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Cook Medical transforms its vision into greater patient safety with GS1 Standards



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Abstract

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

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 Synchronisation Network™ (GDSN®)-certified Data Pool for sharing with healthcare systems. The company is now 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.

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.

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David Reed, Vice President of Operations and Healthcare Business Solutions

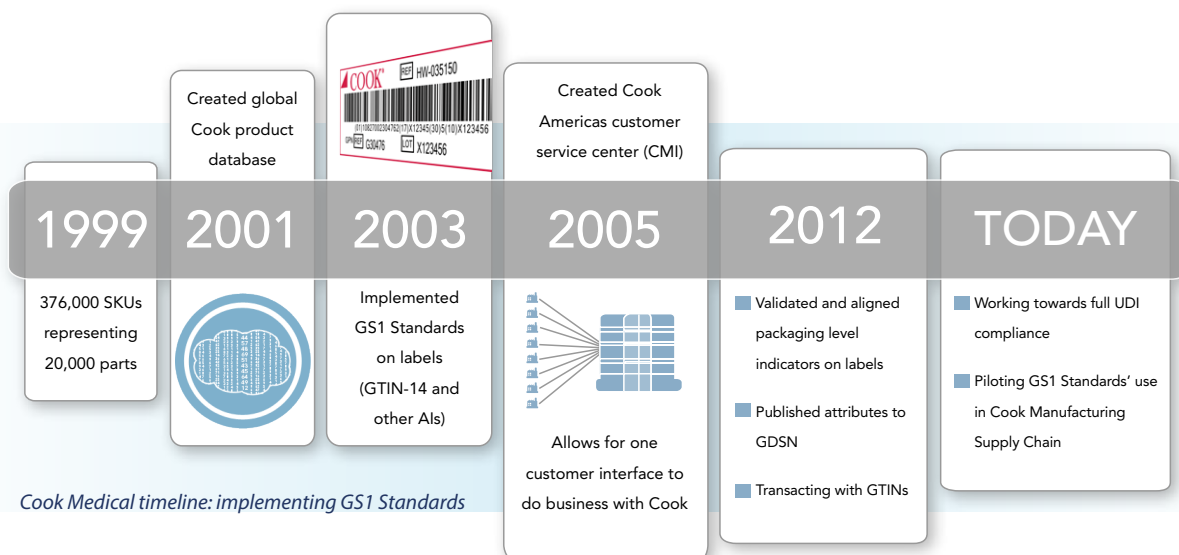
Shared vision

Cook Medical has been at the forefront of minimally invasive medicine since its founding in 1963 by founder, Bill Cook. From the beginning, Cook Medical worked closely with its customers - physicians and other healthcare professionals - to develop less invasive ways to treat patients.

Today’s Cook Medical innovation process continues to put customers first; it 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) catheterisation 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.

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, Ireland and the U.S., and has nearly 2,500 employees in its U.S. headquarters alone.



Cook Medical timeline: implementing GS1 Standards



“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.”

Chuck Franz, Vice President and CIO



GS1 Standards prepare Cook Medical to comply with the U.S. FDA UDI ruling

The right thing to do

By the late 90s, Cook Medical’s entrepreneurial culture had created separate, thriving companies that developed and commercialised 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 Cook to conduct business with its customers around the globe. Moving products through its global supply chain was getting increasingly complex, and tracking products was not as efficient as the company wanted it to be. As a result, Cook decided to unify its business as “one Cook Medical” to better serve customers and patients.

For Cook, using standards was principally about making patients safer - making sure the right product was delivered at the right time to the patient’s bedside. While Cook’s customers did not mandate the use of GS1 Standards, the company was 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.

Cook also recognised the significant efficiencies a shared system of standards could bring to the industry. Based on all these reasons, Cook decided to make standardisation a priority for its business. And as a global company, Cook felt it made sense to select GS1 Standards as the most-used worldwide.

A global language

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

The Cook IT team then worked closely with the company’s quality team and manufacturing entities to identify each of its products with a GS1 Global Trade Item Number® (GTIN®) encoded in a GS1-128 bar code for labels. Global Location Numbers (GLNs) were assigned to customer “touch points” such as orders and distribution centers, returns, and Cook Medical Inc.

One of the hurdles the team had to tackle was all the different entity “standards” in place - the different bar codes, lot numbers and ways of labeling products that had evolved from internal decisions and requests from government.

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.

The UDI provides a common language for trading partners to use about products that travel through the supply chain. 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.

As government gets into the electronic act with national product catalogs and the GUDID, Cook is excited about how much simpler the industry can make the transaction of devices





Cook found this first implementation in 2003 was no small task, but it had to get done. The company was laying the foundation for traceability and greater efficiencies in its supply chain.

Shared conviction

Implementing GS1 Standards on labels also provided a major prerequisite for the creation of 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, a company-wide, cross-functional team was created to help Cook's managers integrate the use of GS1 Standards into business transactions and supply chain processes such as recalls. The team started by focusing on the non-clinical side of the supply chain to make sure Cook products could easily travel from manufacturing centers to customer locations. This meant completing milestones such as ensuring every product bar code was "readable" for scanning at points-of-delivery and that GTINs were marked on appropriate packaging levels like cases and pallets.

In approximately five years, Cook completed this phase for North America-manufactured products only. What carried the team was a shared conviction in the benefits for both 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 standardised, 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.

Cook Medical recognised by Healthcare Transformation Group (HTG)

In a global business like Cook Medical, the move to standards is a multi-year undertaking and the full benefits will only be realised when standardised 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.

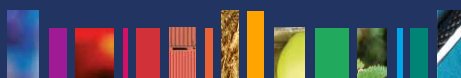
In 2010, five major healthcare systems – Geisinger Health System, Intermountain Healthcare, Kaiser Permanente, Mayo Clinic and Mercy – formed an action-oriented collaboration called the HTG to share best practices and drive needed positive change across the healthcare supply chain.

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.

"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 world-wide."

Chuck Franz, Vice President and CIO





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

David Reed, Vice President of Operations and Healthcare Business Solutions

Shared insights

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

Start. Just make the decision to start. It sounds simple, but it can be hard to do. Accept the fact that not everyone is going to be convinced that implementing standards is the right thing to do, but it is.

Prioritise. Once the decision to start is made, narrow the scope to prioritise and decide what to do first. Remember that taking small steps is still making progress.

Decide. Make decisions based on assumptions and understand there are external forces that cannot be controlled. 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 the company’s resources.

Purpose. Be mindful of the reasons for taking action: patient safety is paramount, and the efficient movement of products through the healthcare system benefits everybody.

About the authors

Chuck Franz is the Vice President and Chief Information Officer for Cook Group. Chuck graduated with a BS in Computer Science from Indiana University, and joined Cook as a software engineer in 1984. Over the past 29 years he has worked in a variety of roles in information technology, operations and management at Cook Group companies. Chuck has served as an operations manager for Cook Incorporated, operational liaison, President of Cook Vascular, President of Cook Urology and interim President of Cook Australia. He has been in his current role since 2005.

David Reed is currently Vice President of Operations, Vice President of Healthcare Business Solutions and Corporate Compliance Officer for Cook Medical Incorporated, a pioneer of many of the devices now commonly used worldwide to perform minimally invasive medical procedures. With over 30 years of life science industry expertise including time as a Sales Representative, National Sales Manager and Vice President of Sales, Mr. Reed has spent the last nine years in an operational role at Cook Medical

overseeing the start up and implementation of the North American customer and distribution services business. Included within the scope of this Cook entity are the areas of customer service, sales operations, and supply chain activities. Additionally he leads Cook’s Healthcare Business Solutions team which focuses on the business and supply chain processes within healthcare. Mr. Reed holds an MBA from California Miramar University and serves as a member of the Indiana University Kelly School of Business Supply Chain and Global Management Academy Advisory Board.

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

