



THE GLOBAL LANGUAGE  
OF BUSINESS

## CASE STUDY



## Cook Medical



**“For us, using standards is principally about making patients safer—making sure the right product is delivered at the right time to the patient’s bedside.”**

— **DAVE REED**, Vice President  
of Operations and Healthcare  
Business Solutions

## Global medical device manufacturer transforms vision into greater patient safety with GS1 Standards

### CHALLENGE

With worldwide manufacturing centers operating as separate entities, Cook Medical (Cook) decided to unify and standardize its business processes to better serve its customers and their patients as “one Cook Medical.”

### SOLUTION

Cook Medical chose GS1 Standards, implementing Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) to uniquely identify all of its worldwide products and locations. The company registered its GTINs and attributes in a GS1 Global Data Synchronization Network™ (GDSN®)-certified Data Pool for sharing with healthcare systems. The company is integrating these GS1 Standards into its processes for greater visibility while also leveraging them to support the U.S. Food and Drug Administration’s (FDA) Unique Device Identification (UDI) ruling.

### BENEFITS

Patient safety is of paramount importance to Cook Medical. With GS1 Standards in place, Cook has improved the traceability of products as they travel through the supply chain for a highly effective track and traceability process. Internal benefits continue to emerge, including an improved customer-centric approach that enhances the Cook brand, and the promise of increased efficiencies as more healthcare systems and suppliers adopt standards-based trade.

## A Shared Vision

Cook Medical has been at the forefront of minimally invasive medicine since its founding in 1963 by founder, Bill Cook. From a spare apartment bedroom, Cook launched the company and, in his own words: “For me to make my product, all I needed was a blowtorch, a soldering iron, and a few little tools and fixtures I could make myself.”

From the beginning, Cook Medical worked closely with its customers—physicians and other healthcare professionals—to develop less invasive ways to treat patients.

“It’s impossible to talk about innovation at Cook Medical without talking about physicians like Dr. Charles Dotter,” says Gavin Seyler, Cook Medical’s global brand marketing manager. “Our best ideas have come from listening to physicians who want less invasive ways to treat patients. This approach to product development was established with Dr. Dotter, more than 50 years ago.”

The Cook innovation process always starts with listening to customers and asking questions to fully understand their needs. Solutions are developed together, whether a new product, technique, procedure, or even business process.

Over the years, this model of innovation—listen, understand and collaborate—has led Cook to develop many new products.

Cook was the first company to package the three primary components for percutaneous (through the skin) catheterization—needles, wire guides, and catheters—in one convenient set for cardiovascular procedures. In less than a decade, its growth trajectory went straight up, allowing the company to expand into Europe and Asia in the 1970s.

The company’s reputation for customization had physicians knocking on Cook’s door to develop other devices to serve gastrointestinal endoscopy, urology and women’s health specialties, leading to the formation of the Cook Medical research and development facility, MED Institute, in the 1980s.

Today, Cook Medical is the world’s largest privately held medical device manufacturer, producing over 16,000 devices globally. It has ten divisions based on the 41 medical specialties it supports, has manufacturing facilities in Australia, Denmark and Ireland, in addition to those in the U.S., and has nearly 2,500 employees in its Indiana headquarters alone.

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**“We didn’t need to develop a business case to make the decision [to adopt standards]. We knew it was the right thing to do, so we took action. For our global company, it only made sense to select GS1 Standards that are most-used worldwide.”**

— **CHUCK FRANZ**, Vice President and CIO

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## The Right Thing to Do

By the late 90s, Cook Medical’s entrepreneurial culture had created separate, thriving companies that developed and commercialized life-changing innovations—in very different ways. Worldwide, the company had approximately 376,000 SKUs with each company using different interpretations of Cook Medical’s approach for numbering the products.

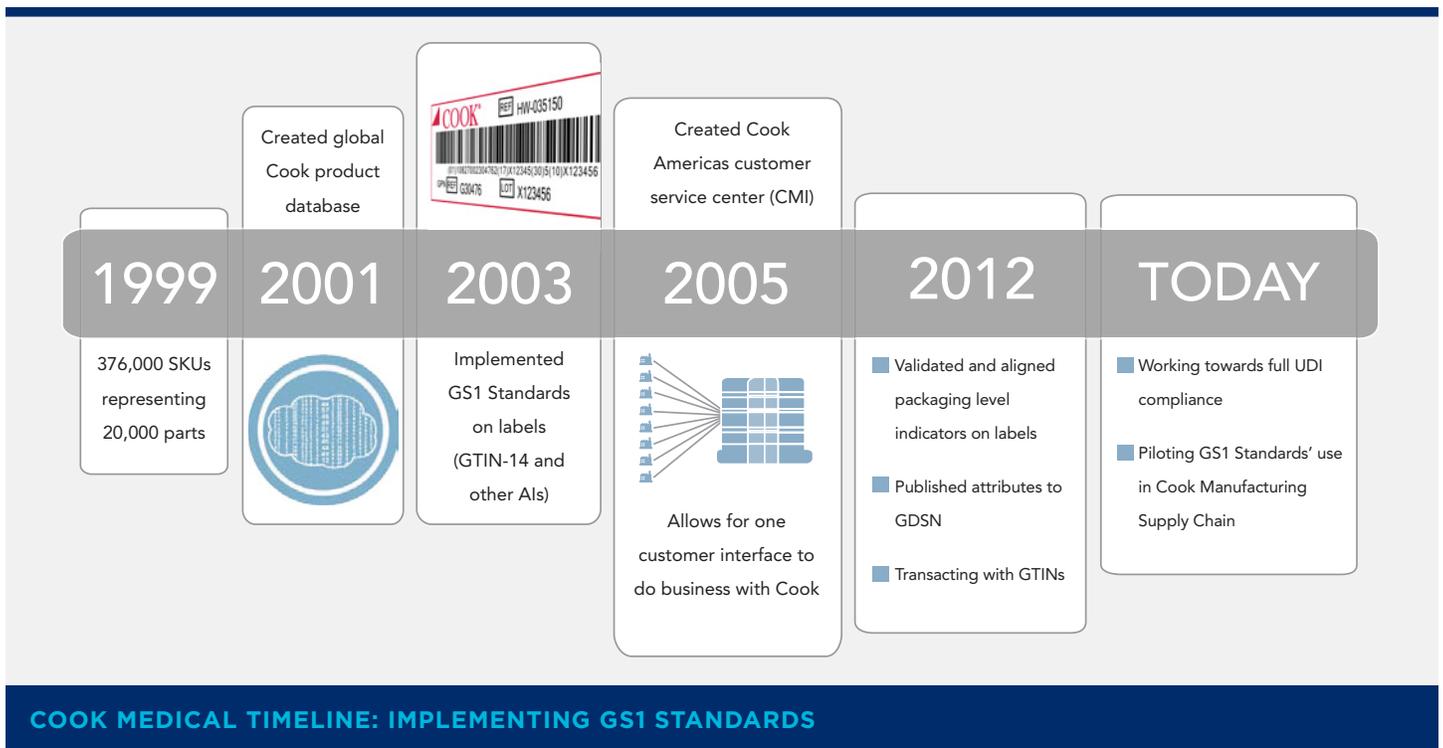
“It wasn’t easy for us to conduct business with our customers around the globe. Moving products through our global supply chain was getting increasingly complex, and tracking products in our supply chain was not as efficient as we wanted it to be,” explains Chuck Franz, vice president and CIO. “We quickly came to the conclusion to unify our business as ‘one Cook Medical’ to better serve our customers and the patients who depend on our products.”

Around that same time, many healthcare systems were beginning to look for better ways to communicate with Cook and their other suppliers. The healthcare industry was under increasing pressure to treat a greater number of patients with less cost—an ongoing challenge today. And regulatory bodies like the FDA had added regulations as well.

“For us, using standards is principally about making patients safer—making sure the right product is delivered at the right time to the patient’s bedside,” says Dave Reed, vice president of Operations and Healthcare Business Solutions. “While our customers did not mandate the use of standards, we were starting to hear from them that a standards-based approach was going to become the preferred, or possibly only way of doing business with them. We also recognized the significant efficiencies a shared system of standards could bring to the industry. Based on all these reasons, we decided to make standardization a priority for our business.”

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## A Global Language

The analogy Seyler uses is an apt one: “Let’s say that you have to get gas, you have to go to the grocery store, to the post office and bank. If you had to speak a different language at each one of those points, it would probably be a little difficult to go about your daily routine. With standards, we adopted a global language to help our business be more efficient and easier to do business with.”

In 2001, Cook Medical took its initial step to transition from separate product portfolios to a single global product catalog.

The company then proceeded to identify each of its products with a GS1 Global Trade Item Number® (GTIN®) encoded in a GS1-128 barcode for labels. Global Location Numbers (GLNs) were assigned to customer “touch points” such as orders and distribution centers, returns, and Cook Medical Inc.

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The Cook IT team worked closely with the company’s quality team and manufacturing entities. “One of the hurdles we had to tackle was all the different entity ‘standards’ in place—the different barcodes, lot numbers and ways of labeling products that had evolved from internal decisions and requests from government,” says Franz. “This first implementation in 2003 was no small task, but had to get done. We were laying the foundation for traceability and greater efficiencies in our supply chain.”

## Shared Conviction

Implementing GS1 Standards on labels also provided a major prerequisite for Cook’s customer service center in North America. Launched in 2005, the center is a shared services operation, providing customers with a single point of contact for questions about any Cook device manufactured anywhere the world.

“With GTINs and GLNs assigned, we created a company-wide, cross-functional team to help Cook integrate the use of standards into our business transactions and supply chain processes such as recalls,” says Reed. “We started by focusing on the non-clinical side of our supply chain to make sure Cook products could easily travel from our manufacturing centers to customer locations.”

**“We had to make the team large enough to be effective, yet small enough to be efficient. I believe we were able to strike the right balance.”**

— **SHELLY BOYD**, Director of Global IT Shared Service Systems

This meant completing milestones such as ensuring every product barcode was “readable” for scanning at points-of-delivery and that GTINs were marked on appropriate packaging levels like cases and pallets.

The cross-functional team met regularly to report on activity status and work out issues. Shelly Boyd, director of Global IT Shared Service Systems, was instrumental in leading the very detailed, multi-functional process to keep interest and accountability high.

“Each team was a champion of their information,” says Boyd. “We had to make the team large enough to be effective, yet small enough to be efficient. I believe we were able to strike the right balance.”

Reed continues, “It took us about five years to complete this phase for North America-manufactured products only. What carried us was a shared conviction in the benefits for our customers and patients.”

The team’s goal was to be prepared for the healthcare industry’s “2012 GTIN Sunrise.” This industry-led initiative defined objectives for healthcare suppliers and providers on the internal use of GTINs as well as sharing GTIN product data and attributes with trading partners via a GS1 GDSN-certified Data Pool. Through the Data Pool, the GDSN connects Cook and its subscribing customers to the GS1 Global Registry® for immediate electronic sharing of standardized, up-to-date, accurate product information. Currently, Cook’s product information is shared with 28 customers.

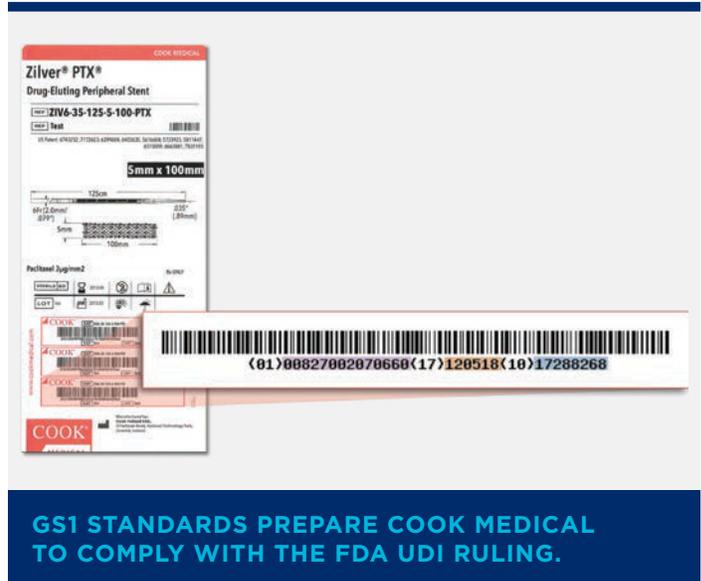
Before orders can be placed, Cook products are assigned GTINs and only loaded into the GDSN after the GTIN attributes have been verified.

To date, Cook has loaded 17,179 GTINs into the GDSN for 13,673 available products. With 16,940 total available products, Cook has published 80 percent of its products in the GDSN.

And nearly 95 percent of the published products’ measures are verified, meaning all dimensions and weights have been validated.

## The Future Today

With GS1 Standards, Cook Medical is prepared to comply with the FDA UDI rule requiring manufacturers to label their products with unique device identifiers. In fact, Cook participated in the FDA UDI pilot in 2012 to help the government agency assess the ruling.



**GS1 STANDARDS PREPARE COOK MEDICAL TO COMPLY WITH THE FDA UDI RULING.**

“Today there is a broader agreement in the industry for standardization of product information—something that is now being expressed with the UDI,” says Reed. “We believe, as suppliers and providers consume more and more of the standardized data, it’s just a matter of time when everyone wins, especially patients.”

The UDI provides a common language for trading partners to use about products that travel through the supply chain. “The GTIN and UDI provide the same data and the same benefits of more accurate, efficient supply traceability and patient safety,” says Franz.

The UDI system is comprised of a UDI code, application of the UDI to device labeling and packaging, and a related database, the FDA Global Unique Device Identification Database or GUDID.

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“As government gets into the electronic act with national product catalogs and the GUDID, it’s exciting how much simpler our industry can make the transaction of devices,” adds Franz. “Over the next ten to fifteen years, it’s going to be a very progressive time for healthcare.”

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### Shared Insights

With years of experience, the Cook Medical team offers advice for others considering the move to standards:

**Start.** “Quite honestly, the first thing is that you just have to make the decision to start. It sounds simple, but it can be hard to do. Accept the fact that you are not going to convince everyone that this is the right thing to do, but it is.”

**Prioritize.** “Once the decision to start is made, narrow the scope to prioritize and decide what you need to tackle first. Remember that taking small steps is still making progress. This approach has given us the ability to be the most successful.”

**Decide.** “You may have to make decisions that assume certain things, based on external forces that you cannot control. Make the best decision and adjust later if necessary. But keep going.”

**Commitment.** “From a technology process standpoint, the transition to standards is not really costly. The ‘cost’ comes from the significant time, effort and commitment it takes from your resources.”

**Purpose.** “Remember why you are doing what you are doing: patient safety is paramount, and the efficient movement of products through the healthcare system benefits everybody.”

“For our business, the move to use global standards was a good decision, because the benefits continue to play out,” says Reed.

Franz adds, “We’re hearing that standards are making customers’ lives better and this is better for patients. If there are benefits for both our customers and patients, then it’s ultimately better for Cook.”

## COOK MEDICAL RECOGNIZED BY HEALTHCARE TRANSFORMATION GROUP

In a global business like Cook Medical, the move to standards is a multi-year undertaking and the full benefits will only be realized when standardized data consumption reaches critical mass. The evolution has begun in North America, due to the importance of supply chain efficiencies driving down overall healthcare costs, and the greater safety afforded by traceability, including expeditious product recalls.

In 2010, five major healthcare systems—Geisinger Health System, Intermountain Healthcare, Kaiser Permanente, Mayo Clinic and Mercy—formed an action-oriented collaboration called the Healthcare Transformation Group (HTG) to share best practices and drive needed positive change across the healthcare supply chain.

By communicating in the marketplace through one voice, the HTG aims to drive the adoption of GS1 Standards by suppliers for improved supply chain efficiencies and enhanced patient safety.

During its 2013 Summit, HTG presented Cook Medical with its inaugural HTG Excellence Award that honors a supplier who serves as a leader in the adoption of GS1 Standards.

## About the Companies

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— **CHUCK FRANZ,**

Vice President and CIO

### CONTACT US

GS1 Healthcare US® provides expertise, tools and resources to help companies implement GS1 Standards to improve patient safety and supply chain efficiency. To learn more, contact GS1 Healthcare US at [GS1HealthcareUS@GS1US.org](mailto:GS1HealthcareUS@GS1US.org) or visit our website at: [www.GS1US.org/healthcare](http://www.GS1US.org/healthcare)

### ABOUT COOK MEDICAL

Since 1963, Cook Medical has worked closely with physicians to develop technologies that eliminate the need for open surgery. Today we are combining medical devices, biologic materials and cellular therapies to help the world’s healthcare systems deliver better outcomes more efficiently. We have always remained family-owned so that we have the freedom to focus on what we care about: patients, our employees and our communities. [www.cookmedical.com](http://www.cookmedical.com)

### ABOUT GS1 US

GS1 US, a member of GS1, is an information standards organization that brings industry communities together to solve supply-chain problems through the adoption and implementation of GS1 Standards. GS1 is an Accredited Issuing Agency for the U.S. Food and Drug Administration for Unique Device Identification (UDI), and GS1 Standards are authorized for use by manufacturers for UDI implementation.

More than 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration and for maximizing the cost effectiveness, speed, visibility, security and sustainability of their business processes. 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](http://www.gs1us.org)

### ABOUT GS1 HEALTHCARE US

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the U.S. healthcare industry 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](http://www.GS1US.org/healthcare)



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