



THE GLOBAL LANGUAGE OF BUSINESS

# FDA UNIQUE DEVICE IDENTIFICATION PROPOSED RULE AND GS1 STANDARDS SYSTEM



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# Identify, Capture, & Share

## ❖ What is UDI?

Explanation, definition, scope

## ❖ Why is it important?

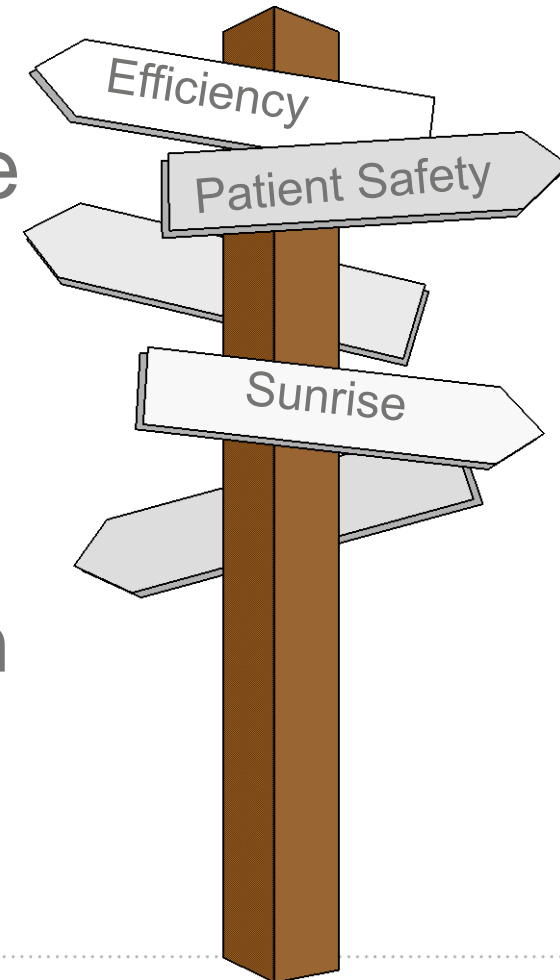
Global overview

## ❖ How can I get support?

Planning and implementation

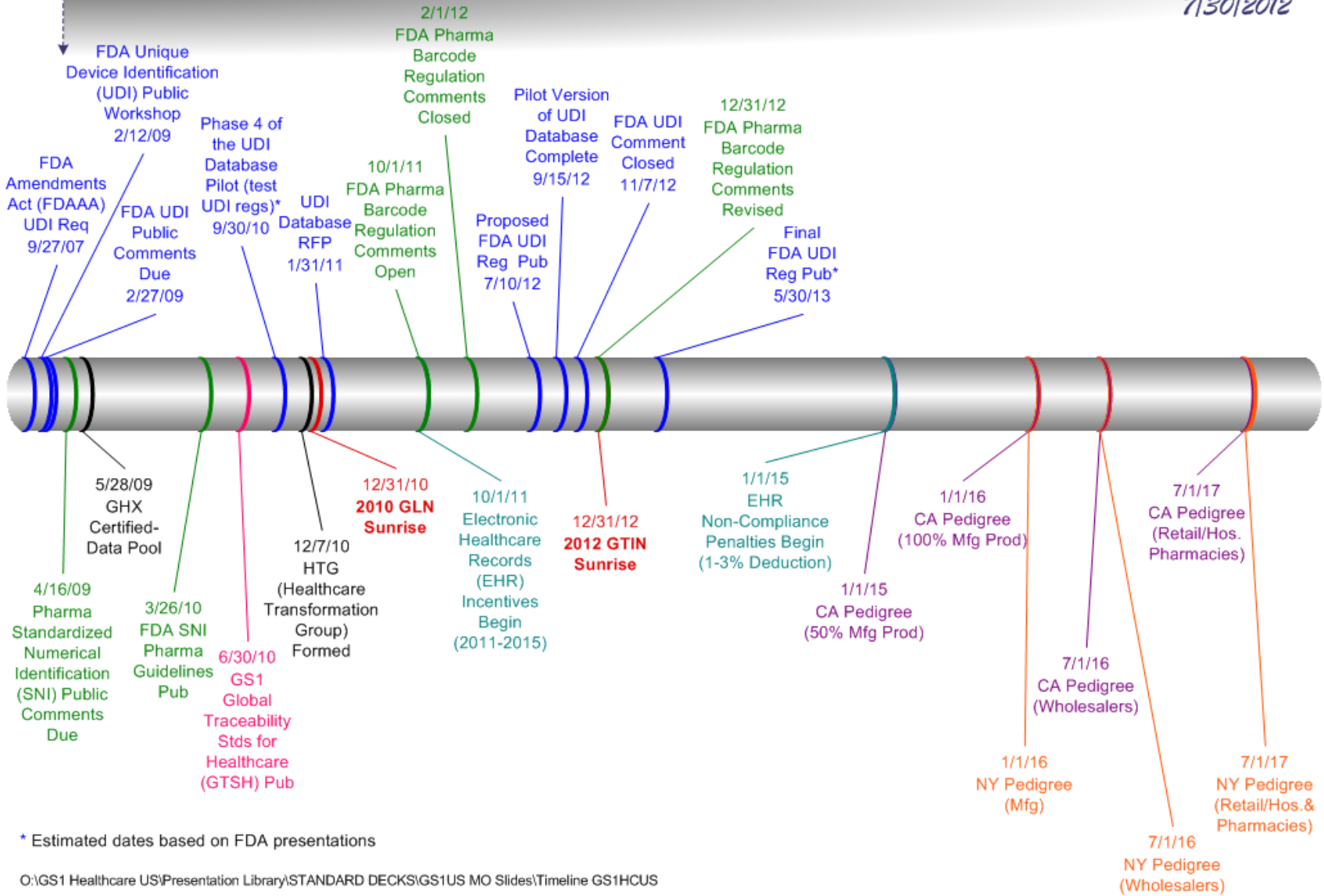
## ❖ Questions and Answers

Where do I go from here?



# U.S. Healthcare Community Initiatives

7/30/2012



\* Estimated dates based on FDA presentations

# DEFINITIONS

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- FDA
  - Unique Device Identification (UDI)
  - Global Unique Device Identification Data Base
    - GUDID / UDID
  - National Health Related Item Code (NHRIC)
  - National Drug Code (NDC)
- GS1 US (formerly the Uniform Code Council)
  - Global Trade Item Number (GTIN) (e.g., U.P.C.)
  - Global Data Sync Network (GDSN)
  - Global Location Number (GLN)

# CAVEAT: GTIN AND UDI

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- GTIN is a UDI.
- U.P.C. encodes a GTIN.
- U.P.C. is a UDI.

# PERFECT STORM

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- FDA UDI is *not* an isolated move to standards
- Echoed in:
  - Other Governments
  - US Healthcare Providers
- Manufacturer approach / response:
  - Coached / budgeted / directed / planned



# PERFECT STORM: GLOBAL



- May 2012 USP workgroup presentations:

- Turkey

- GTIN, serial number, GLN

- Argentina

- GTIN, serial number, GLN

- France

- GTIN, serial, lot, expiry, GLN

- **GHTF UDI - UDID Guideline**

- **GTIN and Lot, GLN**





**GHTF Draft Proposal for**

**a draft guidance on**

**Unique Device Identification (UDI) System  
for Medical Devices**

**Authoring Group: GHTF SC UDI AHWG**

**Proposed by the Global Harmonization Task Force**

**Date: November 4, 2010**

Larry Kelly, GHTF Chair



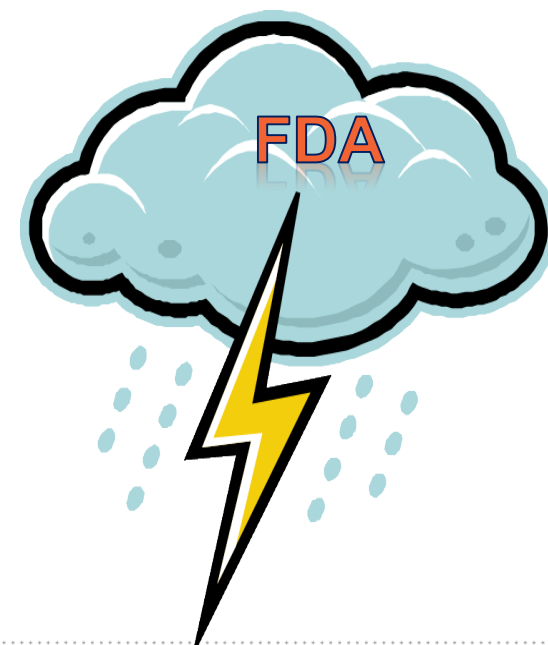
- 
- GHTF: is now the IMDRF
  - International Medical Device Regulators Forum (IMDRF).

<http://www.imdrf.org/>

# PERFECT STORM: FDA REGULATIONS



- FDA Pharmaceutical Bar code Rule 2004
  - FDA proposed rewrite 2011 / 2012
    - Data Matrix
    - 20 of 22 comments supported
  - Serialized Numeric Identifiers
  - SNI Guidance 2010



# PERFECT STORM: U.S. GLN ADOPTION AND 2012 GTIN SUNRISE



- Healthcare grassroots initiatives
- Continuing GLN adoption
  - Scorecards / Best Practices
- 2012 GTIN Sunrise
  - Scorecards
  - Road Map
  - Education



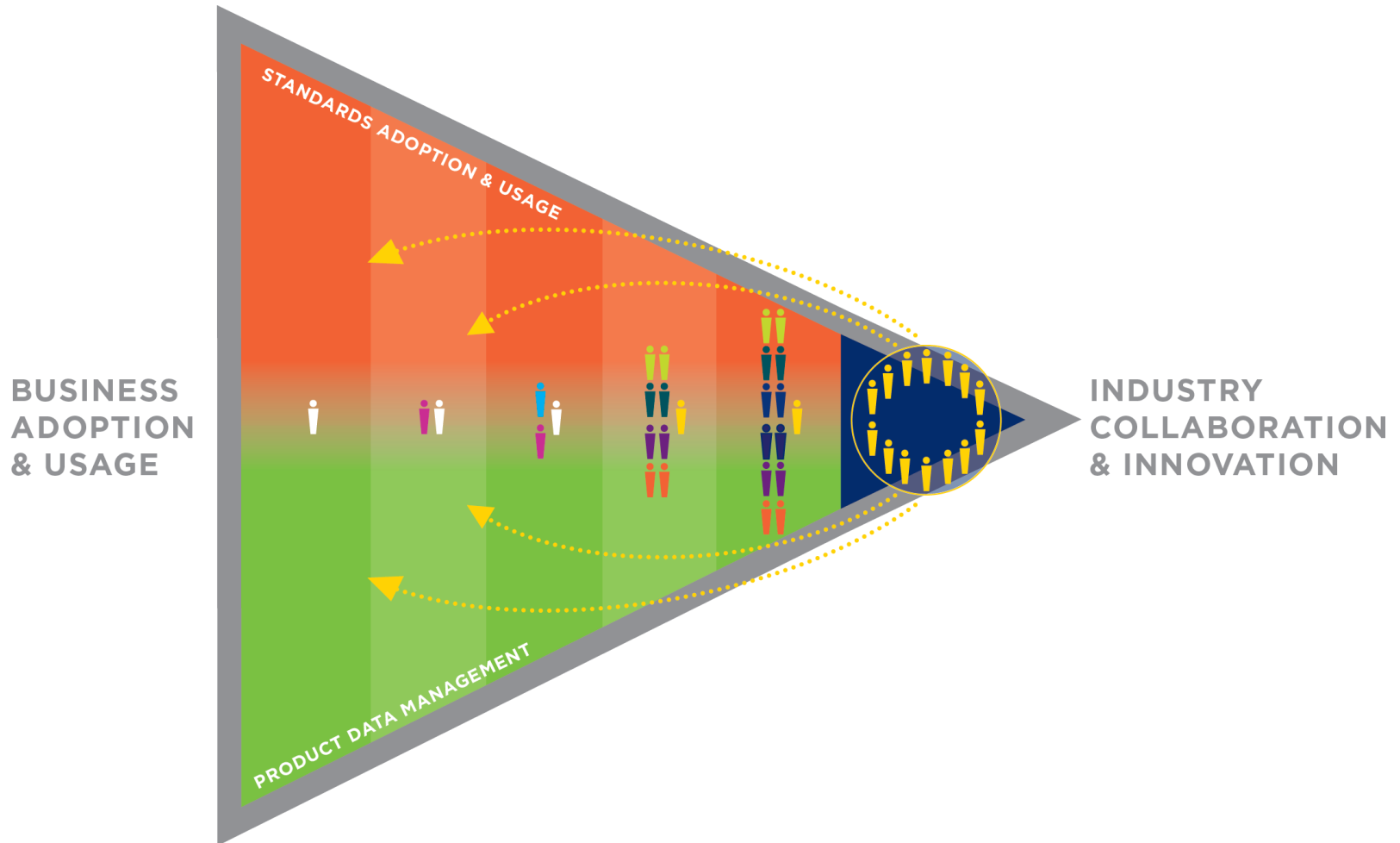
# PERFECT STORM CUSTOMER

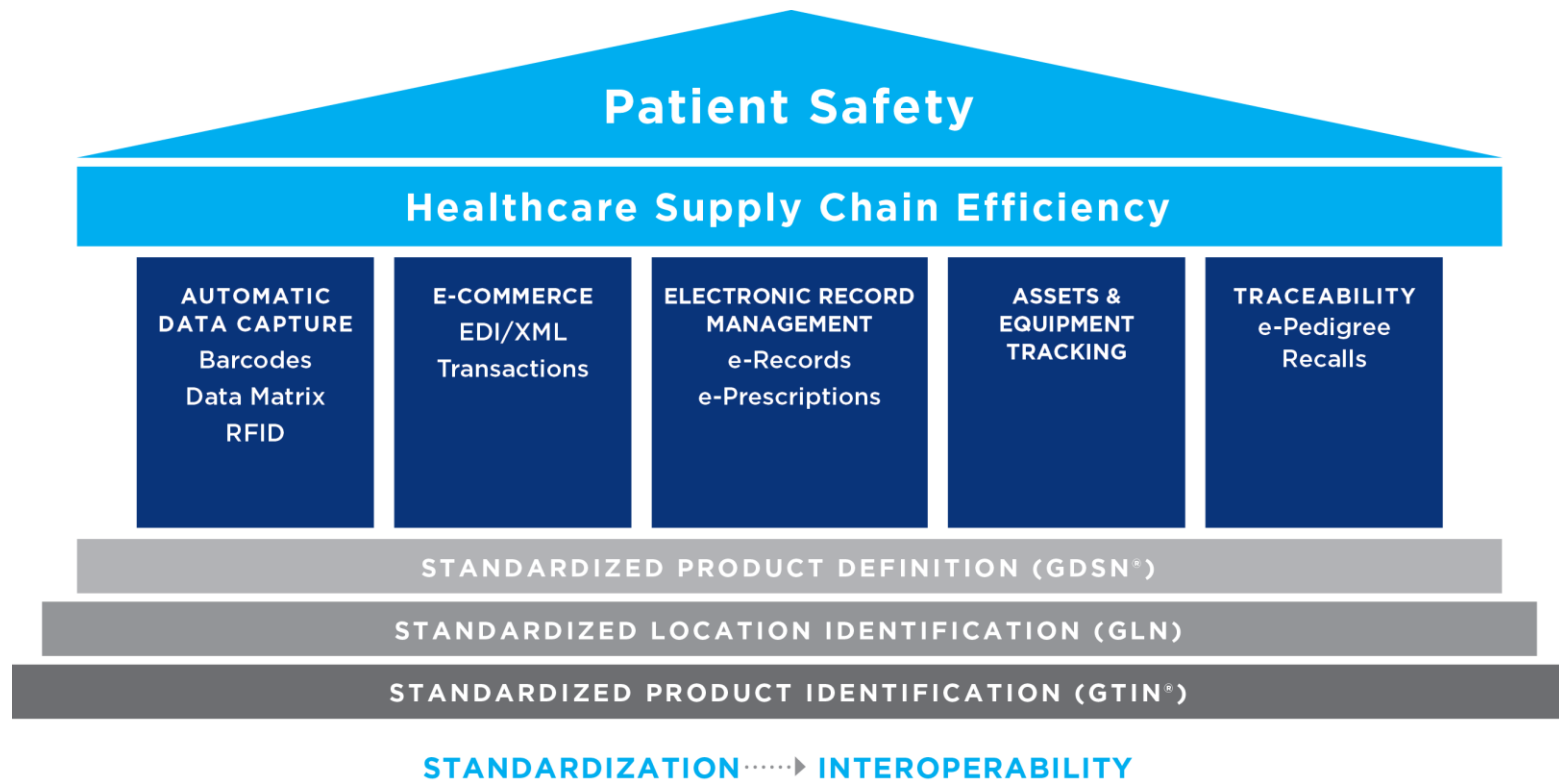


- Group Purchasing Organizations (GPOs)  
Amerinet, MedAssets, Novation, Premier
- Integrated Delivery Networks (IDNs)
  - Healthcare Transformation Group:  
Geisinger, Intermountain, Kaiser,  
Mayo, Sisters of Mercy  
([healthcaretransformationgroup.com](http://healthcaretransformationgroup.com))



# HOW COMPANIES AND INDUSTRIES BENEFIT





# ABOUT GS1

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**GS1 brings together stakeholders across an industry to develop, adopt, and use information standards that revolutionize the way they do business.**

- GS1 Standards make it possible for companies to leverage the power of information by identifying, capturing, and sharing data about products, locations, and more.
- GS1 is a global, not-for-profit organization with more than 110 member organizations (MOs) serving business around the world.
- GS1 is neutral, user-driven, and user-governed.

# ABOUT GS1 US

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**GS1 US serves more than 250,000 businesses across 25 industries in the United States.**

- Leading industry initiatives in Apparel / General Merchandise, Consumer Packaged Goods / Grocery, Foodservice, Fresh Foods, and Healthcare
- Administrating the GS1 System of standards
- Providing support services, tools, education, and training
- Connecting communities through events and online forums

GS1 US is the pioneer of the Universal Product Code (U.P.C.) and the Electronic Product Code™ (EPC®).



# GS1 BY THE NUMBERS

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- **2 million companies around the world** use **GS1 Standards**
- **more than 5 billion GS1 barcodes** are scanned every day
- **5 million products** are assigned U.P.C.s in the **GS1 Data Driver<sup>®</sup>** item management tool
- **5 million products** are registered by brand owners in the **1SYNC Data Pool**

# HOW WE ARE STRUCTURED



THE GLOBAL LANGUAGE  
OF BUSINESS

LEADING INDUSTRY TO ADOPT AND USE GS1 STANDARDS AND SOLUTIONS

## STANDARDS, ADOPTION & USAGE

Engaging communities and companies to solve supply-chain problems by adopting and using GS1 Standards

## PRODUCT DATA MANAGEMENT

Enhancing the GS1 Standards-driven supply chain (e.g., GDSN) by providing services and technologies to help manage product data





# MOVING FORWARD IN HEALTHCARE



- **We make it possible** for healthcare companies to follow drugs and medical devices from the factory to the patient, improving efficiency, safety, and patient care.
- **For Healthcare, GS1 Standards:**
  - Improve patient safety
  - Lower costs through increased efficiency
  - Reduce medication errors
  - Enable supply chain visibility
  - Facilitate faster product recalls
  - Enable efficient tracking of pharmaceutical products/medical devices
  - Reduce the introduction of counterfeit products
  - Enhance inventory management
  - Link critical product data to the patient record
  - Support regulatory compliance
  - Streamline business processes

# GS1 STANDARDS

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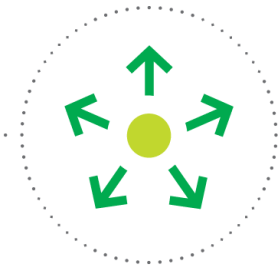
GS1 Standards for identifying, capturing, and sharing information - about products, business locations, and more - make it possible for companies to speak the same language, connect with each other, and move their business forward.



IDENTIFY

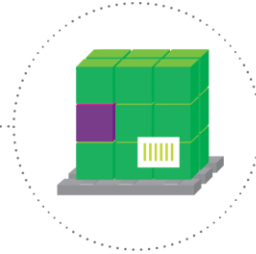


CAPTURE



SHARE

# GS1 STANDARDS IN HEALTHCARE



## ITEM

### Barcodes

Carries a Global Trade Item Number® (GTIN\*)

EAN/UPC



GS1-128



GS1 DataMatrix



(01) 00614141987658  
(21) 00098522

GS1 DataBar™



OR

### EPC®-ENABLED RFID

Carries a Serialized GTIN (SGTIN)



## CASE

### ITF-14

Carries a GTIN



OR

### GS1-128

Carries a GTIN with extended data or a Serial Shipping Container Code (SSCC)



AND

### EPC-ENABLED RFID

Carries an SGTIN or SSCC



## PALLET

### ITF-14

Carries a GTIN



OR

### GS1-128

Carries a GTIN or an SSCC



AND

### EPC-ENABLED RFID

Carries an SGTIN or SSCC

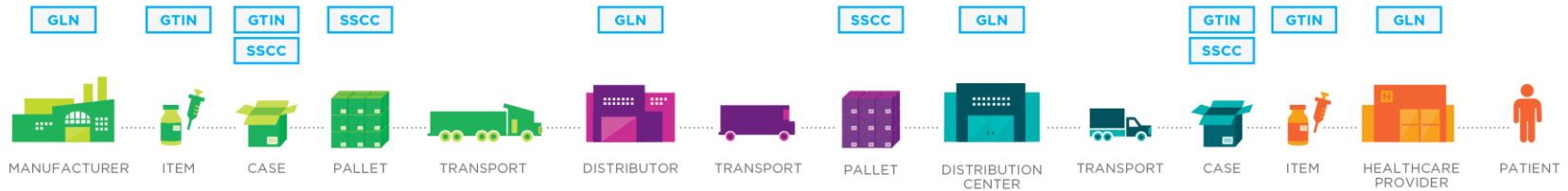


# GS1 STANDARDS IN HEALTHCARE



## IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

**GLN** Global Location Number    **GTIN**<sup>®</sup> Global Trade Item Number<sup>®</sup>    **SSCC** Serial Shipping Container Code    **EPC**<sup>®</sup> Electronic Product Code<sup>™</sup>



## CAPTURE: GS1 SYSTEM DATA CARRIERS

### BARCODES

EAN/UPC



GS1-128



ITF-14



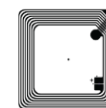
GS1 DataBar<sup>™</sup>



GS1 DataMatrix



### EPC-ENABLED RFID TAGS



## SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

**MASTER DATA** GLN Registry for Healthcare<sup>®</sup>, Global Data Synchronization Network<sup>™</sup> (GDSN<sup>®</sup>)    **TRANSACTIONAL DATA** eCom/EDI    **PHYSICAL EVENT DATA** EPC Information Services



# FDA AMENDMENTS ACT OF 2007

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September 27, 2007, the FDAAA signed into law:

The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.



# FDA UDI PROPOSED RULE

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- Published Federal Register: July 10, 2012
  - Comments due
  - Information collection issues September 10, 2012
    - ✓ (section V)
    - ✓ (paperwork reduction act OMB)
- General comments on rule: published November 7, 2012
  - [www.regulations.gov](http://www.regulations.gov)
  - FDA-2011-N-0090
  - Three comments received
    - 2 were on HRI date

# FDA UDI RULE SUMMARY

- Authority

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- FDAAA 2007

1. All Medical device Label / label package to include UDI

- a) Exception OTC or “Low Risk” items

- b) UDI plain text and in AIDC

- c) UDI direct marked on certain item categories

2. Submission of device information to GUDID (formerly UDID)

Global Unique Device Identification Database

- a) FDA intends to make data base public to ensure that UDI can adequately describe device through it distribution and use

# HEALTH CARE BENEFITS

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- Reduce medical errors
- Simplify the integration of device use information into data systems
- Provide for more rapid:
  - identification of medical devices with adverse events
  - development of solutions to reported problems
  - more efficient resolution of device recalls
- Better-focused and more effective FDA safety communication
- Provide an “easily-accessible” source of definitive device identification information
- Additional benefits:
  - strategic stockpile; inventory management development (EPR)
- Standard format for dates provided on a device label or package:
  - month, day, year (e.g. Jan 1, 2012)

# MAJOR PROVISIONS

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- Labels of medical devices and device packages to include a UDI
  - There are exceptions
  - UDI in plain text and in form that uses AIDC
  - UDI direct marked certain categories
  - UDI data submitted to GUDID
    - Must adequately identify the device
    - No patient information
    - Require dates to be in standard format
  - UDI identify product
    - Lot identification, expiry date, and serial number
  - Exemptions
    - OTC at retail and when delivered directly to healthcare facility
    - FDA class one items by regulation
    - No production data for class 1 items
  - Rule effective in stages

# FDA UDI RESPONSE COMMITTEE

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- GS1 and GS1 US Joint Committee
- Current Members:
  - Manufacturers
  - Distributor
  - Providers
  - GPOs
  - Consultants / solution providers
  - Associations
  - GS1 & GS1 US staff
- Sharing information with other groups
  - AHRMM, AdvaMED, AIM, HDMA

# QUESTIONS: 35

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- Objectives uses of UDI system 1,2,3
- UDI labeling requirements 4,5
- Combination products 6,7
- Combination Products not labeled with NDC 8
- Convenience Kits 9, 10, 11
- Direct marking 12, 13, 14, 15
- UDI labeling exceptions and alternatives 16,17,18,19,20
- Form of a UDI 21,22
- Role of an issuing agency 23,24,25, 26
- Data submission (GUDID) 27,28,29,30,31
- Format of date 32,33,34,35

# SUMMARY

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- Long awaited proposed rule
- Document has raised many issues across U.S. healthcare
- Needs to be read closely
- Need to respond
- Reply should not be U.S. centric, but a global view
- Look for GS1 / GS1 US comments in September

# Reference Material

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<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.

# REFERENCE LINKS

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- Healthcare Industry Sunrise Dates
    - [www.gs1us.org/hcsunrise](http://www.gs1us.org/hcsunrise)
  - GLN and GTIN Industry Readiness Scorecards
    - [www.gs1us.org/hcscorecard](http://www.gs1us.org/hcscorecard)
  - Industry Use Cases
    - [www.gs1us.org/hcstudies](http://www.gs1us.org/hcstudies)
  - Healthcare Tools & Resources
    - [www.gs1us.org/hctools](http://www.gs1us.org/hctools)
  - Education
    - [www.gs1us.org/hcedu](http://www.gs1us.org/hcedu)
  - GS1 Healthcare US Initiative
    - [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare)
  - GLN Registry for Healthcare
    - [www.gs1us.org/glnregistry](http://www.gs1us.org/glnregistry)
-

# SUPPLIER AND PROVIDER TOOL KITS: GTIN, GLN, GDSN, UNSPSC

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

<http://www.gs1us.org/industries/healthcare/tools-and-resources/healthcare-tool-kits>



# TROUBLESOME BARCODE PROCEDURE

*What should happen if a barcode will not scan at the Hospital ?*

## Provider:

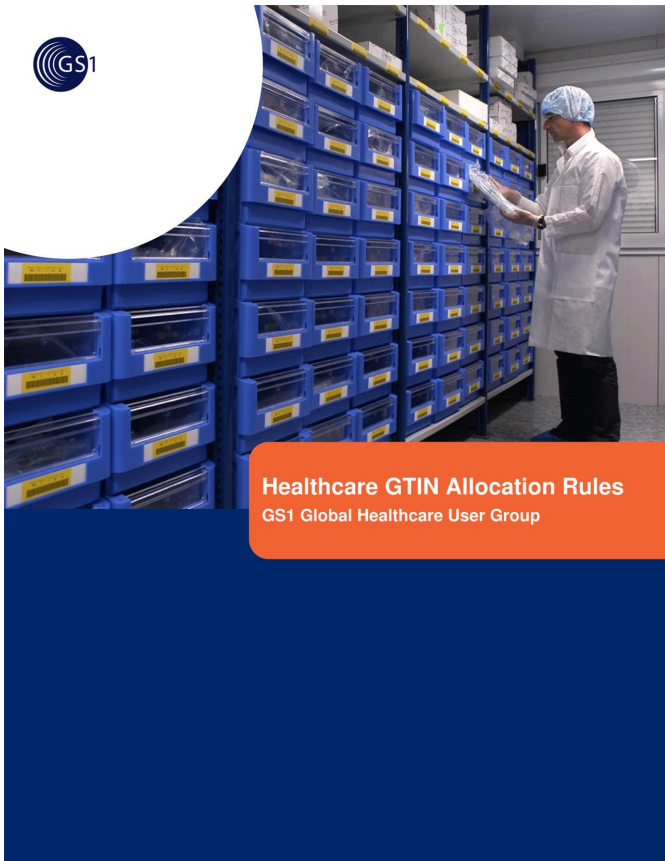
1. Internal simple fixes
2. More complex verifier process
3. **Report to manufacturer**
4. If necessary, report to FDA
5. Document procedure

## Supplier:

1. Take in call
2. Institute correct action if necessary
3. **Inform customer (provider)**
4. Inform FDA, if necessary
5. Document procedure



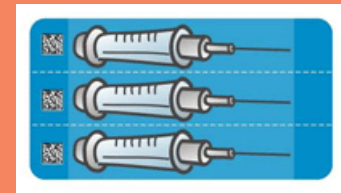
# HEALTHCARE GTIN ALLOCATION RULES



## 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

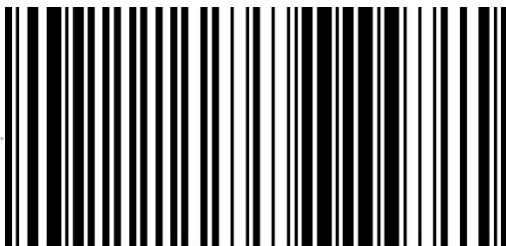


# WHAT IS A GTIN?

- **“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)



(01) 00314141 99999 5

GS1 DataMatrix (14-digit GTIN)



(01) 00314141 99999 5

GS1 Databar (14-digit GTIN)



(01) 00314141 99999 5



# SUPPORT FOR UDI IMPLEMENTATION :

*Simply log on and register to learn*

## Live monthly

Ask the Experts

GTIN Sunrise

3 Gs: presented by Jean Sargent (USC Health Sciences)

## On demand

GS1 System Explained

GS1 Company Prefix

GTIN: Product Identification Number

GDSN: Global Data Synchronization Network®

GIAI: Global Individual Asset Identifier

GLN 101: Location Identification Number

GLN Registry for Healthcare®

GDTI Global document Type identifier

SSCC: Serial Shipping Container Code

## Technical

Barcoding is an Art & a Science

Scanner Versus Verifier

GS1 Data Matrix

## Development

GS1 and UDI

Navigating the GS1 Specification

***Education  
Registration:***

***<http://www.gs1us.org/hcedu>***



Dennis Black  
Director, e-Business, BD  
Alex Zimmerman  
Director, Integrated Business Solutions, ROI

# Perfect Order and Beyond

**BD and Mercy/ROI Achieve Far-Reaching GS1 Standards Integration**

For the first time in the U.S., GS1 global standards are used in every step – from manufacturing plant to patient bedside – illustrating ways the supply chain can impact patient safety and optimize healthcare operations with fully automated order processes and transactions.

Through a collaborative effort, BD (Beckton, Dickinson and Company), Mercy and its supply chain company, ROI, implemented GS1 standards at each step from manufacturing to patient bedside, realizing significant benefits, including those associated with patient safety and an optimized supply chain. This end-to-end global data standard integration represents the first known instance in the United States that a healthcare provider and manufacturer used the Global Location Number (GLN) and Global Trade Item Number (GTIN) in both supply chain and clinical processes, achieving fully automated, accurate electronic processing of order transactions known as Perfect Order.

Perfect Order is an ideal in healthcare that represents true electronic order processing, from order placement to delivery and payment, without human intervention.

BD and Mercy/ROI leveraged the usage of GTIN identification from product conception to patient use and utilized GLNs to synchronize account and location information.

## *Perfect Order and Beyond*

BD and Mercy/ROI Achieve Far-Reaching GS1 Standards Integration

Learn how BD and Mercy/ROI implemented GS1 global standards – from manufacturing plant to patient bedside – illustrating ways the supply chain can impact patient safety and optimize healthcare operations with fully automated order processes and transactions.

### Benefits Achieved

- 30% reduction in days payable outstanding
- 73% reduction in discrepancies (part number and UOM)
- Improved sourcing of products (right product/right order number)
- Less calls to customer service
- Fewer stock outs
- Better charge compliance (scanning @ POU)

Download at [www.gs1us.org/BDMercystudy](http://www.gs1us.org/BDMercystudy)



# UDI APPLICATION EXAMPLE

**ENDURANT®** Stent Graft System

**Bifurcated**

**ENDURANT®** Stent Graft System

**Bifurcated**

REF ENBF2313C124E

SN 0123456789

2000-01-31

Do not reuse

**STERILE R**  
Sterilized using irradiation

Contents: One device

MR Conditional

[www.medtronic.com/manuals](http://www.medtronic.com/manuals)

Consult instructions for use at:  
[www.medtronic.com/manuals](http://www.medtronic.com/manuals)

To view, download, print or order a product manual go to [www.medtronic.com/manuals](http://www.medtronic.com/manuals) or call 1-877-526-7880

Do not use if package is damaged

**PYROGEN**  
Non-pyrogenic

Store at room temperature in a dark, dry place

**Rx only**

Protected by one or more of the following United States patents: 6,306,141; 6,911,039; 7,105,016; 7,264,632, and 7,655,034.

**US CUSTOMER SERVICE / PRODUCT INQUIRIES:**  
Tel: (+1-800) 961-9055  
Fax: (+1-800) 929-2133

**MANUFACTURER: Medtronic, Inc.**  
710 Medtronic Parkway  
Minneapolis, MN 55432 USA  
[www.medtronic.com](http://www.medtronic.com)

**MANUFACTURED IN: Medtronic Ireland**  
Parkmore Business Park West, Galway, Ireland  
Made in Ireland

M708851B007 Rev A

(01)00000000000000 (17)000000 (21)0123456789

REF ENBF2313C124E

SN 0123456789

2000-01-31



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Connect with the GS1 US community on

