

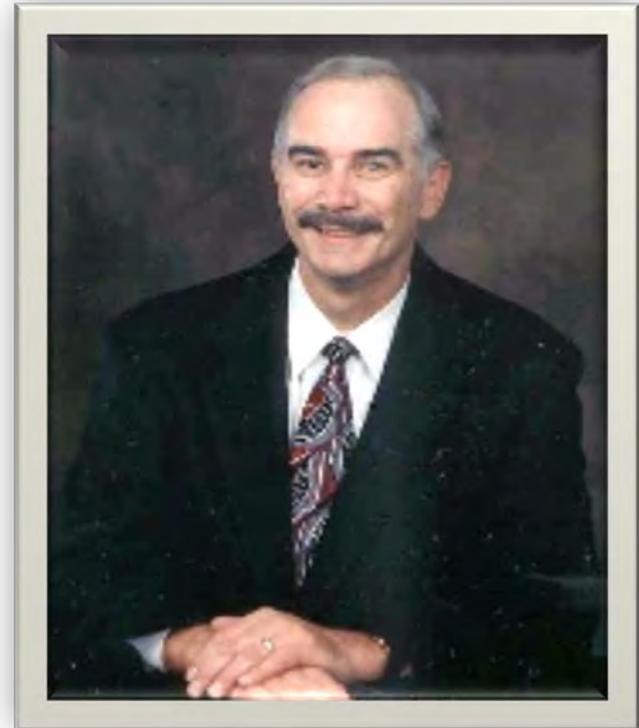
John J. Roberts, JD
Director, Healthcare, GS1 US

EMERGING STANDARDS FOR VACCINE BARCODING - GS1 OVERVIEW

"Reviewed April 2013"

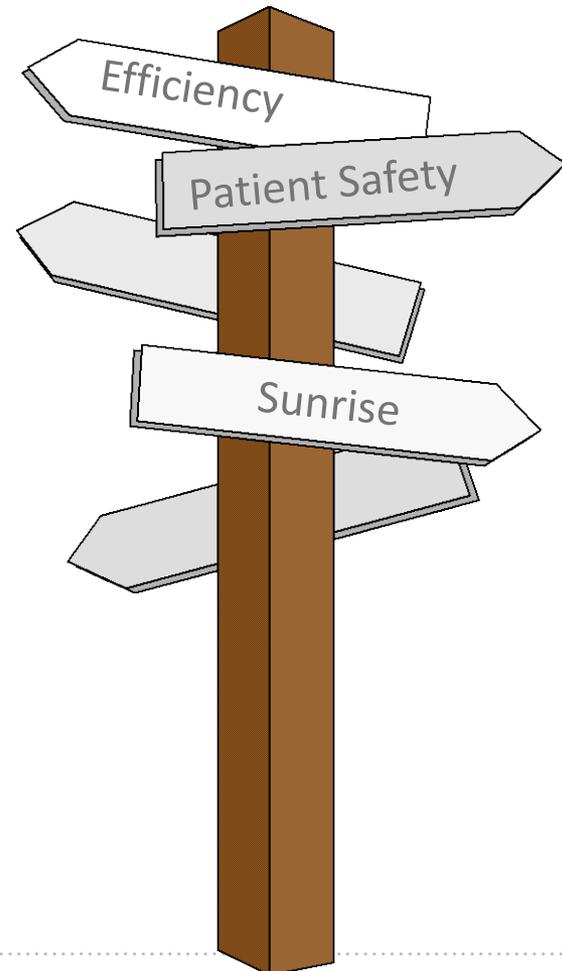
JOHN ROBERTS...

- 14 years GS1 US™
- Program Manager
 - GLN Registry for Healthcare®
2004 to 2010
- Facilitator
 - GLN and GTIN workgroups
- Recipient: Way Paver Award
- 25 years Dept. of Defense
- Directorate Medical Material



Identify, Capture, & Share

- GS1 and GS1 US
- Data standards
 - ✓ Drivers
 - ✓ Why they need to be global
- Global Trade Item Number (GTIN)
- Perfect standards storm
 - GTIN Sunrise
 - FDA 2011 N0719 FDA UDI
 - GHTF UDI
- Questions & Answers

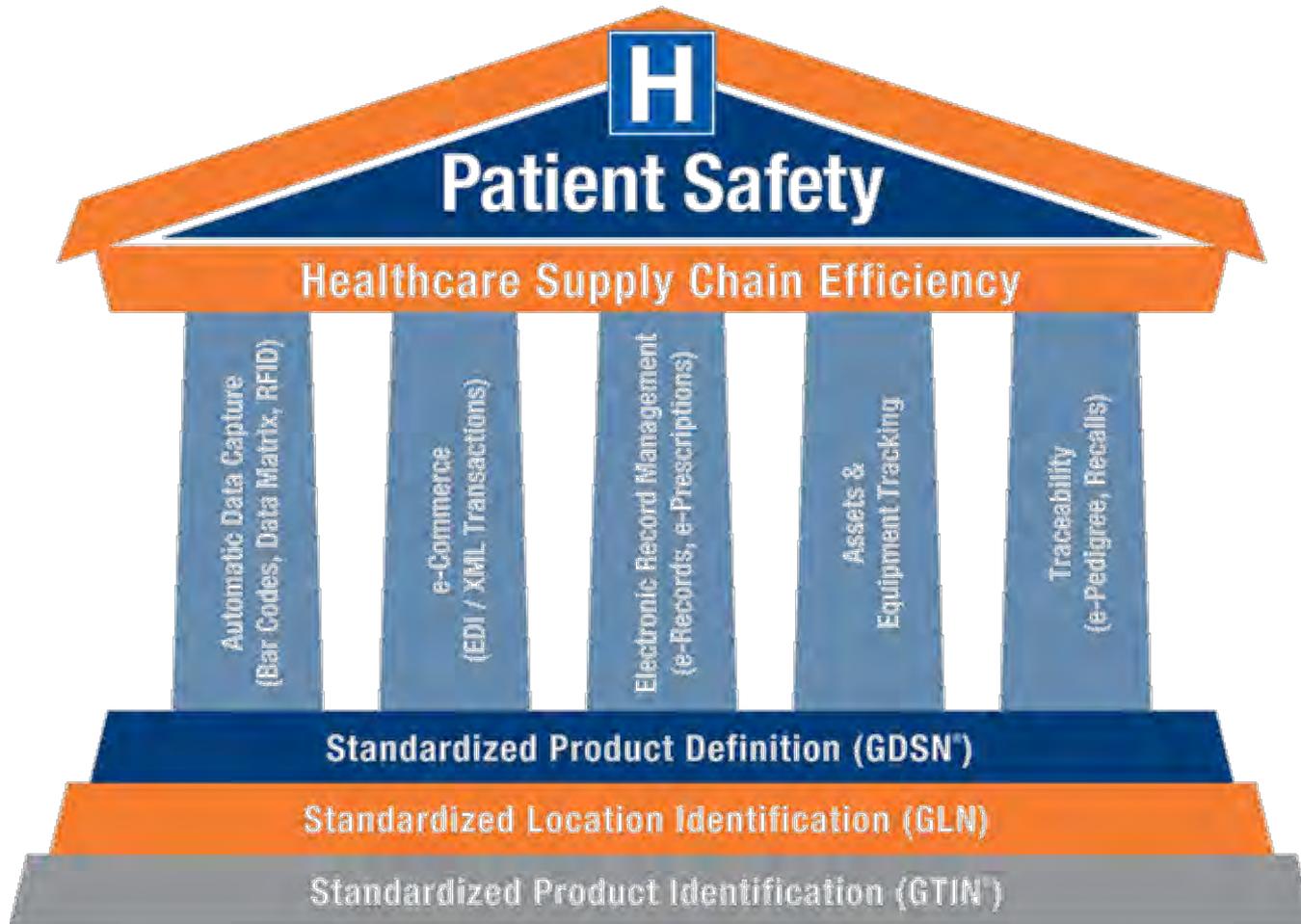


GS1 STANDARDS IN HEALTHCARE ENABLES:

Five Patient Rights

Right Patient (location)	GLN
Right Drug/Device	GTIN
Right Time	
Right Dose	GTIN
Right Route	GTIN

“Building Patient Safety”



Standardization → Interoperability

Copyright 2009 GS1 US



THE GLOBAL LANGUAGE
OF BUSINESS

WHO IS GS1?



GS1 is a not-for-profit organization dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors.

- **107** member organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **5 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world

GS1 is a Holistic Standards System



WHY GLOBAL STANDARDS?



- The package has:
- 6 machine readable codes (5 bar codes, 1 data matrix).
 - 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
 - 12 different language texts (English, French and German are used in more than one country).



SAME NUMBER DIFFERENT PRODUCTS*

Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.

Part Number: 10313 refers to:

Medtronic's "NEEDLE CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"

Hantover's "CARTRIDGE REPLACEMENT STUNNER YELLOW F/CALVES/HEAVY HOGS"

Chattanooga Group's "ACCESSORY TRACTION REPLACEMENT STRAP XL FOR HALTER THORACIC RESTRAINT"

HF Scientific's "TEST KIT WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

Part Number: 1050 refers to:

3M Company's "DRAPE INCISE 35 3/8X 17 5/8IN"

Tyco's "PAD TELFA 3 X 4IN STER"

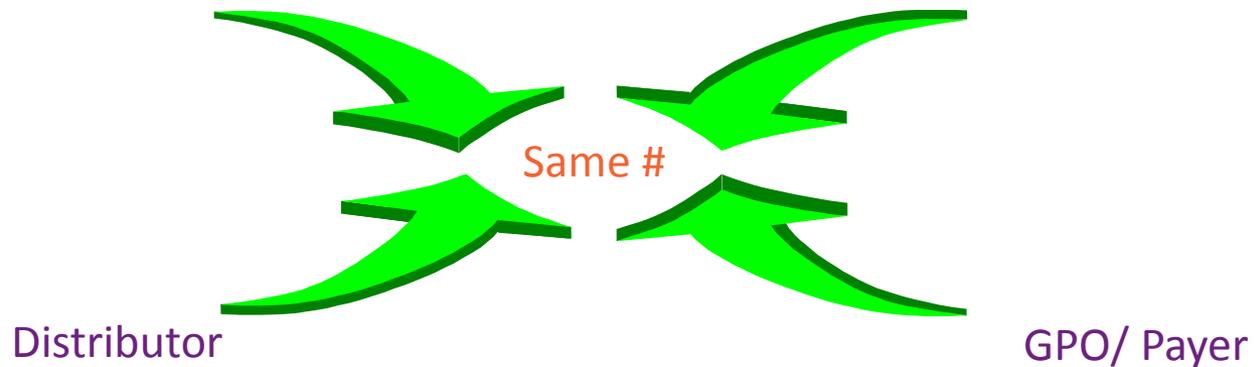
* Source: Premier Inc. Product Item Master

WHY STANDARD PRODUCT IDENTIFICATION?

- One data structure (GTIN) used to reference the item by all members of the supply chain
- No more storing multiple proprietary numbers
- No more cross referencing
- What you see is what you get

Hospital & Retail

Manufacturer



WHO IS GS1 US?



Formerly Known as the UCC

- Established **1973** (*think U.P.C.*)

Implements the GS1 System in the U.S.

- **23** industries, **200,000** members in U.S.
- **1 million** global members, **150** Countries
- **16,000** identified healthcare members in U.S.
- Uniquely identify products, assets, and locations
- Barcodes, EPC, e-Commerce, UNSPSC®



Voluntary, Not-for-Profit, Neutral, Member Driven

GS1 HEALTHCARE US LEADERSHIP TEAM

Healthcare Category	Term ends 12/31/12	Term ends 12/31/13
Acute Care Provider	USC Health Sciences	Intermountain
Alternate Site Provider	Kaiser Permanente	Good Sheppard
Distributor	Cardinal Health	McKesson
Group Purchasing Organization	Amerinet	Novation
Healthcare Associations, Education, Government ¹	SMI	AHRMM
Medical Device Manufacturer	Covidien	BD
Pharmaceutical Manufacturer	Pfizer	Abbott
Retail Pharmacy	Vacant	Vacant
Solution Provider ¹	Election Running	Lawson

¹ Non voting members

GS1 Company Prefix Creates:

GTIN - Global Trade Item Number

GLN - Global Location Number

SSCC – Serial Shipping Container Code

GRAI – Global Returnable Asset Identifier

GIAI – Global Individual Asset Identifier

GSRN – Global Service Relation Number

GSIN - Global Shipment Identification Number

GINC - Global Identification Number for Consignment

GDTI Global Document Type Identifier

WHAT IS A GTIN?

- “GTIN” is a **Global Trade Item Number**®
- A globally unique 8, 12, 13, or 14-digit number that uniquely identifies products and services .
- An identification number of the GS1 System.
- Unique and unambiguous .
- Uniquely identifies a product at every level of packaging
 - A non-intelligent number
 - **GTIN Allocation Rules**
- It is about the data not the carrier.

Examples:

GS1 -128 (14-digit GTIN)



GS1 DataMatrix (14-digit GTIN)



GS1 Databar (14-digit GTIN)



1 GTIN – 2 ROLES

PHYSICAL

Encoded in barcodes

EPC – unique identity

Scanned at point-of-care/ use/ sale, warehouses, etc. accurate data capture

GTIN drives applications

ELECTRONIC COMMERCE

Intra-company: Stored in product masters to uniquely identify items

Registered in GDSN and synchronized between trading partners

Used in ongoing electronic transactions between trading partners, e.g., purchase orders, invoices, advanced ship notices, etc. (UK)

HEALTHCARE GTIN ALLOCATION RULES



5.1.6 Declared change in net content

Any modification which leads to a declared change in net content of a healthcare item requires a new GTIN to be assigned...

Requires New GTIN

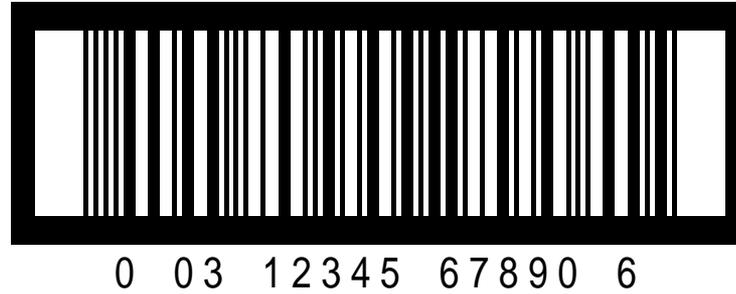
The diagram shows two blue boxes. The left box contains a single syringe. The right box contains three syringes, stacked vertically. This visualizes a change in the net content of a healthcare item, which requires a new GTIN.

GS1 DATA CARRIERS

GTIN - 12 (UPC)



ITF - 14



GS1 - 128



GS1 Databar™



GS1 Databar with Composite Component



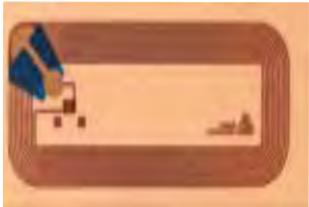
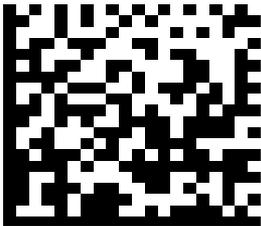
GS1 DataMatrix



EPC in RFD Tag



GTIN: HEALTHCARE EXAMPLE



(01) 1022222333334 (17) 091231 (10) A1345B (21) 1234

GTIN (Global Trade Item Number)

Expiry Date

Lot Number

Serial Number

Traceability Ladder of Precision

GTIN and Serial Number identifies a precise product and packaging size.

- 1 0300710362403 (21) 123456asd
- Product Blister
- Serial Number 123456asd

GTIN and Lot Number identifies products within a defined group.

- 1 0300710362403 (10) 05724f
- Product Blister
- Lot number 05724F

GTIN identifies product and package.

- 1 0300710362403
- Product Blister



WHAT IS EPC? (ELECTRONIC PRODUCT CODE™)

- A numbering scheme that uniquely identifies all objects
 - incorporating GS1 System identification numbers, US DOD constructs such as CAGE and DoDaaC and future numbering methods
- The base of a network of trading partners engaged in the capture, sharing, and discovery of EPC related visibility data
- Mechanism for connecting physical objects to computer networks

Perfect Standards Storm

- 2012 GTIN Sunrise
 - User driven (**voluntary**)
- FDA 2011 N0719
 - Pharmaceuticals
- FDA UDI
 - Medical Devices
- GHTF UDI
- California Pedigree 2015

Issues and Answers

- **No Provider Regulatory Driver**
 - Voluntary Initiative
 - Healthcare Transformation Group (HTG)
- **MMIS Systems**
 - GLN / GTIN Sunrise
- **Return on Investment (ROI)**
 - Case Studies
- **Lack of Understanding**
 - Education Forums, Webinars, Tool Kits



2012 GTIN Sunrise

“Adoption of GTIN in Healthcare by 2012*”

Global Trade Item Numbers (GTINs)**

- GTINs are assigned to healthcare products
- GTINs are marked on appropriate packaging levels
- GTINs are used in business transactions
- GTINs are scanned at points-of-delivery to enhance clinical process
- GTINs are used in product returns and recalls
- GTINs are registered in a GS1 GDSN-certified Data Pool

**December 2012*

***Unique Product Identifiers*



<http://www.gs1us.org/healthcare>



Industries

- Apparel
- CPG/Grocery
- Foodservice
- Fresh Foods
- Healthcare**

- Standards and Initiatives
- Tools and Resources
- Education

Standardized Data for Safer Healthcare

GS1 US is connecting the dots across the healthcare supply chain for improved patient safety and supply chain efficiency

We're working together with healthcare leaders to adopt and use standards that will help organizations share data, promote accuracy, and work more efficiently—to improve patient safety and lower healthcare costs. Learn more about our [standards](#) and the [industry-wide initiatives](#) to adopt them.

Standardization... Stat!: Our Industry's Responsibility

See why healthcare leaders are calling for the industry to step up and address the standards challenge. [Click here](#) to view the video.

CONTACT INFORMATION



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Connect with the GS1 US community on



Reference Material



PROVIDER TOOL KITS:

GTIN, GLN, GDSN, UNSPSC

- Introduction to the Standards
- Implementation Steps
- Lessons Learned
- Benefits to Healthcare Providers
- ROI Hot Spots
- FAQs

http://www.gs1us.org/sectors/healthcare/healthcare_provider_tool_kit



SUPPLIER TOOL KITS:

GTIN, GLN, GDSN

- Introduction to the Standards
- Implementation Steps
- Lessons Learned
- Benefits to Healthcare Providers
- ROI Hot Spots
- FAQs

http://www.gs1us.org/sectors/healthcare/healthcare_supplier_tool_kit



SCORECARDS

“Unless you keep score, it is just practice”.

Vince Lombardi



GS1 INDUSTRY READINESS STATISTICS JANUARY 2012

US Healthcare Readiness – Sunrise December 2010										
Business Partner	Can Receive GLNs via EDI Purchase Orders	# of Providers using GLN's in PO's	GLN's can be stored and used in PO's	GLN's can be used in 850, 855, 856, & 810's	# of Hospital Facilities Reporting	# of all other Facilities Reporting	Able to transact using a GLN in PO via EDI	# of Suppliers using GLNs in PO's		
Mfr's & Distributors	32	749								
Software Suppliers			11	11						
Healthcare Providers					511	285	Yes	95		
US Healthcare GTIN Readiness – Sunrise December 2012										
	Assigning GTINs to all packaging levels by Sunrise or before	Receive PO's using GTIN's by Sunrise or before	Using GTIN in product recalls by Sunrise or before	Publishing GTIN's to GDSN by Sunrise or before	Committed to Using GTIN's by Sunrise	Currently Using GTIN's in Item Master File	Currently scanning GTINs on all products when received	Currently ordering products using GTINs in POs	Currently accepting GTINs & tracing in product recalls	Currently subscribing to GTINs via GDSN
Mfrs & Distributors	10	10	9	10	10					
Healthcare Providers					272	272	0	0	0	0
Software Suppliers										

DRAFT

GTIN Industry Readiness

Self-Reported Scorecard*

(Healthcare Manufacturers and Distributors)

GTIN Implementation Activity for Healthcare Manufacturers and Distributors:

Healthcare Organization Name & GLN	Are you committed to be ready for the 2012 GTIN Sunrise?	Assigning GTINs to products	Marking GTINs on all appropriate packaging levels	Receiving purchase orders with GTINs	Using GTINs in product recalls	Publishing GTINs in GDSN
3M Company 0021200000013	Y	Dec-10	Dec-10	Dec-10	Dec-12	Dec-12
Action Products, Inc. 0089904000002	Y	Dec-06	May-12	Nov-12	Jan-11	Mar-12
AliMed, Inc. 0733657000009	Y	Dec-12	Dec-12	Dec-12	Dec-12	Dec-12
Johnson & Johnson 0705038000007	Y	Dec-11	Dec-12	Dec-12		Sep-11
Kimberly-Clark Corporation 068651000002	Y	Sep-11	Sep-11	Nov-11	Dec-12	Dec-12
Kreisers, Inc. 1100001013135	Y	Dec-12		Dec-12	Dec-12	
Medline Industries 0080196000008	Y	Jun-12	Dec-12	Dec-12	Dec-12	Sep-12
STERIS Corporation 0724995000004	Y	Dec-12	Dec-12	Dec-12	Dec-12	Dec-12
Stryker Sustainability Solutions	Y	Jul-11	Dec-12	Dec-12	Dec-12	Jul-11
WL Gore & Associates	Y	Dec-12	Dec-12	Dec-12		Dec-12

* This "Scorecard", reported voluntarily by the organizations listed, is provided to demonstrate the progress achieved in the GS1 Healthcare US community initiative. It is not and should not be construed, as any type of "Preferred Supplier" list.

GTIN Implementation Activity for Healthcare Providers:

Healthcare Provider Facility & GLN	# of Hospital Facilities Reported	# All Other Facilities Reported	Are you committed to be ready for the 2012 GTIN Sunrise?	Currently using GTINs in item master file to identify products	Currently scanning GTINs on all products when received	Currently ordering products using GTINs in POs	Currently accepting GTINs and tracing in product recalls	Currently subscribing to GTINs via GDSN
Denver Health 1100005823426	1	0	Y	Jan-12	Nov-12	Jan-12	Dec-12	Y
Intermountain Healthcare 1100005442719	23	257	Y	Jul-11				
Mayo Clinic 1100002356804	23	170	Y	Apr-11			Jan-11	Y
Waldo County General Hospital 1100002960315	1	0	Y	Apr-10	Apr-10	Apr-10		Apr-10
Subtotal:	48	427						

(Note: 475 total healthcare provider facilities are represented on this Scorecard)

* This "Scorecard", reported voluntarily by the organizations listed, is provided to demonstrate the progress achieved in the GS1 Healthcare US community initiative. It is not and should not be construed, as any type of "Preferred Provider" list.

The HTG has developed an adoption status tracker to follow our member healthcare systems' progress on adopting and utilizing GS1 Standards. View the [Provider Adoption Status](#) document for more information.

News+Resources

News Releases

December 12, 2011: [National Healthcare Providers Share Product Usage Data; Launch New Website](#)

March 7, 2011: [National Healthcare Providers Evaluate Supplier Adoption of GS1® Standards](#)

December 7, 2010: [National Healthcare Providers Collaborate For Implementation of GS1® Standards](#)

HTG in the News

December 2011: Healthcare Purchasing News
[National healthcare providers share product usage data, launch website to advance standards adoption](#)

December 2011: Healthcare Finance News
[National healthcare providers share product usage data](#)

December 2011: Healthcare IT News
[Big providers compare notes on product usage](#)

November 2011: HTG Members to Present at World Congress
[The World Congress 6th Annual Leadership Summit on Health Care Supply Chain Management](#),
January 30-February 1, 2012 in Orlando, FL

July 2011: Healthcare Purchasing News
[GS1 declares: No sunset on horizon](#)

July/August 2011: GS1 US Between the Lines Newsletter
[EXPERT'S VOICE: UDI Driven Improvements for Patient Safety](#)

QUESTIONS?