associated packaging size constraints, the team decided that the 2D GS1 DataMatrix barcode was the obvious choice. Instead of continuing to bridge differences in processes and protocols at manufacturing sites, a GS1 DataMatrix barcode would be applied to all products, regardless of manufacturing location.

For Siemens Healthineers, implementing U.S. FDA UDI using GS1 Standards involved marking regulated products with a GS1 barcode encoding a GTIN, expiration date, batch/lot number, and serial number. The team evaluated GS1 barcode options as well as product and packaging constraints before deciding to go with the GS1 DataMatrix barcode.

The GS1 DataMatrix barcode can hold large amounts of data in a very small footprint. GS1 DataMatrix can encode all of the GS1 identifiers (like the GTIN and Global Location Number or GLN) as well as the GS1 Application Identifiers (AIs) to accommodate a broad spectrum of data (including the Production Identifiers in the U.S. FDA UDI Rule).

"GS1 DataMatrix is a powerful, yet small barcode that can encode thousands of characters. We started to see the potential that this had for being a tremendous foundation on which we could build," Bowling says. In addition, they saw an opportunity for significant operational transformation.

As Chuck Fives, vice president of Manufacturing and an executive sponsor of the UDI project explains: "We were expanding the deliverables from the [UDI] project. We were putting a GS1 DataMatrix barcode on everything [other than what is required by the regulation], because we recognized the improvement it makes; not just for us and our product tracking, but throughout the supply chain, ease-of-clearance through customs and utilization by our customers. That's successful!"

> **The GS1 DataMatrix barcode on products reduces errors. We're not relying on a person to type in the lot number, the expiration date, and other information associated with our products. We can now have confidence in the data."**
>
> **Bob King** *Senior Director, Quality Management*

The Dream Team Goes Further

While the executive sponsors were the central nervous system of UDI implementation, the UDI project team acted as the heartbeat, powering its messages and directives through the organization's arteries and motivating a vast team toward the goal. The two teams worked in tandem for successful execution of the UDI deliverables and also to extend the organization's understanding and use of GS1 Standards-enabled solutions in the process.

The project leadership needed to mobilize a complex organization of global scale into action. Loosely following "The Law of the Few,"[3] Siemens Healthineers set out to create a group of less than 15 leaders—the right leaders—that would drive the project to all corners of the organizations. *Mavens* are the experts who love to share their knowledge and never stop learning; *Connectors*, with their strong networks, are crucial to getting into the organization's bloodstream; and *Influencers*, are adept at making ideas more attractive, to energize the effort. These professionals gave the Siemens Healthineers organization an exponentially higher likelihood of success, not only in UDI execution, but in changing the status quo.

"Yes, we were looking for people who knew about the standards and regulation, but we also needed people with unique and precious skillsets," Bowling says. "We found that people wanted to come join the team because it was dedicated and doing something unprecedented: We certainly had to comply with the U.S. FDA regulation, but the people involved really wanted to do more for the company and our customers."

From experienced subject matter experts to junior-level interns, members of the Siemens Healthineers UDI implementation team had the opportunity to learn about the benefits of utilizing GS1 Standards and contribute creative "future-proofing" innovation that could transform the healthcare landscape.

"We wanted to have one standard for automatic identification and data capture (AIDC) and we got it with the 2D GS1 DataMatrix," explains Bodo Winkler, head of Siemens Healthineers' Quality and Program Management Office and an executive sponsor of the Global Siemens Healthineers UDI implementation.

A Collaborative and Communicative Approach

The UDI Project Team was given decision-making responsibility and accorded influence over end-to-end product design and supply chain changes, an extraordinary level of control. The cross-functional team members of the project included:

- Executive Oversight
- Project Management
- Regulatory Affairs
- Quality Management
- Information Technology
- Data Governance
- Manufacturing
- Marketing
- Product Lifecycle Management
- Engineering
- Product Labeling
- Customer Service

A strong communications structure was also critical for the successful implementation of GS1 Standards across Siemens Healthineers.

The project team met every Monday for 1.5 hours for the three-year duration of the project. This allowed the team to keep focused and engaged and remain closely connected to messages, issues, and risks with the consistent mantra of "no surprises!"

The caliber of professionals on the project team and the consistency of leadership support kept everyone abreast of developments in the UDI environment and allowed ample opportunity for sharing cross-functional learnings.

"It was a fully collaborative effort across all team elements. This was a first for me: It was fun to work as a team to find solutions to complex problems," says Matthew Flashner, project manager for Point of Care Labeling.

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Elisa Bowling *Program Director, Supply Chain Management Strategy and UDI Project Lead*

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3   Gladwell, Malcolm. (2000). *The Tipping Point: How Little Things Can Make a Big Difference*. Little, Brown and Company.

GS1 Standards are a requirement in almost every tender or quote that we're seeing from our customers. As we became UDI-ready, we were ahead of the curve and used that to our advantage. Now, as we launch new products, we know the data is correct and the labeling is correct, because we have processes and standards that are aligned."

Sue Read *Senior Manager, Product Lifecycle Management*

Originating Best Practices

The opportunity for significant operational transformation was part of the package.

"Product identification and product serialization connects all of the functions in the commercial value chain: logistics, regulatory affairs, quality control, research and development, and commercial product support," says Scott Mathis, vice president of Engineering and business process owner of Product Labeling for UDI implementation.

Today, Siemens Healthineers' products—regardless of UDI requirements—are marked with a GS1 DataMatrix barcode, which is encoded with key attributes, including a GTIN, expiration date, batch/lot number, and serial number.

A single AIDC standard and a common implementation framework helped propel the company forward by aligning the company's global manufacturing operations consisting of 11 internal and 30 external manufacturing sites.

"The GS1 DataMatrix barcode on products reduces errors," adds Bob King, senior director of Quality Management. "We're not relying on a person to type in the lot number, the expiration date, and other information associated with our products. We can now have confidence in the data."

"GS1 Standards are a requirement in almost every tender or quote that we're seeing from our customers," says Sue Read, senior manager of Product Lifecycle Management and data management subject matter expert for the UDI project.

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Foundational Quality

One of the central outcomes of the team effort on UDI, was the recognition of the importance of data quality—no small matter in the era of Big Data.

Early on, the Siemens Healthineers team recognized that the data elements that were part of the U.S. FDA's GUDID submission requirement presented an ideal opportunity to elevate its data management and governance practices. Despite the diversity of functions in the cross-functional team, it was agreed unanimously that precision in gathering, cleansing, organizing, and submitting UDI-relevant data directly to the U.S. FDA was essential.

In order to safeguard the ability to sell medical devices in the United States market, each data element must be considered a valuable asset, requiring housekeeping and maintenance to yield immediate value and provide a platform on which to build sustained value in the future.

The requirement from the U.S. FDA was relatively straightforward: Provide a certain number of data elements related to each registered medical device sold by Siemens Healthineers.

Obvious questions arose, though answers were not always straightforward. How can we verify the accuracy of incoming data? How can we build an infrastructure that will maintain data integrity? Can we guarantee future processes built upon today's data are secure?

These high-level questions begged important basic questions: Who knows the required data best? Do those people have the ability to input correct data? Can they input data at the correct time?

From a data governance perspective, this project highlighted the importance of clean master data and collaboration across all the business functions to work towards the common goal of data accuracy."

Troy Palmer *Business Process Engineer, Data Governance*

The exercise forced a re-thinking of the master data management process overall. This is where the team's leadership qualities, innovative spirit, technical expertise, and GS1 Standards helped tremendously.

To tackle these questions, the team created a rejuvenated underlying structure for gathering product data for submission to the GUDID. The team refined a list of data stewards, individuals who "own" and supply accurate information for each data field; and defined a strategy for fulfilling data needs at the right time in the product development or design-change process.

An equal partnership was formed between the Siemens Healthineers Information Technology group and the data governance organization, which worked to design customized functionality in the company's enterprise resource planning (ERP) system. Together, they established the framework for a common IT solution and a common set of tools that each of the sites could use for the gathering and electronic submission of UDI data to the GUDID.

"From a data governance perspective, this project highlighted the importance of clean master data and collaboration across all the business functions to work towards the common goal of data accuracy," says Troy Palmer, business process engineer for Data Governance.

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Data quality is one important byproduct that came out of this project. The project created a focus on data as a valuable asset, as a competitive advantage, and as a cornerstone for future improvements. There is now a clear organizational awareness of the value of data, and an ongoing focus on data quality supported by a strong data governance process."

Bodo Winkler *Head of Siemens Healthineers' Quality and Program Management Office and Executive Sponsor of Global Siemens Healthineers UDI Implementation*

One Size—Accuracy—Fits All

In its manufacturing operations, Siemens Healthineers applies labels with barcodes on very large products and on very, very small products.

But regardless of product size, the data structure and methodology had to be identical. In response, the team developed detailed requirements for uniquely identifying the company's range of products for an efficient and successful implementation.

A robust technical mechanism became the centralized "single source of truth" for maintaining and controlling the most sensitive GS1-structured and UDI-relevant data.

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Treating our data as the valuable asset that it is, not only for compliance purposes but also for streamlining our operation, has created new value both internally and externally. Internally, we can use the data as a basis for business intelligence and analytics and externally, to reinforce trust with trading partners."

Scott Mathis *Vice President, Engineering*

And Accessibility for Many

An additional component of the company's refreshed data governance and data integrity strategy was assuring that high-quality product information was gathered from and is accessible to as many contributors as possible. This included team members who were not expert users of the Siemens Healthineers ERP system, but who were owners of key data.

"We designed and created our own SharePoint-based web application tool for all our users who may not be SAP-savvy. We made it very simple and easy for them to use," Bowling says and added that product photos were included to highlight where to look on a product for specific pieces of information, along with product descriptions, helpful hints, and wikis.

Using the GS1 GTIN structure as the glue that would hold the data gathering and product identification together, the GUDID data-gathering model began to take shape, with enhanced quality and integrity at its core. "It really demonstrates another pillar of Siemens Healthineers, which is quality," adds Read. "We are a quality company and we stand behind what we say."

Into the Future

"Treating our data as the valuable asset that it is, not only for compliance purposes but also for streamlining our operation, has created new value both internally and externally. Internally, we can use the data as a basis for business intelligence and analytics and externally, to reinforce trust with trading partners," Mathis says.

"There's obviously a major benefit to our customers," continues Mathis. "The GUDID data set can be used in their local hospital processes for their benefit and the benefit of patients. The larger GDSN data set helps improve supply chain and logistics efficiencies, for us and for our customers. It's a huge benefit to be able to efficiently manage inventory availability and other patient-impacting processes."

Taking Best Practices Global

Siemens Healthineers is now positioned to efficiently address other emerging UDI regulations around the world. And its keen focus on data quality, governance, and management now differentiates Siemens Healthineers as a manufacturer and contributor to the healthcare landscape of the future.

> **With GS1 Standards as a foundation, we have gained compliance and so much more. We now have the ability to scale continually, support digitalization, and connect to our customers and their demands—achieving all this throughout our global supply chain."**
>
> **Elisa Bowling** *Program Director, Supply Chain Management Strategy and UDI Project Lead*

The digital applicability of GS1 Standards has enabled Siemens Healthineers to realize its vision to improve its supply chain and logistics processes, has automated its identification of products through complaint-handling channels, has initiated the use of barcode content for product receipt in distribution management and analytics, and will continue to find more value opportunities for its commercial channels and manufacturing.

GS1 Standards-based product identification, barcoding, and data quality management is now part of the culture at Siemens Healthineers.

Using GS1 Standards has allowed Siemens Healthineers to not only drive a high level of standardization, but also set the stage for realizing its supply chain of the future.

"We no longer treat GS1 Standards or UDI as a project or as an initiative," Bowling says. "It is now a supply chain management—even a customer solution—strategy. It's in our veins now. GS1 Standards are providing the foundation on which to build the next level."

In the near term, Siemens Healthineers will continue expanding the use of GTINs and GLNs in transactions and increase the list of attributes available on the GDSN as healthcare providers expand their own use.

The team has many plans on the horizon—all using GS1 Standards—to automate and improve the efficiency of logistics and supply chain processes: labeling cases, pallets, and logistics units and tracking product movement; expanding its use of internal processes in manufacturing to better manage data collected on equipment; supporting predictive data analytics; and enhancing upstream applications by applying GS1 DataMatrix barcodes on subcomponents' labels. The team is also looking toward encoding additional GS1 AIs in their DataMatrix barcodes for a number of applications.

"With GS1 Standards as a foundation, we have gained compliance and so much more. We now have the ability to scale continually, support digitalization, and connect to our customers and their demands—achieving all this throughout our global supply chain," concludes Bowling.

Siemens Healthineers UDI Program

Three year collaborative effort for successful UDI implementation

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About Siemens Healthineers

Siemens Healthineers is a leading medical technology company with over 170 years of experience and 18,000 patents globally. With more than 48,000 dedicated colleagues in over 70 countries, Siemens Healthineers continues to innovate and shape the future of healthcare. The company's purpose is to enable healthcare providers to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare. An estimated five million patients globally everyday benefit from the company's innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine, as well as digital health and enterprise services. usa.healthcare.siemens.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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