The Global Language of Business

ASK THE EXPERTS
GS1 DataMatrix

The Basics and…
…an Example Implementation

GS1 Healthcare Conference – Mexico City

22 April 2015

Ask the Experts – GS1 DataMatrix…

Today's presenters…

- GS1 DataMatrix – The Basics
  - Chuck Biss - GS1 Global Office
  - Senior Director, AIDC Healthcare
- GS1 DataMatrix – An Implementation
  - Bivian Pereira - CEFA, Central Farmacéutica S.A.
  - Manager Regulatory Affairs
  - Daniel Chaves - CEFA, Central Farmacéutica S.A.
  - Manager Logistics

Ask the Experts – Topics…

A General Discussion of GS1 DataMatrix, with a GS1 Healthcare Application Standards Focus

- Why GS1 DataMatrix in Healthcare
- Data Matrix… The Symbology
  - "GS1 DataMatrix" or "ISO/IEC Data Matrix"
- Thoughts on Structure & Quality
- Practical Application - Printing / Reading
- A Practical Application – CEFA
- Audience Q & A

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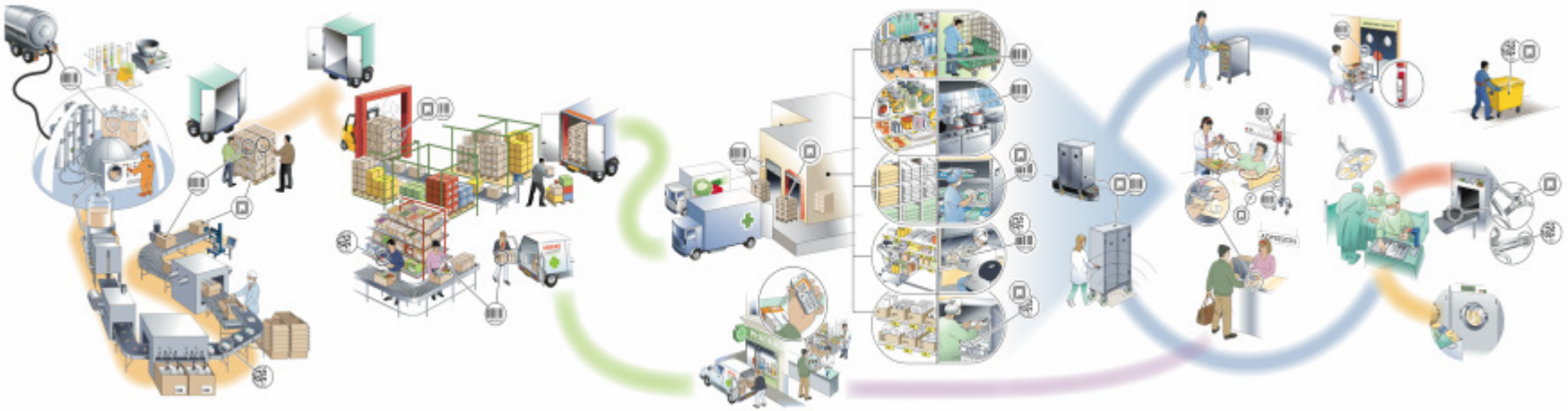
Healthcare – A need for "Unique" ID…

"Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration"* …generally using documented & recorded "unique" identification.



Healthcare – A need for "Unique" ID…

AIDC – Unique Product Identification

The goal is unambiguous identification of a specific product. From an AIDC standpoint this identification would have two (2) parts:

- The **Product Identifier** – Meant to be the identification of the "generic" product – GS1 **GTIN** enables this.
- The **Product Attribute** – Meant to be whatever "control" numbers or data a manufacturer uses in their process – GS1 **Application Identifiers** (**AI's** such as lot/batch number, serial number, expiry, in any combination with a GTIN) enable this aspect.

GTIN + AI(s) = Unique Product ID

Healthcare – Data & Data Carrier needs…

Expiry Date, Lot, and/or Serial Number

Small space

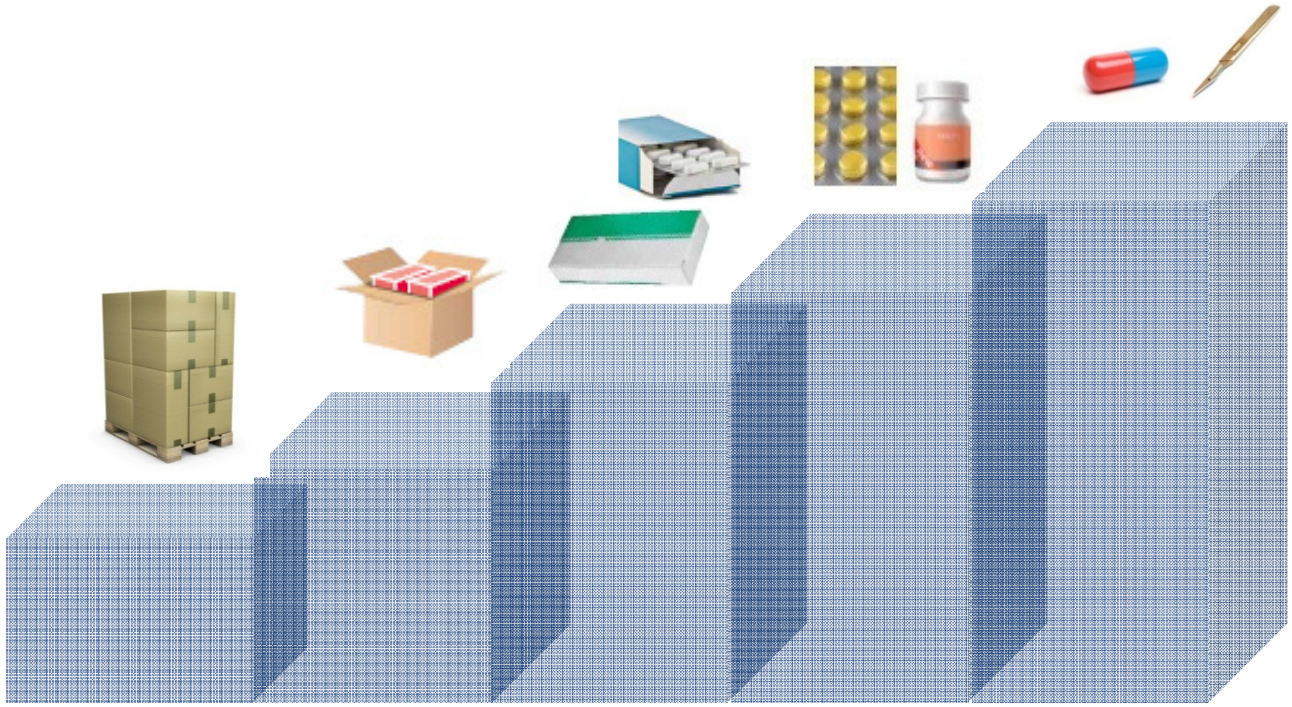
Direct part marking

Additional data & variable data at high production rates

Non-retail channels

And more…

Healthcare – Data & Data Carrier needs…



Pallet (Tertiary*) | **Case / Shipper (Tertiary*)** | **Secondary package** | **Primary package** | **Single Unit package**

Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

Healthcare – Data need beyond GTIN…

GS1 Keys prevail… but some users need more detailed information about that specific unit

Healthcare – GS1 DataMatrix global…


Argentina


Jordan


India


Algeria


T…y


…rea


Saudi Arabia


Brazil


EU


USA

GTIN – Global Trade Item Number

Plus attributes

- Lot number
- Expiry date
- Serial number (2016)

In a GS1 DataMatrix

Changes often… shown here for illustration of adoption emphasis / need…
!! NOT FOR CIRCULATION or DUPLICATION !!
GS1 Global Healthcare Members have direct access to updated information

Healthcare – GS1 Data Carrier choices…

GS1-128 &
GS1 DataBar
Preferred options if:
✓package allows

GS1 DataMatrix
Preferred option if:
✓ Large amount of data in a small space
✓ Variable information at high production rates
✓ Direct part marking

EPC/RFID
Additional option
✓ Non-line of sight
✓ Large amount of data

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Data Carriers – Some symbology history…

Bar code symbology “evolution”…
or “revolution”…

1D “Linear” 2D “Multi Row” 2D “Matrix”

Data Carriers – Some symbology history…

First Scan
1974

1968-75
2 of 5

1972
Interleaved
2 of 5

1973
UPC

1976
EAN

Data Carriers – Some symbology history…

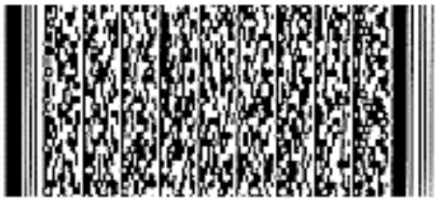
1981-82
Code 128

1989
Data Matrix

1992
PDF-417

1992-99 RSS / GS1 DataBar

(01)07612345678900(17)100503
(10)AC3453G3

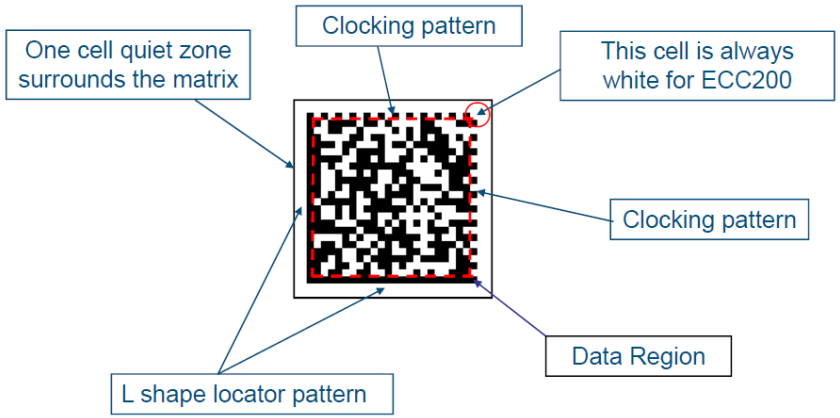


Data Carriers – 2D/Matrix technology…

- Mature Technology
- Weak Vertical and Horizontal Redundancy
- “Strong” Finder Patterns
- Omnidirectional Design for Scanning
- Inherent Robust Error Detection and Error Correction
- Complex Algorithms
- Data Compaction Modes
- Structured Append
- Extended Channel Interpretation (ECI)
- Image Reverse and Color Reverse

Data Carriers – 2D/Matrix technology…

- General Components of a 2D Symbol
  - Finder Patterns
    - Robustness & Weakness
  - Data Region(s)
    - Balanced by amount of Error Detection & Correction
  - Error Correction Region(s)
    - Balanced by amount of Error Detection & Correction



Data Carriers – 2D/Matrix symbologies…

Many to choose from… are they all "the same"…

Data Matrix

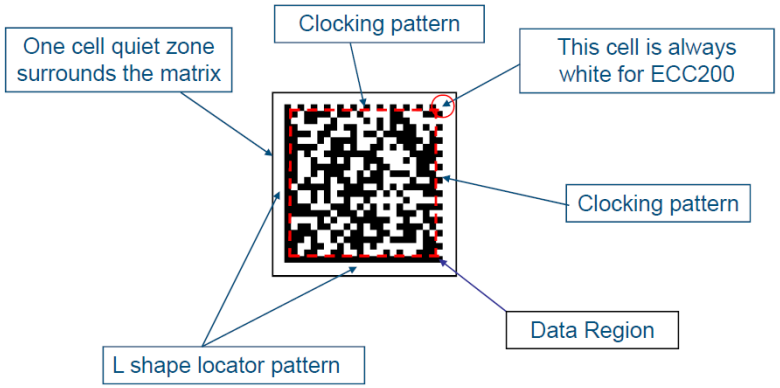
QR Code

MaxiCode

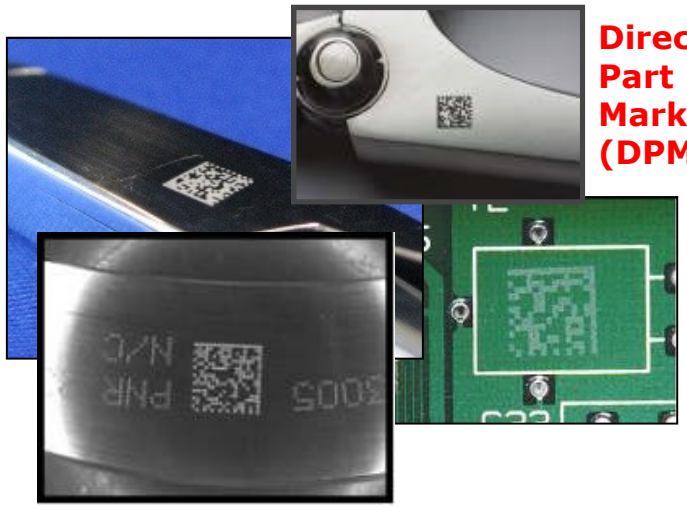
Aztec Code

Data Carriers – ISO/IEC Data Matrix…

- Established 1989 by International Data Matrix
- Internationally standardized in ISO/IEC 16022
- Scaleable matrix from 9 x 9 to 49 x 49 modules
  - (Size Change w/ Data Content… in "block steps"…)
- Error Detection & Multiple Error Correction Levels
- Multiple encoding formats and macros
- More adaptable to "direct" marking (DPM)
- Primary Applications - Parts marking (Aerospace, Automotive, Semiconductor, Medical instruments), Pharmaceutical packaging, Documents



Data Carriers – ISO/IEC Data Matrix…



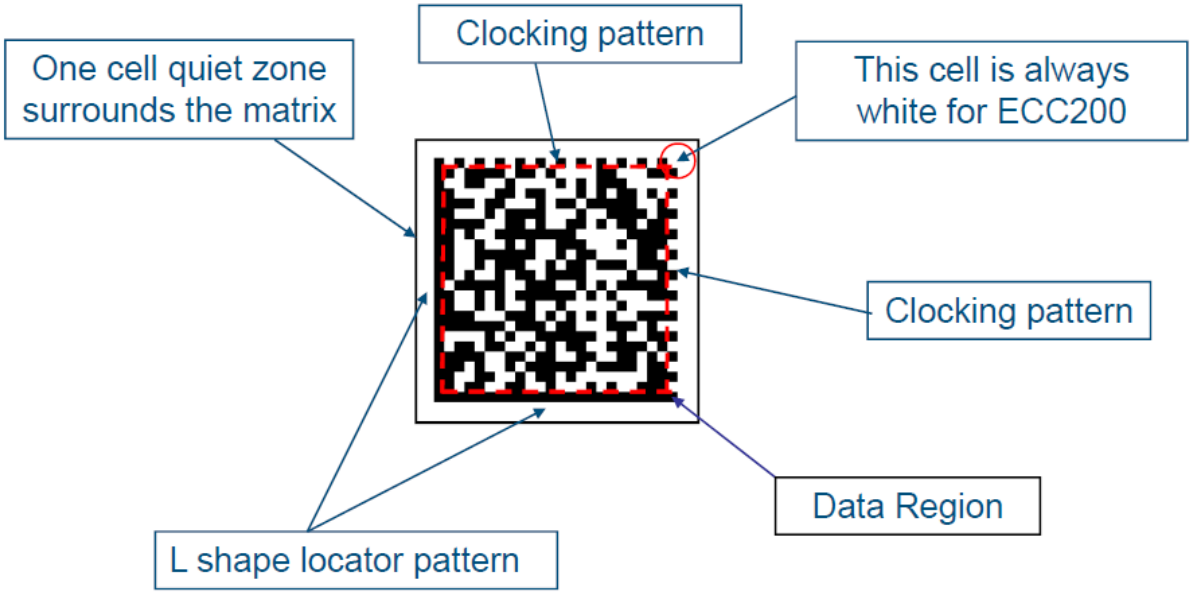
Direct Part Marking (DPM)

Identification & Document Tracking

Item Package & Label Marking

Packaging Verification

Data Carriers – GS1 DataMatrix…



- ISO/IEC 16022 Data Matrix… as "GS1 DataMatrix":
  - Similar to the Code 128 / GS1-128 "relationship", an FNC1 in the first data position signals GS1 formatted data & a GS1 DataMatrix
  - Is always "ECC 200" & Alpha-Numeric encodation capable
  - GS1 DataMatrix has a specific ISO/IEC Symbology Identifier

Data Carriers – 2D/Matrix size change…

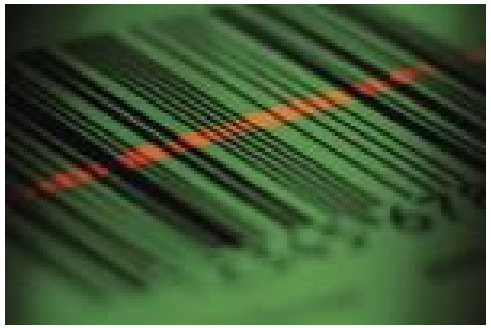
GS1 DataMatrix… Size Change w/ Data Content… in “blocks”

Symbol 1 - GTIN Only		0.107in x 0/107in (0.011 sq inch)
Symbol 2 - GTIN + AI(17)		0.121in x 0.121in (0.015 sq inch)
Symbol 3 - GTIN + AI(17) + AI(10) of 4 numeric & 6 alpha		0.134in x 0.134in (0.018 sq inch)
Symbol 4 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha		0.147in x 0.147in (0.022 sq inch)
Symbol 5 - Symbol 4 + AI(21) of 3 numeric		0.468in x 0.468.in (0.219 sq inch)
Symbol 6 - Symbol 4 + AI(21) of 13 numeric & 1 alpha		0.507in x 0.507in (0.257 sq inch)
Symbol 7 - Symbol 4 + AI(21) of 15 numeric & 2 alpha		0.507in x 0.507in (0.257 sq inch)
Symbol 8 - Symbol 4 + AI(21) of 17 numeric & 3 alpha		0.507in x 0.507in (0.257 sq inch)

Data Carriers – 2D/Matrix scanning…

Linear Scanners:

- Laser line or linear imager based
- Massive, long-term installed base
- Scans 1D / Linear and some 2D Stacked symbols



Area Image Scanners:

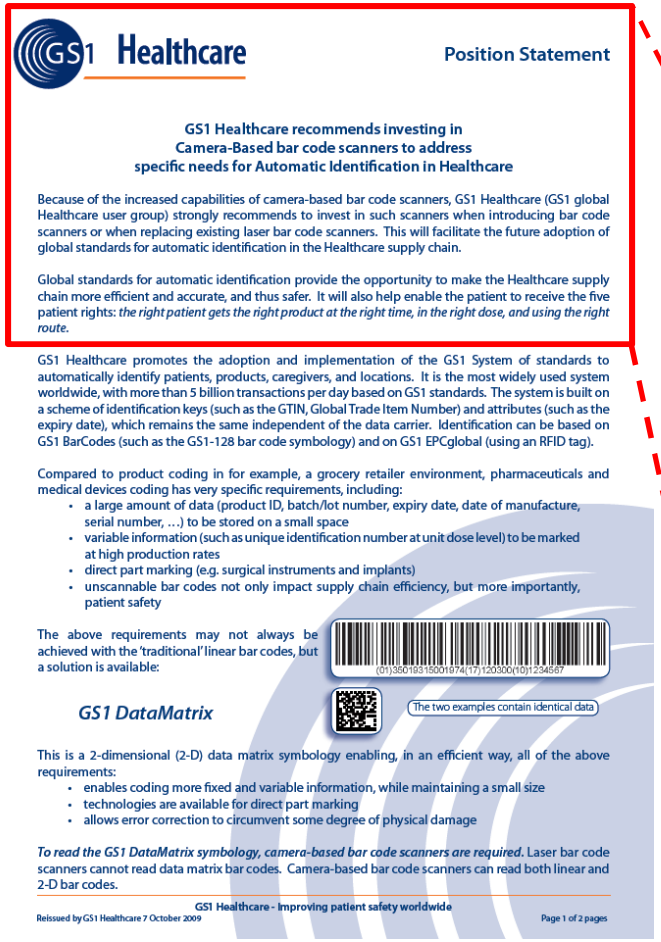
- Camera based
- Growing installed base in all sectors
- Scans 1D/Linear, 2D/Stacked & 2D/Matrix symbols

Camera-based bar code scanners… needed in Healthcare AND are GS1 Healthcare Leadership Team recommended!!

GS1-128 & GS1 DataBar

GS1 DataMatrix

Position – 2D Imager/Camera scanners…



GS1 Healthcare — Position Statement

GS1 Healthcare recommends investing in Camera-Based bar code scanners to address specific needs for Automatic Identification in Healthcare

Because of the increased capabilities of camera-based bar code scanners, GS1 Healthcare (GS1 global Healthcare user group) strongly recommends to invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain.

Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. It will also help enable the patient to receive the five patient rights: *the right patient gets the right product at the right time, in the right dose, and using the right route.*

GS1 Healthcare promotes the adoption and implementation of the GS1 System of standards to automatically identify patients, products, caregivers, and locations. It is the most widely used system worldwide, with more than 5 billion transactions per day based on GS1 standards. The system is built on a scheme of identification keys (such as the GTIN, Global Trade Item Number) and attributes (such as the expiry date), which remains the same independent of the data carrier. Identification can be based on GS1 BarCodes (such as the GS1-128 bar code symbology) and on GS1 EPCglobal (using an RFID tag).

Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- a large amount of data (product ID, batch/lot number, expiry date, date of manufacture, serial number, …) to be stored on a small space
- variable information (such as unique identification number at unit dose level) to be marked at high production rates
- direct part marking (e.g. surgical instruments and implants)
- unscannable bar codes not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar codes, but a solution is available:

(01)35018315001974(17)120300(10)1234567

The two examples contain identical data

GS1 DataMatrix

This is a 2-dimensional (2-D) data matrix symbology enabling, in an efficient way, all of the above requirements:

- enables coding more fixed and variable information, while maintaining a small size
- technologies are available for direct part marking
- allows error correction to circumvent some degree of physical damage

To read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Laser bar code scanners cannot read data matrix bar codes. Camera-based bar code scanners can read both linear and 2-D bar codes.

GS1 Healthcare - Improving patient safety worldwide

Reissued by GS1 Healthcare 7 October 2009 — Page 1 of 2 pages

Preparing members, solutions providers and end users for the future…

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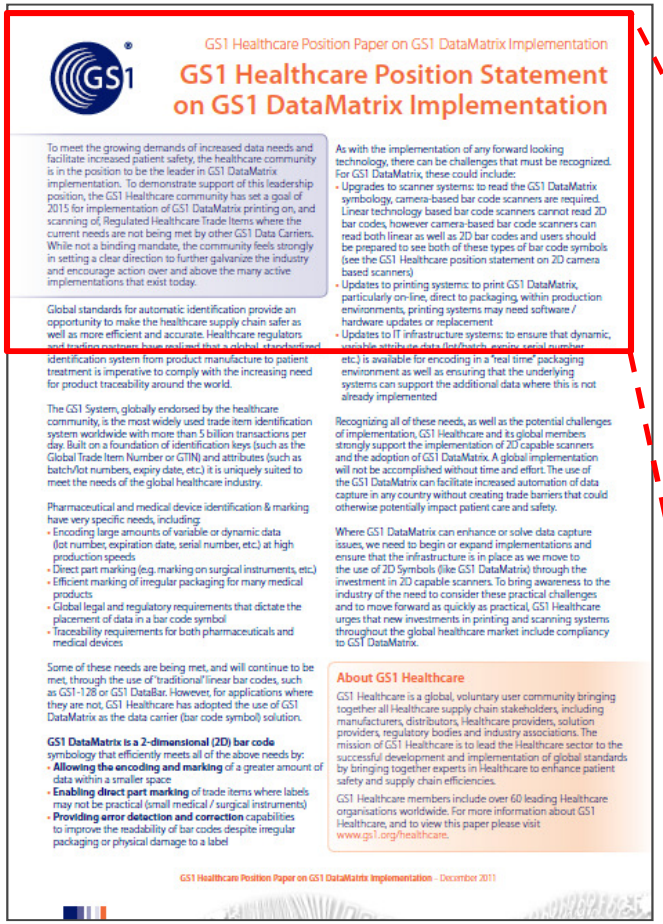
Get your copy at:

http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

Position – GS1 DataMatrix adoption…



GS1 Healthcare Position Paper on GS1 DataMatrix Implementation

GS1 Healthcare Position Statement on GS1 DataMatrix Implementation

To meet the growing demands of increased data needs and facilitate increased patient safety, the healthcare community is in the position to be the leader in GS1 DataMatrix implementation. To demonstrate support of this leadership position, the GS1 Healthcare community has set a goal of 2015 for implementation of GS1 DataMatrix printing on, and scanning of, Regulated Healthcare Trade Items where the current needs are not being met by other GS1 Data Carriers. While not a binding mandate, the community feels strongly in setting a clear direction to further galvanize the industry and encourage action over and above the many active implementations that exist today.

Global standards for automatic identification provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realized that a global, standardized identification system from product manufacture to patient treatment is imperative to comply with the increasing need for product traceability around the world.

The GS1 System, globally endorsed by the healthcare community, is the most widely used trade item identification system worldwide with more than 5 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number or GTIN) and attributes (such as batch/lot numbers, expiry date, etc.) it is uniquely suited to meet the needs of the global healthcare industry.

Pharmaceutical and medical device identification & marking have very specific needs, including:

- Encoding large amounts of variable or dynamic data (lot number, expiration date, serial number, etc.) at high production speeds
- Direct part marking (e.g. marking on surgical instruments, etc.)
- Efficient marking of irregular packaging for many medical products
- Global legal and regulatory requirements that dictate the placement of data in a bar code symbol
- Traceability requirements for both pharmaceuticals and medical devices

Some of these needs are being met, and will continue to be met, through the use of "traditional" linear bar codes, such as GS1-128 or GS1 DataBar. However, for applications where they are not, GS1 Healthcare has adopted the use of GS1 DataMatrix as the data carrier (bar code symbol) solution.

GS1 DataMatrix is a 2-dimensional (2D) bar code symbology that efficiently meets all of the above needs by:

- **Allowing the encoding and marking** of a greater amount of data within a smaller space
- **Enabling direct part marking** of trade items where labels may not be practical (small medical / surgical instruments)
- **Providing error detection and correction** capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label

As with the implementation of any forward looking technology, there can be challenges that must be recognized. For GS1 DataMatrix, these could include:

- Upgrades to scanner systems: to read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Linear technology based bar code scanners cannot read 2D bar codes, however camera-based bar code scanners can read both linear as well as 2D bar codes and users should be prepared to see both of these types of bar code symbols (see the GS1 Healthcare position statement on 2D camera based scanners)
- Updates to printing systems: to print GS1 DataMatrix, particularly on-line, direct to packaging, within production environments, printing systems may need software / hardware updates or replacement
- Updates to IT infrastructure systems: to ensure that dynamic, variable attribute data (lot/batch, expiry, serial number, etc.) is available for encoding in a "real time" packaging environment as well as ensuring that the underlying systems can support the additional data where this is not already implemented

Recognizing all of these needs, as well as the potential challenges of implementation, GS1 Healthcare and its global members strongly support the implementation of 2D capable scanners and the adoption of GS1 DataMatrix. A global implementation will not be accomplished without time and effort. The use of the GS1 DataMatrix can facilitate increased automation of data capture in any country without creating trade barriers that could otherwise potentially impact patient care and safety.

Where GS1 DataMatrix can enhance or solve data capture issues, we need to begin or expand implementations and ensure that the infrastructure is in place as we move to the use of 2D Symbols (like GS1 DataMatrix) through the investment in 2D capable scanners. To bring awareness to the industry of the need to consider these practical challenges and to move forward as quickly as practical, GS1 Healthcare urges that new investments in printing and scanning systems throughout the global healthcare market include compliancy to GS1 DataMatrix.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.

Preparing members, solutions providers and end users for the future thru global positions…

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Get your copy at:

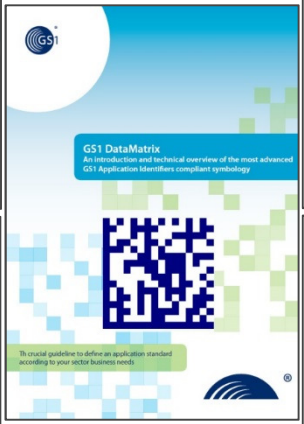
http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf

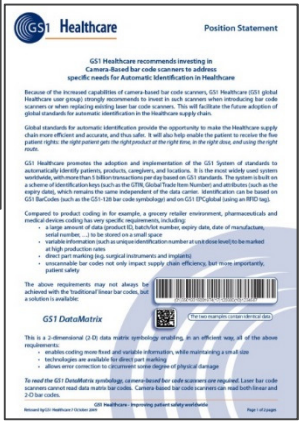
GS1 DataMatrix & unique product ID…

GS1 DataMatrix

(01) 00012345678905

As we see more AIDC marking on small Pharmaceutical and Medical Device products (and/or on their packaging) we will see more GS1 DataMatrix due to its ability to efficiently and securely carry more data in smaller areas, and also due to its promotion for use by the GS1 Healthcare global members.
Becoming familiar with the available support materials is advised...



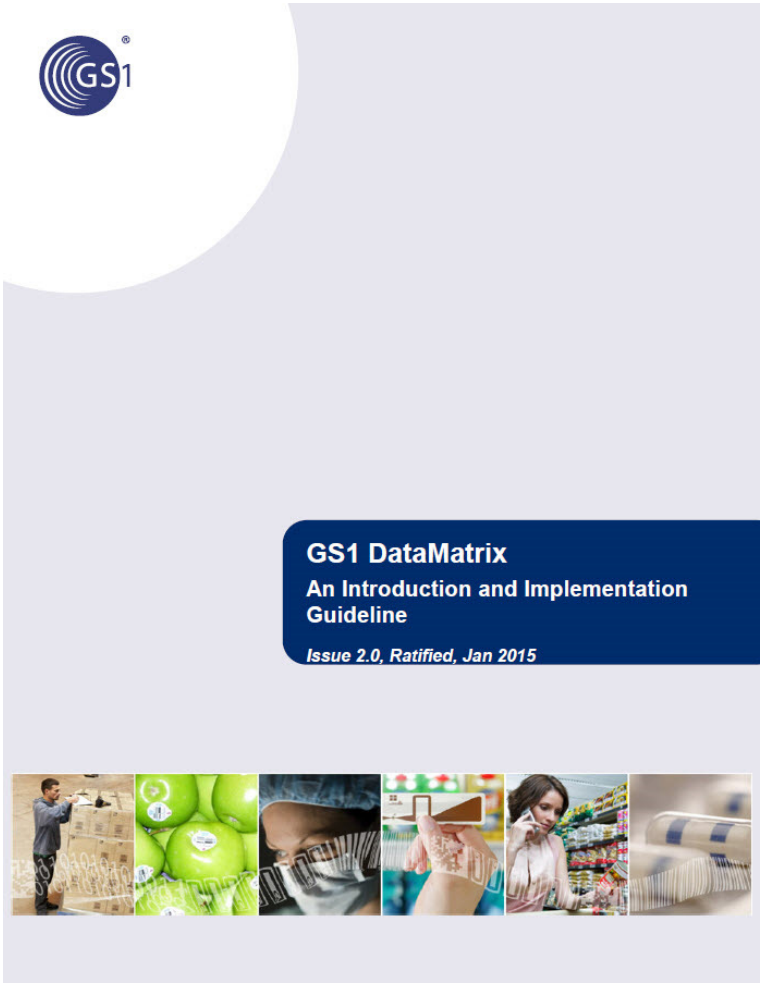


CHECK OUT: http://www.gs1.org/healthcare/library
http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf

GS1 DataMatrix – technical help…

GS1 DataMatrix
An introduction and technical overview of the most advanced GS1 Application Identifiers compliant symbology

This document facilitates processes by offering detailed information on GS1 DataMatrix and its technical characteristics encoding, printing and reading. It is a repository of reference information that can support the implementation of GS1 DataMatrix in any sector, industry or country.



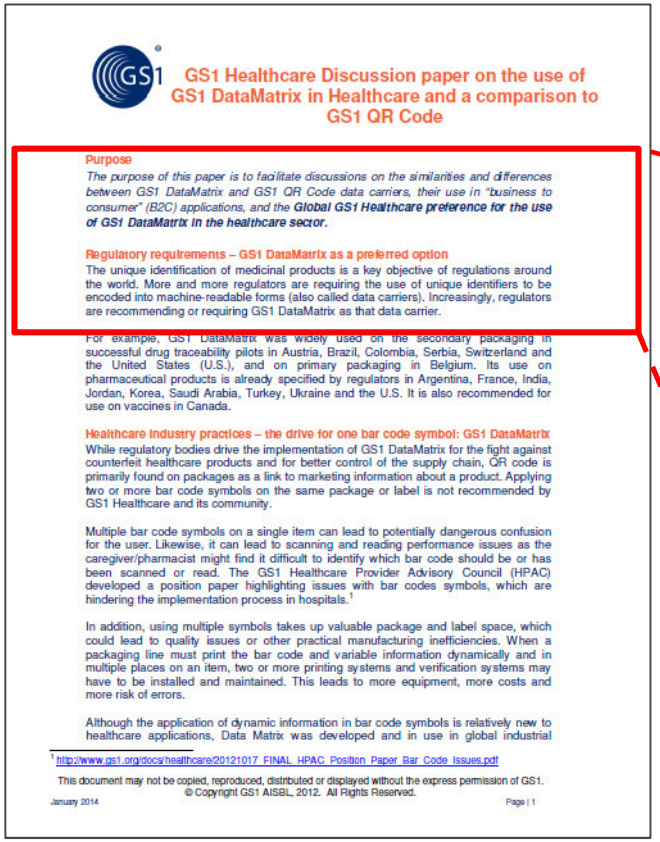
http://www.gs1.org/services/publications/online/

GS1 DataMatrix versus GS1 QR Code…

Data Matrix

QR Code

Position – DataMatrix or QR Code…



GS1 Healthcare Discussion paper on the use of GS1 DataMatrix in Healthcare and a comparison to GS1 QR Code

Purpose

The purpose of this paper is to facilitate discussions on the similarities and differences between GS1 DataMatrix and GS1 QR Code data carriers, their use in "business to consumer" (B2C) applications, and the ***Global GS1 Healthcare preference for the use of GS1 DataMatrix in the healthcare sector.***

Regulatory requirements – GS1 DataMatrix as a preferred option

The unique identification of medicinal products is a key objective of regulations around the world. More and more regulators are requiring the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). Increasingly, regulators are recommending or requiring GS1 DataMatrix as that data carrier.

For example, GS1 DataMatrix was widely used on the secondary packaging in successful drug traceability pilots in Austria, Brazil, Colombia, Serbia, Switzerland and the United States (U.S.), and on primary packaging in Belgium. Its use on pharmaceutical products is already specified by regulators in Argentina, France, India, Jordan, Korea, Saudi Arabia, Turkey, Ukraine and the U.S. It is also recommended for use on vaccines in Canada.

Healthcare industry practices – the drive for one bar code symbol: GS1 DataMatrix

While regulatory bodies drive the implementation of GS1 DataMatrix for the fight against counterfeit healthcare products and for better control of the supply chain, QR code is primarily found on packages as a link to marketing information about a product. Applying two or more bar code symbols on the same package or label is not recommended by GS1 Healthcare and its community.

Multiple bar code symbols on a single item can lead to potentially dangerous confusion for the user. Likewise, it can lead to scanning and reading performance issues as the caregiver/pharmacist might find it difficult to identify which bar code should be or has been scanned or read. The GS1 Healthcare Provider Advisory Council (HPAC) developed a position paper highlighting issues with bar codes symbols, which are hindering the implementation process in hospitals.[1]

In addition, using multiple symbols takes up valuable package and label space, which could lead to quality issues or other practical manufacturing inefficiencies. When a packaging line must print the bar code and variable information dynamically and in multiple places on an item, two or more printing systems and verification systems may have to be installed and maintained. This leads to more equipment, more costs and more risk of errors.

Although the application of dynamic information in bar code symbols is relatively new to healthcare applications, Data Matrix was developed and in use in global industrial

[1] http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

Reinforcing the GS1 Global Healthcare direction for **ONE** 2D Matrix data carrier… **GS1 DataMatrix**…

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Get your copy at:

http://www.gs1.org/sites/default/files/docs/healthcare/GS1%20QR%20DM%20discussion%20paper_20140113_FINAL.pdf

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GS1 system – Bar code symbol quality…

GS1 General Specifications

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols
ISO/IEC 15426-2 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 2: Two-dimensional symbols
ISO/IEC 16022 Information technology -- International symbology specification -- Data Matrix
ISO/IEC TR 24720 Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)
ISO/IEC TR 29158 Information technology -- Automatic identification and data capture techniques -- Direct Part Mark (DPM) Quality Guideline

Have the right "tools" for the job, starting with proper documentation, education, training…

Symbol quality - 1D/Linear vs. 2D/Matrix…

Common Quality Parameters

- Decode / RDA
- X Dimension / Module Size
- Data Structure, Validity
- Human Readable Interpretation
- Symbol Contrast
- Modulation
- Quite Zones, as applicable

1D Only

- Bar Height
- Minimum Reflectance
- Edge Contrast
- Defects
- Decodability

2D Only

- Fixed Pattern Damage
- Axial Nonuniformity
- Grid Nonuniformity
- Unused Error Correction
- Print Growth
- Clock Track Regularity

Symbol quality – Reference decode…

GS1 DataMatrix… or not… how do you know?

Symbol decode:

GS1 DataMatrix - (FNC1 & AIs)

]d2011085767400201717141120 10KMB11205201[GS]21CEB630078700

Whether you use a Verifier or go "more manual"… it's all in the data… and the ISO Symbology Identifier!

ISO Symbology ID's are Internationally agreed (ISO/IEC 15424) 3 character codes that scanner/imagers output at the beginning of a data string that tells what bar code symbology has been read. It is in the form:

]cm

where:

] - (ASCII 93) the ID flag character
c - code (symbology) character as ISO defined
m - modifier character(s)

Symbol decode:

]d1011085767400201717141120 10KMB11205201[GS]21CEB630078700

ISO Data Matrix - (No FNC1)

Symbol quality – There is help…

Bar Code Print Quality Verifiers are available for testing 2D Matrix symbols like GS1 DataMatrix

Check the AIM Buyer's Guide for a listing of most manufacturers

Ask the Experts – Topics…

A General Discussion of GS1 DataMatrix, with a GS1 Healthcare Application Standards Focus

- Why GS1 DataMatrix in Healthcare
- Data Matrix… The Symbology
  - "GS1 DataMatrix" or "ISO/IEC Data Matrix"
- Thoughts on Structure & Quality
- **Practical Application - Printing / Reading**
- A Practical Application – CEFA
- Audience Q & A

GS1 DataMatrix – Implementation…

Overview – Most early adopters have been hesitant to share details as yet on implementation challenges, this can be for many reasons such avoiding operational comparisons, keeping competitive advantage, protecting an active pilot implementation project, lack of long term cost information, etc. Many times we have been told the more significant costs are in IT infrastructure changes. We are all learning...

Costs - Manufacturing? – When it comes to implementation costs anecdotal estimates have run from $50K to about $500K (or more) USD per manufacturing line for printing / scanning updates (without serial number addition). Many note that with printing software it is critical to ensure automatic inclusion of the leading Function 1 character.

GS1 DataMatrix – Implementation…

Productivity? – In all cases we have heard that no one would even attempt to install systems if they were not assured that it would not negatively affect productivity.

Costs – User? – IT infrastructure changes may be the major unknown cost as it is different user to user. Scanner costs will depend on the type & use case need, however single, tethered/corded handheld "gun" type scanner imagers can cost about $250 - $350 USD per unit… from there (depending on quantities, type of unit, features, etc.) the costs can go slightly lower but also can rise into the $1000's USD for some systems. Bar code symbol print quality verifiers can run $2000 USD and up, but are available.

GS1 DataMatrix – Implementation…

Printing / Marking:

- Many existing "demand" label printers can print Data Matrix well
- May not be the case for all "in line" printers (validity of inks, needed speeds, etc.)
- DPM brings on a whole new set of challenges
- Beware the missing FNC1

Printing / marking must be matched to the application use case needs… as with other bar code symbol generation

(01)07612345678900(17)100503
(10)AC3453G3

GS1 DataMatrix

GS1 DataMatrix – Implementation…

Area Image Scanners:

- Camera / area imager based
- Growing installed base in industrial, commercial, healthcare
- Scans 1D / Linear, 2D Stacked & 2D Matrix symbols
- Competitive pricing more apparent

Camera-based bar code scanners are needed in Healthcare AND are a GS1 Healthcare Leadership Team recommendation!!

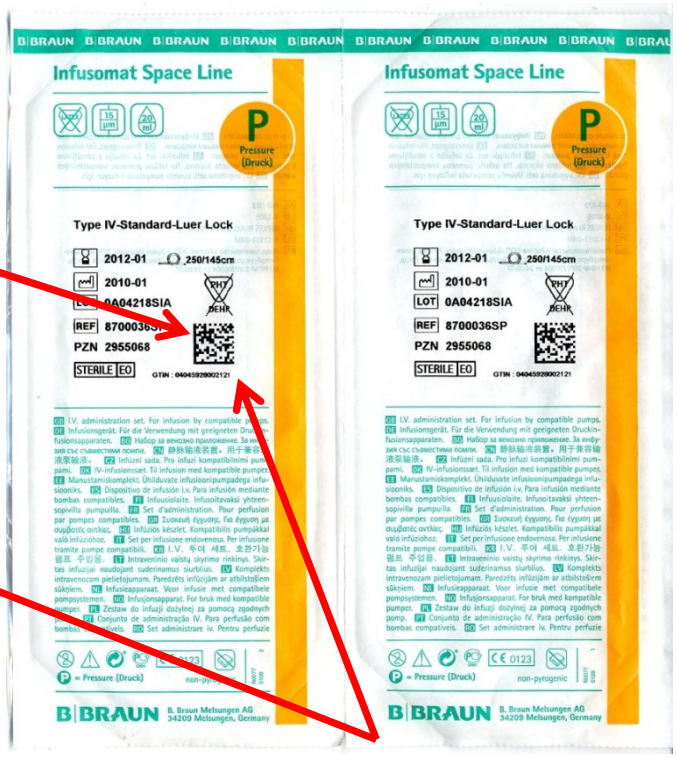
(01)07612345678900(17)100503
(10)AC3453G3

GS1 DataMatrix

GS1 DataMatrix – Unique product ID…

For pharmaceutical & medical device…

GTIN (static data)



AI's (variable attribute data)

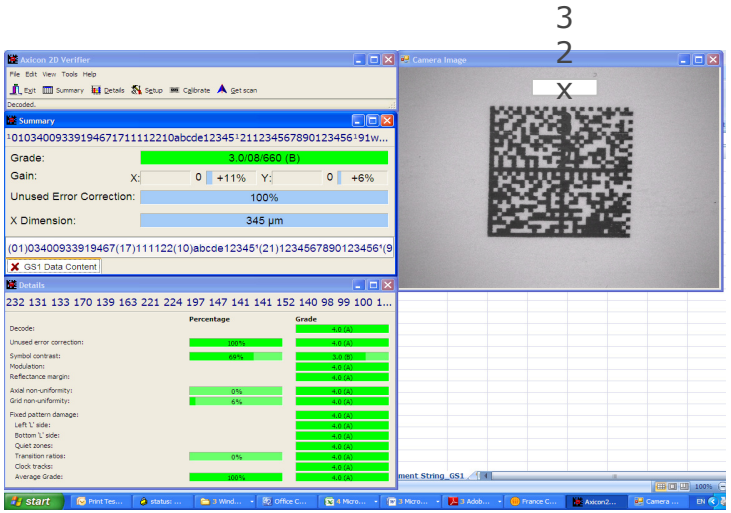
…in <u>one</u> bar code symbol (GS1 Data Carrier)

GS1 DataMatrix – Implementation test…

- To meet the French "CIP" requirements
- Identification of the product with "Lot/Batch" & "Expiry"
- Tests already run to add Serial Number and a country specific NHRN (National Healthcare Reimburse Number)
- Running at "normal" line speeds - 300 cartons/minute, 45m/min
- Print sizes – 300 DPI, Module size of 345µm, Wolke m600A, Universal Black UB 7482 HP Inkjet cartridge
- Read & verify – On and off-line camera based & verifier systems

GS1 DataMatrix – Implementation test…

- Tests have also been run to add Serial Number, a country specific NHRN (National Healthcare Reimbursement Number) and a URL
- Run at "normal" line speed - 300 cartons/minute, 45m/min
- Again print sizes – 300 DPI, Module size of 345µm, Wolke m600A, Universal Black UB 7482 HP Inkjet cartridge
- Data: 74 Alphanumeric characters (GTIN, Expiry, Lot/Batch, Serial, NHRN, URL)
- Symbol Size: 32x32 matrix, physical size of 11x11mm
- 94% of run achieved an ISO/IEC 15415 Grade of "B" - 3.0/08/660 (with the remainder a "C" grade)



GS1 DataMatrix – Implementation test…

DMX through the camera of the verifier

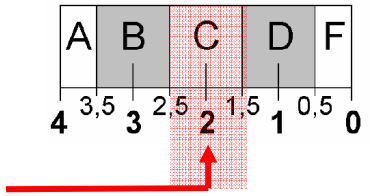
Technical challenges

Limited space means → small carriers + high data density

- e.g. DMX size : 6x6 - 10x10 mm
- Production/packaging line speed
- Packaging materials
- Printing technology
- Inks

Quality challenges

- Quality verification (ISO)
- Translucent paper
- Impact on contrast

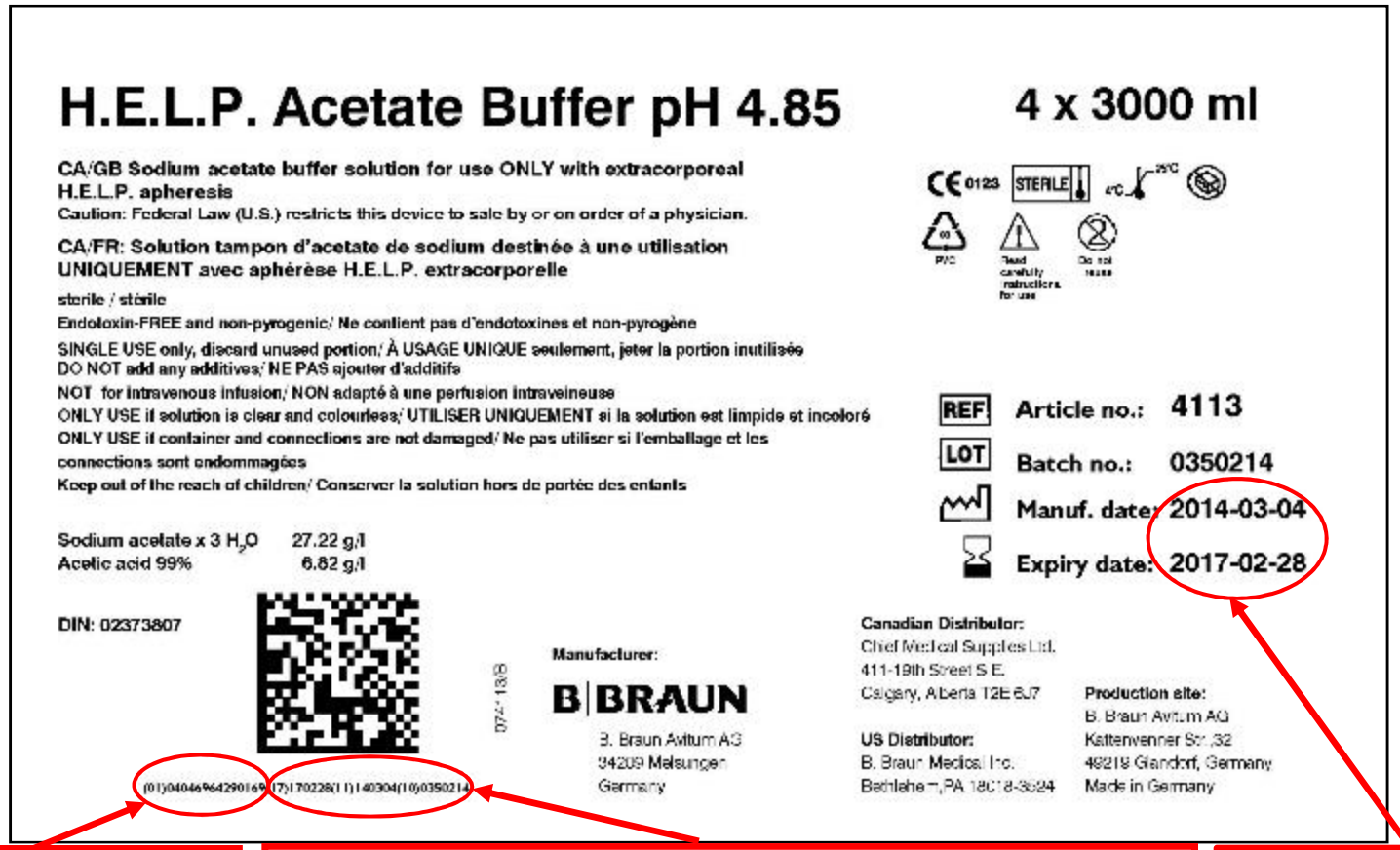


ISO required = C (1.5 – 2.5)

GS1 DataMatrix – Implementation test…

- Only 2D DataMatrix possible at present
  - Consistent reading… min. area of 3x3mm needed
- Size of surgical instruments extremely limited
  - Not all can be encoded (size, material, etc.)
- Implants (!?!?)
  - Size, corrosion, bio-compatibility, warranty issues, etc.
  - High-quality DPM technology required (laser, dot peen, etc.)

GS1 DataMatrix - UDI label – B.Braun…



Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required
ISO 8601 date format

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GS1 Healthcare

Datamatrix

A sucessful case

Dr. Bivian Pereira A.
Regulatory Affairs Manager

Ing. Daniel Chaves
Logistics Manager

April, 2015

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REGULATORY ASPECTS

Traceability Definition

International and Local Regulations

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Next Steps

CLOUSURE AND QUESTIONS

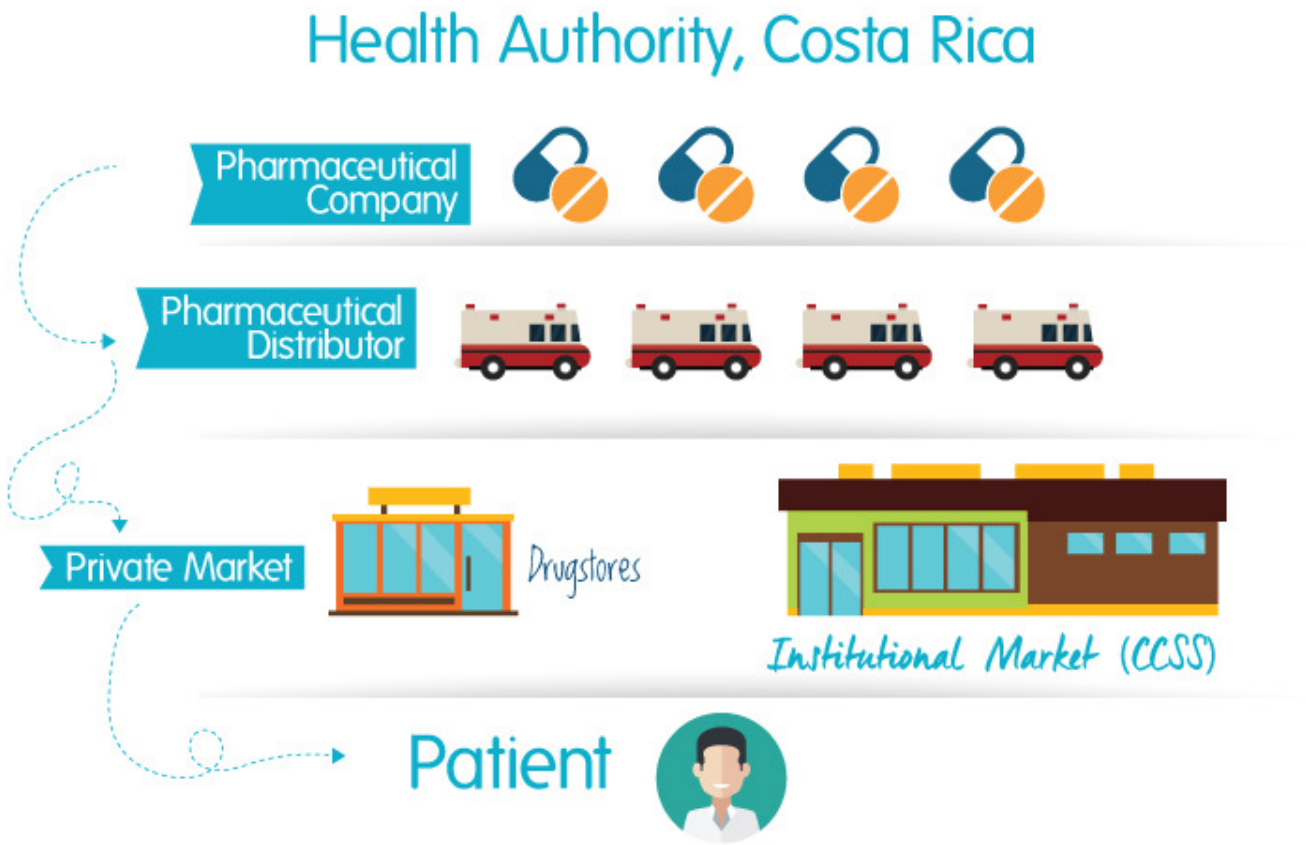
INTRODUCTION

Dr. Bivian Pereira A.
Regulatory Affairs Manager

REGULATORY ASPECTS

Dr. Bivian Pereira A.
Regulatory Affairs Manager

Traceability is all the processes carried out through the supply chain that determines the various steps by which a product goes from its source to its current location.



Costa Rica Health Authority:

37700-S Regulation: Good Distribution Practices for Pharmaceutical Products

'There must be product traceability through the chain of production, storage and distribution. This is a shared responsibility between all parties involved.

Procedures should be in place to ensure products documentary traceability by the pharmaceutical distributor from reception through commercialization that facilitates, if needed, recalls and product research if counterfeit suspicion or any other request by Health authorities.

To be approved: National System of Techno-Vigilance Regulation

'Implement a tracking system that allows medical devices traceability through commercialization and uses. This traceability system must be available to Health Authority if required.

37700-S REGULATION

REQUIREMENTS:

- Quality Control System
- Qualified personnel
- Pharmaceutical regency responsibilities
- Documentation
- Traceability
- Facilities
- Storages Areas
- Handling and pharmaceutical products disposal
- Labeling
- Reception and release
- Distribution
- Transportation
- Claims or complaints
- Recall
- Returns
- Counterfeit
- Contracts
- Audits or self-inspections
- Control and verification

We are constantly subjected to audits from Health Authority and our suppliers (Pharmaceutical Companies)

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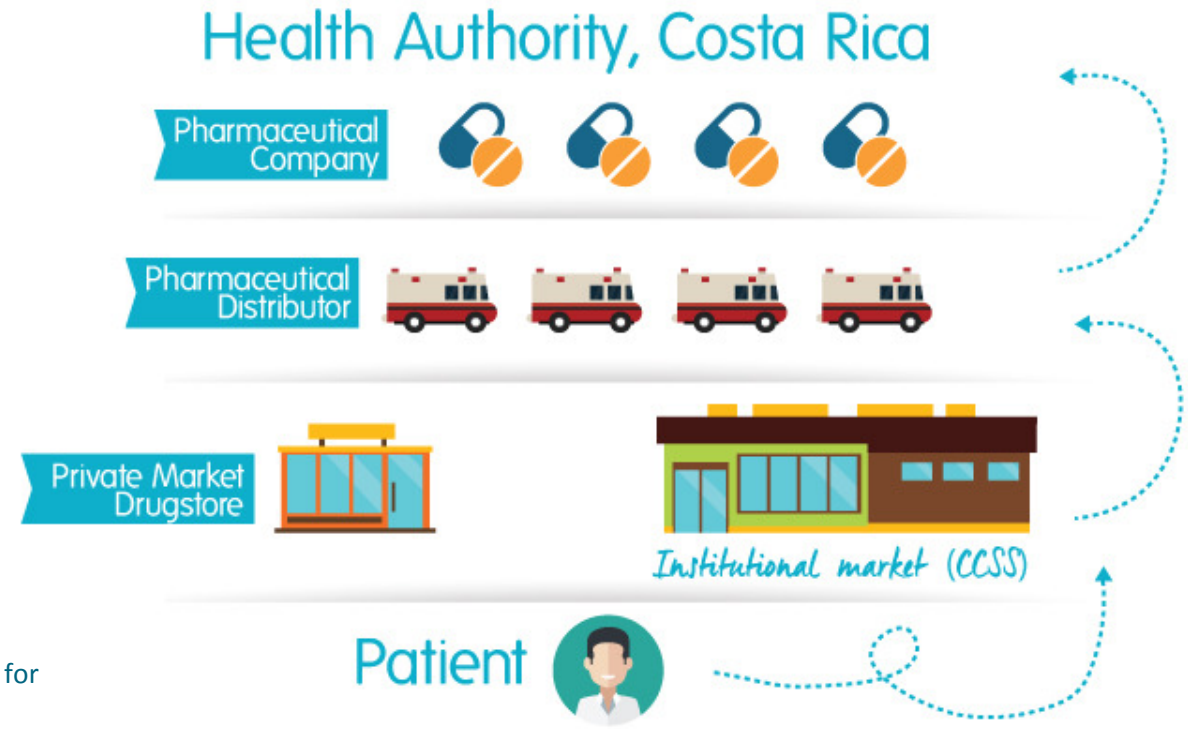
PHARMACEUTICAL RECALL

A voluntary procedure or required by Health Authorities, by which a manufacturing batch is recalled.



37700- S Regulation:
Good Distribution Practices for Pharmaceutical Products

TRACEABILITY PURPOSE: RECALL

Traceability has different meanings and purposes depending on who is the protagonist of the recall:

- Health Authorities: allows them to quickly immobilize unsafe products and, if necessary, recall them from the market.
- Pharmaceutical Company: allows them to quickly locate a defect batch, so that the rest of the production is not affected. Also, allows to deliver products to specific target markets, which guarantee origin and history
- Pharmaceutical Distributors and Drugstores: allows them that if an alert about a pharmaceutical products occurred, controls will work properly to ensure patient safety.

Cefa has conducted about 30 recalls of pharmaceutical products (class II and III) in recent years effectively, in compliance with the requirements of our pharmaceutical suppliers and Health Authorities.

PHARMACEUTICAL COUNTERFIET

Refers to the product manufactured in a deliberately and fraudulently way with respect to its identity or origin. They may include products with the right ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or whose packaging and its labeling or accompanying information contains false, ambiguous or misleading information about their identity, composition, qualities, usefulness or safety.

37700- S Regulation:
Good Distribution Practices for Pharmaceutical Products

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SITUATION IN OUR COUNTRY

Costa Rica

Invirtieron más de $3 millones en la producción de Lipitor falso

Una inyección de capital por más de $3 millones (¢1.395 millones) sirvió para financiar la producción del medicamento Lipitor que se falsificó en Costa Rica.

Fuente: La Nación

Policía allana vivienda distribuidora de 'Cofal' falso

POR KRISIA CHACÓN / krissia.chacon@nacion.com - Actualizado el 7 de abril de 2015 a: 10:56 a.m.

En Desamparados comercializaban Cofal falso proveniente de Centroamérica

Imagen cortesía

Durante los últimos cinco meses, las acciones se concentraban en dar con lo que sucedía en una casa ubicada en San Rafael Abajo de Desamparados, donde funciona la distribuidora

Fuente: crhoy.com 7/04/2015

TRACEABILITY PURPOSE: COUNTERFEITING

Through to traceability, you can clearly identify the location of the drug in a pharmaceutical company, distributor or drugstore and it is relatively easy to establish mechanisms against counterfeiting:

- Only pharmaceutical companies legally established can produce drugs. From this point, the traceability system can controlled step-by-step the drugs up to drugstores.
- Pharmaceutical distributor must only purchase from companies that meet the above requirements and sell just to legally established drugstores.
- Drugstores must not accept drugs outside of a recognize traceability system.

Next step:

Give consumers the option of consulting traceability of a particular unit to ensure the reliable origin and supply chain.

CONCLUSIONS

- ✓ Comply with international and local regulations.
- ✓ Comply with the requirements of our suppliers (pharmaceutical companies).
- ✓ Allow effective control and regulatory requirements in case of a recall of any pharmaceutical product due to quality, safety or efficacy.
- ✓ Validate an original product and prevent counterfeiting and smuggling.
- ✓ Supply chain transparency.
- ✓ Increase patient safety.

LOGISTICS ASPECTS

Ing. Daniel Chaves
Logistics Manager

OUR EXPERIENCE

- ✓ Began implementation of traceability system in 2010 with GS1 Costa Rica Assistance
- ✓ DATAMATRIX four elements chosen by CEFA:
  - ✓ GTIN
  - ✓ Batch Number
  - ✓ Expiry Date
  - ✓ Serial Number
- ✓ Started by labeling items as they came, and simultaneously adding labels to low turnover products in Distribution Center
- ✓ 100% of shipments under GS1 DATAMATRIX Traceability by mid 2010.

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INBOUND PROCESS

RECEIVING DOCKS

Check: one batch per box

RECEIVING DOCKS

Each box is Labeled with LPN

PRINTING STATION

Scann LPN info and Print DATAMATRIX labels

WORK TABLES

Labeling by hand

QUALITY ASSURANCE

Batch Inspection sampling

RELEASING

Product realease for sell by Pharmaceutical Regent

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OUTBOUND PROCESS

PICKING

By Radiofrequency Hand Held

PACKING STATION

Scann each DATAMATRIX

PACKING STATION

Serial numbers are associated with each order

PACKING STATION

Invoice printed with batch number & expiration date

In Case of Recall

LOGISTICS

Batch number deliveries report generated

CALL CENTER

Contact customers and coordinate returns

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CHALLENGES, HOW WE OVERCAME THEM?

1 Service time

Dock-to-stock time increase due to labeling process:

- ✓ Simultaneous Labeling with product check-in
- ✓ Managing priorities with commercial department
- ✓ Increase of safety stocks was not necessary
- ✓ Minimum impact on time in availability of stock

CHALLENGES, HOW WE OVERCAME THEM?

2 Supplier Collaboration

Suppliers support was vital for the success of the project:

- ✓ Involving Suppliers in the traceability concept
- ✓ “Reception Guide for CEFA Suppliers” was developed and shared
- ✓ Comply by suppliers of the Reception Guide was key to reduce inbound delays and product rejection
- ✓ Improving suppliers Fill Rate

CHALLENGES, HOW WE OVERCAME THEM?

3 High volume in small batches labeling processes

Inbound: to label between 500,000 and 800,000 units of 1,800 SKUs per month

- ✓ Average: between 300 and 400 units per SKU
- ✓ Automatic labeling or direct inkjet printing is not possible
- ✓ CEFA Distribution Center contracted a Value Added Service Supplier.
- ✓ An skilled Operator can label 6,000 units per shift
- ✓ Manual task is outsourced, supervision and Quality Control are CEFA´s responsibility

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CHALLENGES, HOW WE OVERCAME THEM?

4

Initial Investment

Change scanners and acquire 2D printers.

- ✓ Scanners were replaced on packing stations
- ✓ Agreement with Label Supplier included the printers, its maintenance and replacement

CHALLENGES, HOW WE OVERCAME THEM?

5 Cost Allocation

Who should assume the cost of DATAMATRIX labeling?

- ✓ The Commercial Unit? Since it was a sales requirement
- ✓ Or Regulatory Unit? Since it was a traceability requirement
- ✓ Or a Logistic Unit? Since it was an operational activity

- ✓ Cost of applying label can vary depending on product size and type.
- ✓ An average cost related to DATAMATRIX system is added to product cost.
- ✓ DATAMATRIX cost is insignificant compared to inventory value.

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DATAMATRIX ADDITIONAL BENEFITS

1 Expiration date control on deliveries

To deliver product with short shelf life could upset customers

- ✓ DATAMATRIX system allows to set up a minimum shelf life parameter to avoid shipping products not accept by costumers.
- ✓ Help to detect operating errors in warehouse locations
- ✓ To ensure that only products with sufficient shelf life go to market.
- ✓ Increases distributor credibility, prevents customer displeasures, and reduces returns

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DATAMATRIX ADDITIONAL BENEFITS

2 Financial benefits on product returns

Marketing conditions are constantly changing: price, discounts, offers.

- ✓ Normally in returns is difficult to associate the product with the invoice price and conditions at delivery.
- ✓ With DATAMATRIX, is possible to identify the marketing conditions given at purchase moment. Therefore CEFA can recognize the exact amount to each customer when product is return.
- ✓ Avoid product returns sold by another Distributor.
- ✓ Identify informal supply channels.

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DATAMATRIX ADDITIONAL BENEFITS

3 Customer Claims

24 hours policy to submit any claims for missing or damage product. This policy allows more efficient use of distribution resources

- ✓ DATAMATRIX is an accurate tool for verifying shipment dates and accept or reject drugstores claims
- ✓ Reinforces credibility with customers and prevents frauds
- ✓ Delivery process at packaging station is video taped. Using DATAMATRIX scanning is possible to find the specific time when an order was prepared.

DATAMATRIX ADDITIONAL BENEFITS

4 Quality Product Investigations

Real Case: Drugstore in Guanacaste, 250 km from our Warehouse

- ✓ A consumer was very upset because they sold a cough syrup bottle labeled "*Sample, Not for Sale*".
- ✓ A DATAMATRIX photo was sent by WhatsApp.
- ✓ Batch number was identified and Quality Assurance inspected the remaining stock, finding bottles with "sample text" printed mixed with regular product.
- ✓ Pharmaceutical company was informed and others drugstores were contacted to inspect the batch received. Others non-conforming units were recovered fast and easy.

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DATAMATRIX ADDITIONAL BENEFITS

5

Cooperating with Authorities

Cooperation with Authorities in investigating robberies at drugstores and tracking controlled products.

DATAMATRIX can provide evidence to support an robbery indictment:

- ✓ Define what Drugstore purchase the products
- ✓ Delivery date
- ✓ Cost of the products

Another traceability case:

- ✓ Morphine inj. found in a illegal drug confiscation
- ✓ CEFA tracked that morphine inj. found was sold to a drugstore that closed several months ago

NEXT STEPS

At Pharmaceutical Market

- ✓ A Private Hospital is developing a project to record the product batch number administered to a patient.
- ✓ Using supplier DATAMATRIX a drugstore chain is evaluating alternatives to provide traceability from their distribution center to drugstores at POS

Our own pharmacy chain “Fischel”

- ✓ Traceability to consumer: Through our CRM and DATAMATRIX scan at the purchase moment
- ✓ Inventory management tools: Stock expiration date control and return to Distribution Center.

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CONCLUSIONS

- ✓ In CEFA, we deeply believe in the innovation supported by technology, best practices and the best talent to provide health solutions to final consumer.
- ✓ Our experience has been very positive. It was easy to overcome the obstacles that arose in the DATAMATRIX implementation
- ✓ Fulfilling traceability requirements, we obtained many additional benefits. With DATAMATRIX we have taken our supply chain to a higher level of reliability and develop collaborative relationships with suppliers and customers.
- ✓ Traceability carried out by world standards, helps to assure pharma products that meet the quality, safety and effectiveness required.
- ✓ Traceability is a growing need to preserve the security of patients; and it is essential to implement a valid and satisfactory solution to comply with all regulations required.

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THANK YOU
QUESTIONS

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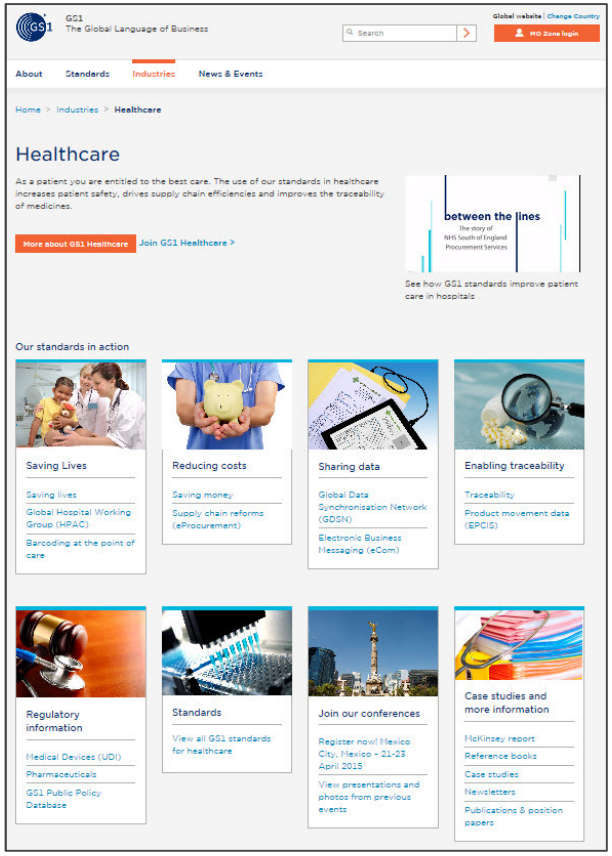
And now… audience questions…

GS1 DataMatrix & Healthcare…

Find information & support at GS1 Global Healthcare on the web…



Check out: http://www.gs1.org/healthcare

AIDC in Healthcare

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