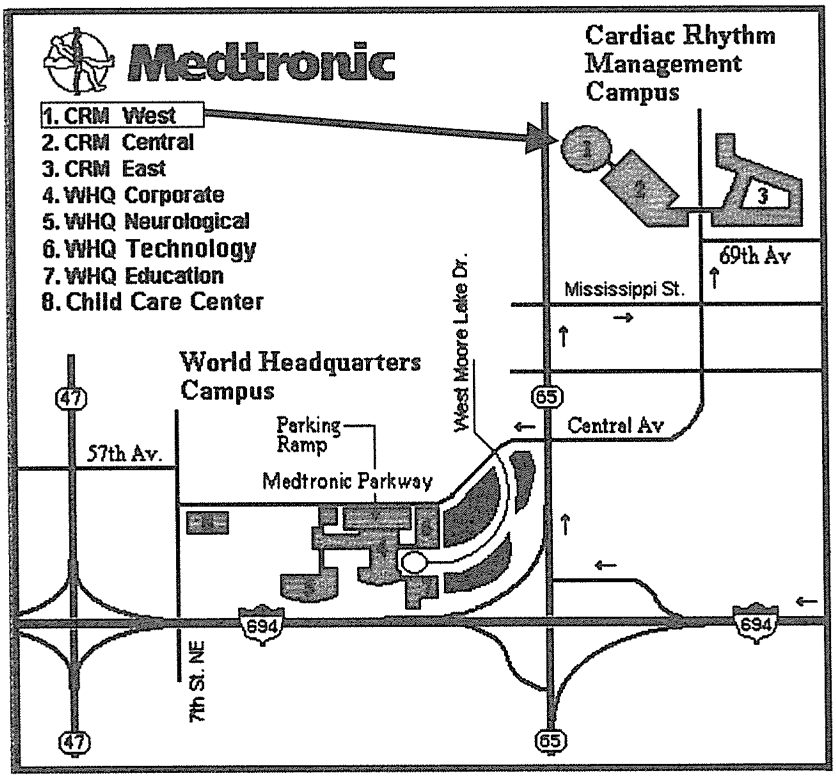
GS1 HUG

GS1 HUG™ Global Healthcare User Group
Minneapolis, Minnesota, USA 13-15 June 2006

PARKING details:

- Cross over 69th Avenue
- Enter the Parking Lot on the West side (your left)
- Continue to drive West to the last building in the lot
- and look for open parking spaces in front of CRM West building.
- Enter into the building and walk straight toward the reception desk.
- The receptionist will provide temporary security badges and further instructions.

Click here to see a Google Map



HOSTED BY Medtronic *Alleviating Pain · Restoring Health · Extending Life*

Implementation of Barcode Labeling of Ethical Drugs in Japan

15 June 2006

The global language of business

www.gs1.org

The Barcode Labeling of Ethical Drugs by GS1-128 & RSS composite symbology

The Japanese ministry of Health and Welfare notified the Pharmaceutical manufacturers industry the document entitled "Standardizing a code system to specify the Ethical Drugs (In hospital use) & Blood products" on 13, September 2005.

March 2006, " Implementation of Bar Code labeling of Ethical Drugs" for preventing accidents of mix-up dugs and assuring traceability has been developed.

The three medical industry group will begin the source marking by the GS1-128 bar code and RSS composite symbology by these ministry's Notification documents.

The medical industry group are,

- ●Japan Federation of Pharmaceutical Industry Associations(≒1,500members)
- ●The Association of Dental manufacturers & Distributers in Japan
- ● The Association of Blood products manufacturers in Japan

→ July 2006, The source marking guidelines (manuals) will issued.
→ The time limit of source marking is 2 years.

Labeling items & data to be indicated (1) Formulation (unit dose) package unit

Labeling items shall be <u>ethical drugs (In hospital use)</u>.
A product code(GTIN), expiration date, manufacturing No. or code and quantity shall be indicated as mentioned below according to the unit of packaging forms And types of ethical dugs (Note 1, Page 6).

(1) Formulation (unit dose) package unit (Note 2)

	Type of ethical drug	Product code	Expiration date	Manufacturing No. or code
(Note 6)	Specific biological product	◎	◎	◎
	Biological product (excluding specific biological products)	◎	○	○
	Oral medicine (excluding biological products)	◎	○	○
	Injection (excluding biological products)	◎	○	○
	External medicine (excluding biological products)	◎	○	○

◎: shall be indicated (essential indication), ○: not necessary (voluntary indication)

Labeling items & data to be indicated (2) Marketing (inner) package unit

(2) Marketing (inner) package unit (Note 3)

Type of ethical drug	Product code	Expiration date	Manufacturing No. or code
Specific biological products	◎	◎	◎
Biological products (excluding specific biological products)	◎	◎	◎
Oral medicine (excluding biological products)	◎	○	○
Injection (excluding biological products)	◎	○	○
External medicine (excluding biological products)	◎	○	○

◎: shall be indicated (essential indication), ○: not necessary (voluntary indication)

Labeling items & data to be indicated (3) Logistics (outer) package unit

(3) Logistics (outer) package unit (Note 4)

Additional data

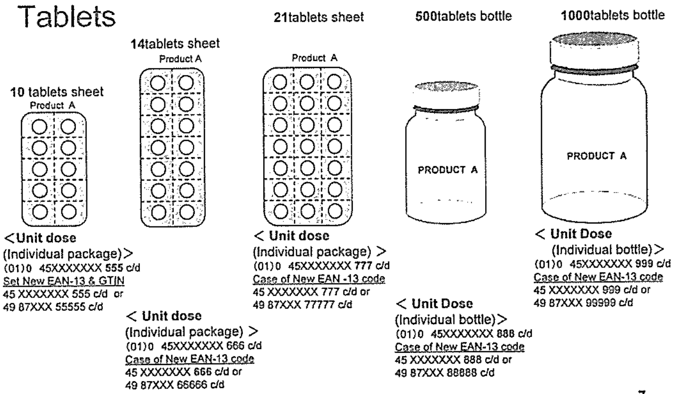
Type of ethical drug	Product code	Expiration date	Manufacturing No. or code	Quantity (Note 5)
Specific biological products	◎	◎	◎	◎
Biological products (excluding specific biological products)	◎	◎	◎	◎
Oral medicine (excluding biological products)	O	O	O	O
Injection (excluding biological products)	O	O	O	O
External medicine (excluding biological products)	O	O	O	O

◎: shall be indicated (essential indication), O: not necessary (voluntary indication)

Note of labeling items and data

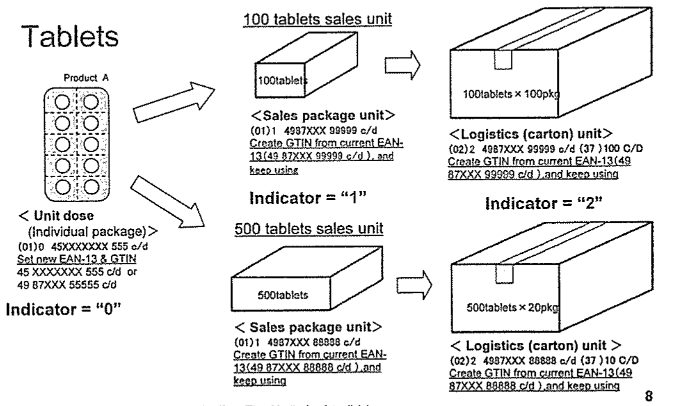
(Note 1)
"◎" means those which shall be indicated (essential indication), and "O" means those which are not necessarily indicated (voluntary indication).
(Note 2)
The formulation package unit refers to the smallest unit of the package of drugs marketed by marketing business license holders; i.e. a PTP sheet and pill bottle for tablets and capsules, and an ampoule and vial for injections.
(Note 3)
The marketing package unit refers to, in general, the smallest package unit of drugs sold by wholesale distributors to medical institutions; i.e. a box containing 100 formulation package units of PTP sheets for tablets and capsules, and a box containing 10 ampoules for injections.
(Note 4)
The logistics package unit refers to a package unit that several marketing package units are packed by marketing business license holders; i.e. a carton box containing 10 marketing package units of boxes.
(Note 5)
The quantity refers to the number of marketing package units included in an original package unit.
(Note 6)
Biological products : Medicine that extraction refinement is done from human and animal

Conditions:
Pharmaceutical manufacturers will be allocated a new GS1 company prefix.
New EAN-13 code : "45 XXXXXXX OOO c/d"
Current EAN-13 code : "49 87XXXOOOOO c/d" ※ c/d : Check digit

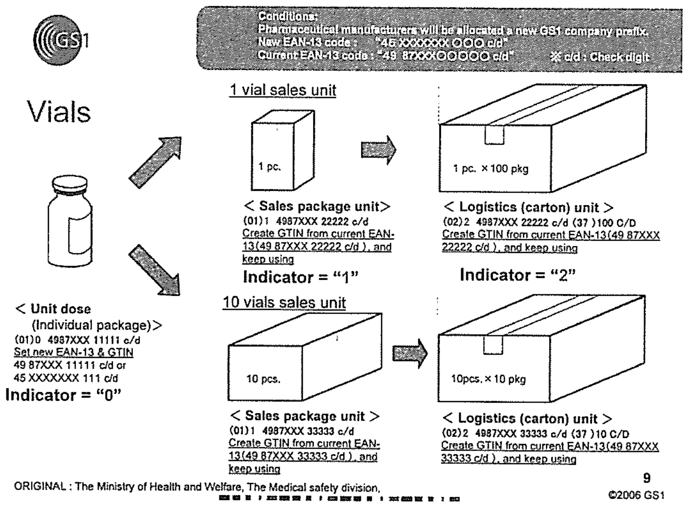


Unit dose Indicator = "0"

Conditions:
Pharmaceutical manufacturers will be allocated a new GS1 company prefix.
New EAN-13 code : "45 XXXXXXX OOO c/d"
Current EAN-13 code : "49 87XXXOOOOO c/d" ※ c/d : Check digit



ORIGINAL : The Ministry of Health and Welfare, The Medical safety division,


Conditions:
Pharmaceutical manufacturers will be allocated a new GS1 company prefix.
New EAN-13 code : "45 XXXXXXX ○○○ c/d"
Current EAN-13 code : "49 87XXX○○○○○ c/d" ※c/d : Check digit
Vials
1 vial sales unit
1 pc.
1 pc. × 100 pkg
< Sales package unit>
(01)1 4987XXX 22222 c/d
Create GTIN from current EAN-13(49 87XXX 22222 c/d), and keep using
Indicator = "1"
< Logistics (carton) unit >
(02)2 4987XXX 22222 c/d (37)100 C/D
Create GTIN from current EAN-13(49 87XXX 22222 c/d), and keep using
Indicator = "2"
< Unit dose
(Individual package)>
(01)0 4987XXX 11111 c/d
Set new EAN-13 & GTIN
49 87XXX 11111 c/d or
45 XXXXXXX 111 c/d
Indicator = "0"
10 vials sales unit
10 pcs.
10pcs. × 10 pkg
< Sales package unit >
(01)1 4987XXX 33333 c/d
Create GTIN from current EAN-13(49 87XXX 33333 c/d), and keep using
< Logistics (carton) unit >
(02)2 4987XXX 33333 c/d (37)10 C/D
Create GTIN from current EAN-13(49 87XXX 33333 c/d), and keep using
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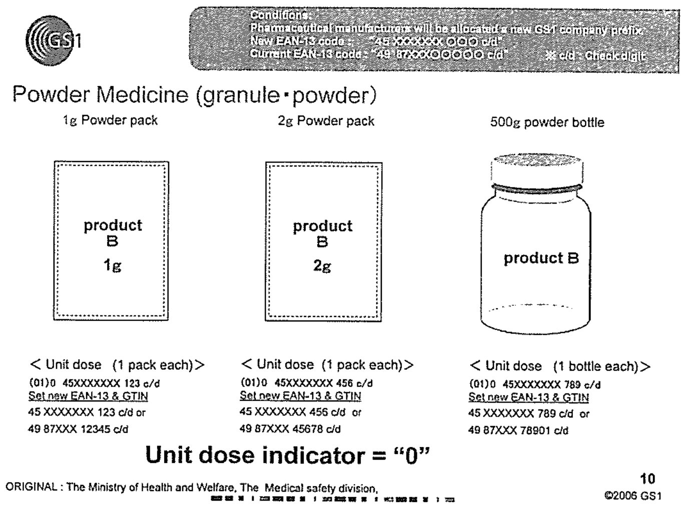
Conditions:
Pharmaceutical manufacturers will be allocated a new GS1 company prefix.
New EAN-13 code : "45 XXXXXXX ○○○ c/d"
Current EAN-13 code : "49 87XXX○○○○○ c/d" ※c/d : Check digit
Powder Medicine (granule・powder)
1g Powder pack
2g Powder pack
500g powder bottle
product B 1g
product B 2g
product B
< Unit dose (1 pack each)>
(01)0 45XXXXXXX 123 c/d
Set new EAN-13 & GTIN
45 XXXXXXX 123 c/d or
49 87XXX 12345 c/d
< Unit dose (1 pack each)>
(01)0 45XXXXXXX 456 c/d
Set new EAN-13 & GTIN
45 XXXXXXX 456 c/d or
49 87XXX 45678 c/d
< Unit dose (1 bottle each)>
(01)0 45XXXXXXX 789 c/d
Set new EAN-13 & GTIN
45 XXXXXXX 789 c/d or
49 87XXX 78901 c/d
Unit dose indicator = "0"
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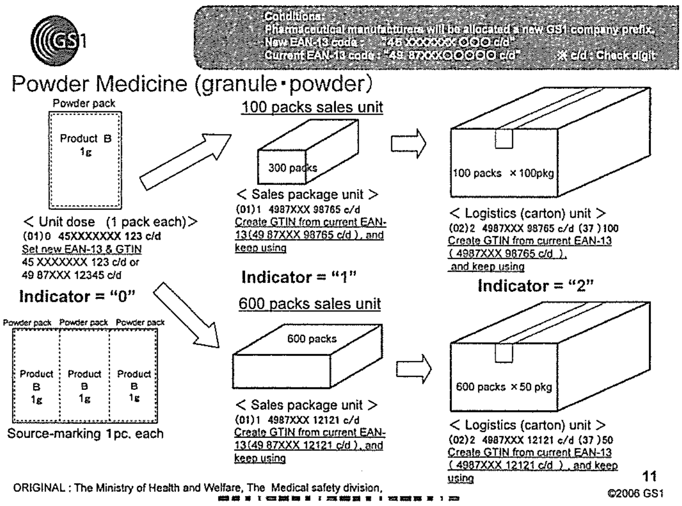
Conditions:
Pharmaceutical manufacturers will be allocated a new GS1 company prefix.
New EAN-13 code : "45 XXXXXXX ○○○ c/d"
Current EAN-13 code : "49 87XXX○○○○○ c/d" ※c/d : Check digit
Powder Medicine (granule・powder)
Powder pack
Product B 1g
< Unit dose (1 pack each)>
(01)0 45XXXXXXX 123 c/d
Set new EAN-13 & GTIN
45 XXXXXXX 123 c/d or
49 87XXX 12345 c/d
Indicator = "0"
Powder pack Powder pack Powder pack
Product B 1g Product B 1g Product B 1g
Source-marking 1pc. each
100 packs sales unit
300 packs
< Sales package unit >
(01)1 4987XXX 98765 c/d
Create GTIN from current EAN-13(49 87XXX 98765 c/d), and keep using
Indicator = "1"
100 packs × 100pkg
< Logistics (carton) unit >
(02)2 4987XXX 98765 c/d (37)100
Create GTIN from current EAN-13 (4987XXX 98765 c/d), and keep using
Indicator = "2"
600 packs sales unit
600 packs
< Sales package unit >
(01)1 4987XXX 12121 c/d
Create GTIN from current EAN-13(49 87XXX 12121 c/d), and keep using
600 packs × 50 pkg
< Logistics (carton) unit >
(02)2 4987XXX 12121 c/d (37)50
Create GTIN from current EAN-13 (4987XXX 12121 c/d), and keep using
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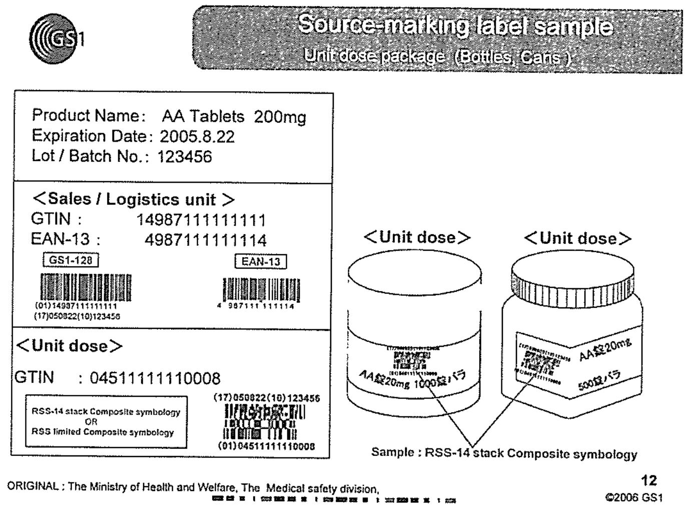
Source-marking label sample
Unit dose package (Bottles, Cans)
Product Name: AA Tablets 200mg
Expiration Date: 2005.8.22
Lot / Batch No.: 123456
<Sales / Logistics unit >
GTIN : 14987111111111
EAN-13 : 4987111111114
GS1-128
EAN-13
(01)14987111111111
(17)050822(10)123456
<Unit dose>
GTIN : 04511111110008
RSS-14 stack Composite symbology
OR
RSS limited Composite symbology
(17)050822(10)123456
(01)04511111110008
<Unit dose>
<Unit dose>
AA錠20mg 1000錠バラ
AA錠20mg 500錠バラ
Sample : RSS-14 stack Composite symbology
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Source-marking

Symbology sample is not actual size.

	Unit dose	Sales unit	Logistics unit
Standardized Marking (addition) The time limit of source marking is 2 years.	RSS-14 stack Composite symbology OR RSS limited Composite symbology (01)04987111111114 (17)050822(10)123456 GTIN:04987111111114 *New source-marking* *New data format*	RSS-14 stack Composite symbology OR RSS limited Composite symbology (01)14987111111114 (17)050822(10)123456 GTIN: 14987111111111 *New source-marking* *New data format*	GS1-128 (02)24987111111111 (17)050822(37)25000(10)123456 AI : (02) & (37) GTIN: 24987111111118 *New source-marking* *New data format*
	Unit dose	**Sales unit** (Parallel Marking 5 years)	**Logistics unit** (Parallel Marking 5 years)
Current Marking	*Marking none*	EAN-13 4 987111 111114 EAN-13: 4987111111114	ITF-14 14987111123459 GTIN: 14987111123459

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Appendix

Label samples,

Laser direct marking,

Scanners,

Verification system,

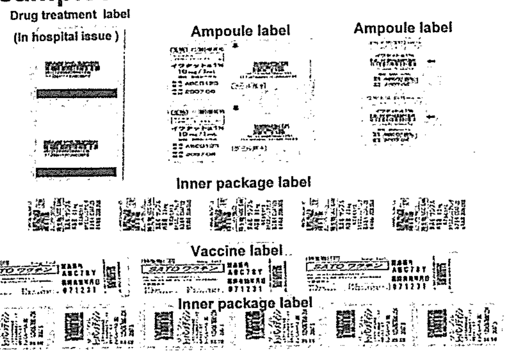
Appendix
Label sample, Laser marker, Scanners

Label samples

RSS stacked Composite symbology

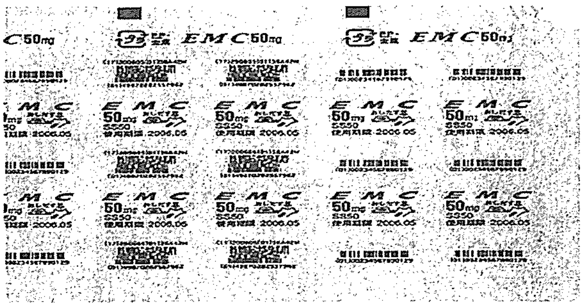
OR

RSS limited Composite symbology



Appendix
Label sample, Laser marker, Scanners

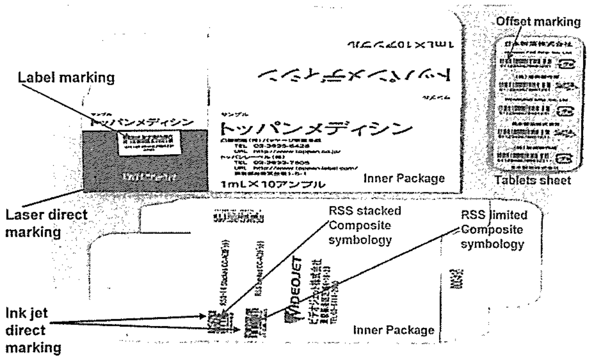
Tablet sheet marking samples in packaging line



(Aluminium coting films)

Appendix
Label sample, Laser marker, Scanners

The inner package samples



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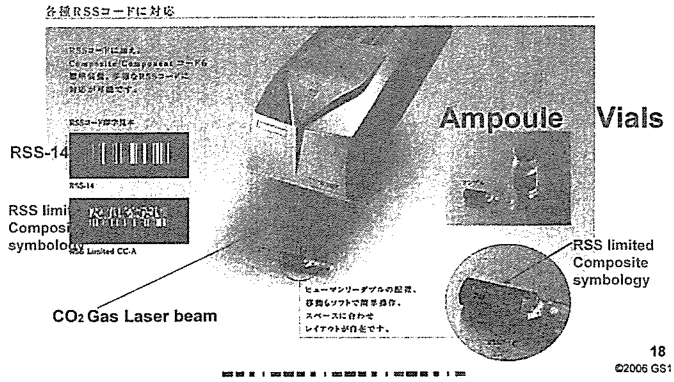
Appendix
Label sample, Laser marker, Scanners

The Laser direct marking equipment (label-less marking)



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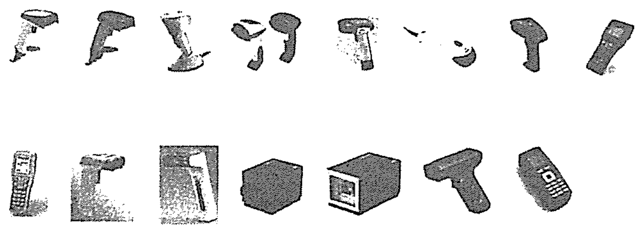
Appendix
Label sample, Laser marker, Scanners

The RSS / Composite Scanners (Handheld & Fixed Mount)



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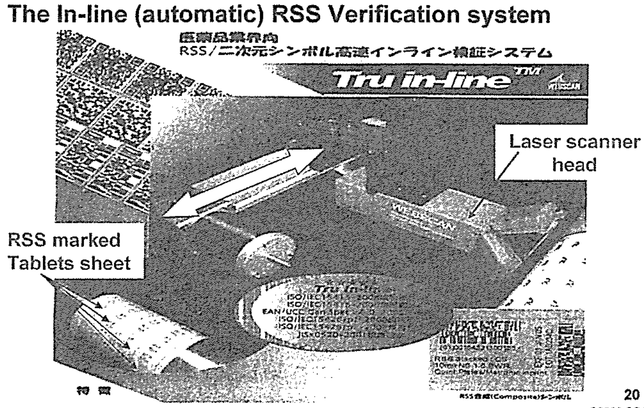
Appendix
Label sample, Laser marker, Scanners

The In-line (automatic) RSS Verification system



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F. + 81 3 5414 8529
E. kurosawa@gs1jp.org / miyahara@gs1jp.org
W. www.gs1jp.org

The global language of business

GTIN Allocation Team

Minneapolis, June 2006
Mark Walchak/ Mark Hoyle/David Buckley

The global language of business
www.gs1.org

Work Group – GTIN Allocation

Summary Today's of Presentation:

1. Introduction to HUG GTIN Allocation Work Team
2. Demonstration of GTIN Allocation Rules Website (www.gs1.org/gtinrules)
3. GTIN Allocation Rules – Basic Top Level Principles for Healthcare
4. Complex Issues – open questions
5. Next Steps – your input

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1) Work Group – GTIN Allocation

Co-Chairs

Mark Walchak- Pfizer
Mark Hoyle- Tyco Healthcare

Members

David Buckley - GS1
Leen Danhieux - GS1
Ulrike Kreysa - GS1
Sue Schmid - GS1
Tom Werthwine – J&J
Heribert Wirges - Phoenix
Volker Zeinar – Braun
Jill Buss - 3M
Colleen Dooley- Sobey
Pat Morrison - Lawtons
Peter Tomicki- Baxter
Jim Wilmott – Smiths Medical
Nigel Wood - GS1

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Charter

- Simple and easy to use worldwide standard for GTIN Allocation in Healthcare
  - Developed using published GS1 GTIN Allocation Booklet
- Easy naviagation based upon
  - General Rules and Over-the-Counter (OTC)
  - Specific rules Prescription (Rx)
  - Specific rules Medical Devices
- Schedule
  - Today (Minneapolis) finalise concept and table of content
  - September 2006 – Provide HUG with final draft

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Table of Contents – Top Level

1. Scope and Background
2. Introduction to Global Trade Item Number in Healthcare
   2.1. Definition of a GTIN
   2.2. Healthcare Items (definitions)
3. Allocating the Numbers
4. Regulators
5. GTIN Allocation Scenarios
   5.1. Over the Counter (OTC)
   5.2. Prescription (Rx)
   5.3. Medical Devices
6. Glossary

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TofC: 1. Scope and Background

Main Statements:

- voluntary guideline
- developed by the Healthcare User Group www.gs1.org/hug
- aiming at consistent world-wide use of GTIN
- provides details on GTIN Allocation within Healthcare

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TofC: 2. Introduction to Global Trade Item Number in Healthcare

Main Statements:

- Overview of GTIN
- While all GS1 standards are voluntary, the rules are intended to drive consistent implementation in the Global Healthcare Community.
- NOTE: *National, federal or local regulations may apply and take precedence. For example, some healthcare regulators may dictate a new GTIN for a given change*
- Definitions of:
  - Over The Counter (OTC)
  - Prescription (Rx)
  - Medical devices

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TofC: 3. Allocating the Numbers

Main Topics Covered:

- General rule
- Responsibility
- Guidelines for Allocating Global Trade Item Numbers
  - Best Practice in Healthcare is not to reallocate any GTIN that has previously be used on a product which has become obsolete.
- Packaging Levels
- Data Requirements in Healthcare
  - GTIN and Batch and Expiry Date
  - GTIN and Serial Number
- Acquisitions and Mergers
- Data alignment

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TofC: 4. Regulators

Main Statements:

- When in doubt, obey the law

- For a summary information, by country regulator, see:

http://www.gs1.org/hug/work_teams/standards_implementation/

(HUG Page of Standards Implementation / Regulatory Affairs)

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TofC: 5. GTIN Allocation Scenarios

5.1 Over the Counter Rules:

New Language - New language on a package sold in one Market/Country- NEW GTIN

Plus many more (see draft document)

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TofC: 6. Glossary of Terms?

GLOSSARY Open question:

- Reference the 'existing' GS1 Glossary?
- Reference a wider 'HUG' Glossary (which would have to be developed)?
- Include here a short summary of the key terms used in this document?

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Team meetings & Working Drafts

- 23 February 2006 Kick-Off Telecom
- 10 March 2006 – Telecom
- 27 March 2006 - ROME HUG meeting (formal review)
- 19 May 2006 – Telecom
- tbd June 2006 – Next Telecom

http://www.gs1.org/hug/work_teams/gtin_allocation/

Version	Date	Responsible	Changes
Version 0.2	14 March 2006	David Buckley	Summary of work team results
Version 0.3	15 March 2006	Ulrike Kreysa	Comments of Leen Danhieux
Version 0.4	10 May 2006	David Buckley	Comments following Rome HUG Meeting
Version 1.0	10 June 2006	David Buckley	DRAFT For Minneapolis HUG meeting (update from 19 May 2006 team call and image updates)

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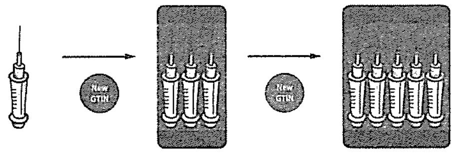
We are making good progress

Packaging Levels

Each packaging level needs a different GTIN



Example Syringe: Different GTIN for single, pack of three, pack of five

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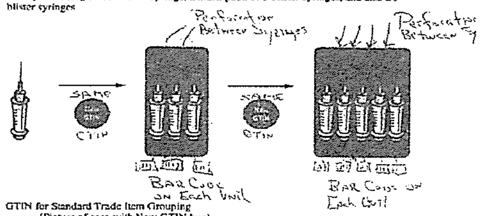
But still a lot of work to do?

DIFFERENT QUANITITIES / Perforated Blister/GTIN on Each Blister Cell

Type of Change to Trade Item
Grouping of the same item containing different quantities
Example: A single item- loose syringe, a multi-pack of 3 blister syringes, and also a 5 blister syringes



GTIN for Standard Trade Item Grouping
(Picture of case with New GTIN bug)

Rationale
GTIN for a single unit should be the same if it is for a single pack or a multi pack.

Consequence if Rule Not Applied
The GTIN identifies all aspects of the standard trade item grouping for ordering, stocking or billing systems. The GTIN for a single unit should not

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2) www.gs1.org/gtinrules

- Modern technology (database)
- Simplified/quicker maintenance
  - Simplified translation
- Detailed hit reports:
  - At scenario level
- Ability to link to Associated Rules
  - *discussion?*
- Search Feature
- Integrated into GS1 Website look and feel

Have a look new:
GTIN Site

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Areas of Concerns and Resolution

- Country Specific?
  - Make reference to Standards Implementation and Regularly Affairs Group
  - Countries not using Systems coding not compatible with GTIN
- Multiple bar codes on the package
  - one GTIN and another country required (example Germany, Austria, Italy)
- Assigning GTINs to lowest level
  - Unit of use
  - Multiple bar codes on the same package (UPC and Data Matrix)
- The Bar Coding of Expiry Dates which are not day related
  - (e.g., Expiration in March 2009 (which is not 1 March 2009 nor 15 March 2009 nor 31 March 2009)).

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3) GTIN Allocation for Healthcare

- GTIN Allocation Rules – Basic Top Level Principles
  e.g. Package Level Indicators
  Internal or External Affect
- GTIN Allocation Rules – Basic to Complex Devices / Kits
  - Application
  - When is a Package not a Package?
- GTIN Allocation Rule Concepts
  What Signifies a Change?
  - Commercial Variance, Price of Trade Item?
    and / or
  - Regulation alignment.....
  - Form, Fit or Function, Configuration Management Principles?

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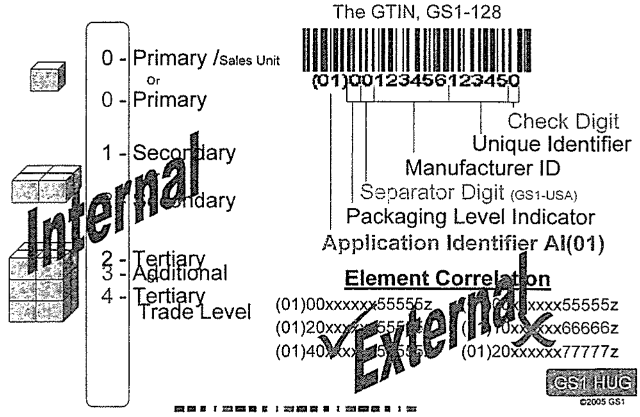
Top Level Principles



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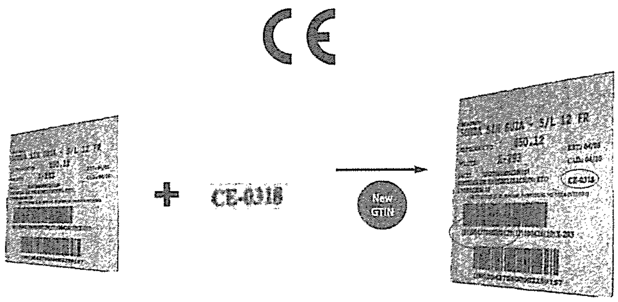
Top Level Principles



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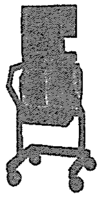
4) Complex Devices

Ventilator



Three Component Parts

1. GUI
2. Primary Unit
3. Battery

Independent Serial Numbers

Master Serial Number AI(21)

New GTIN ?

Configuration	Commercial	Form, Fit or Function
1. Language	✓	✓
2. Country of Use	✓	✓
3. Firmware Revision	×	✓
4. Software Options	✓	✓ Additional Option GTIN's
5. Hardware Revision	×	✓

What are the Boundaries and Degree of Change before GTIN Modification is Necessary? Define!

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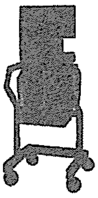
Complex Devices



Configuration

- Software Options

1. Installable Options (CD Rom / Modem / Internet Download)
2. Activated Options (Authorisation Code)

If an Option is Purchased or Transacted FOC the Option Must Have a GTIN Assignment, Manufacturers Configuration Management Databases Will Track the Build State Over the Lifetime of the Device by Association to it's Serial Number.

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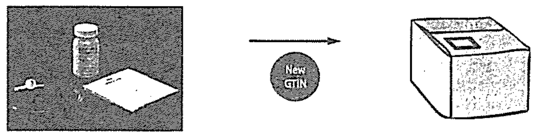
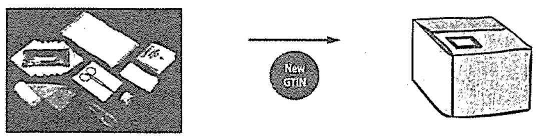
Kits – GTIN Allocation

Combinations of Independent Trade Items Each Having a Separate GTIN

Suction Catheter / Sterile Saline & Exam Gloves



Swabs, Gauze sponge, Forceps, Scissors etc.



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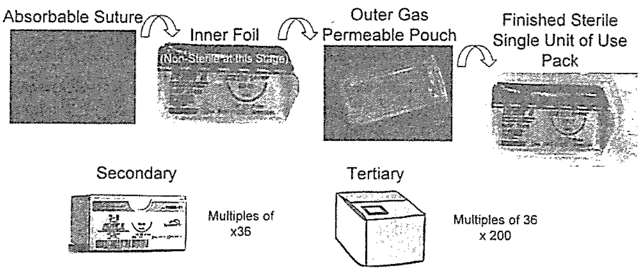
When is a Package not a Packaging Level ?

When Two Levels are Used to Form the Sterile Barrier

Sealing Inner Through Outer (SITO)



Does both Inner & Outer require a GTIN with different Packaging Level assigned?

23

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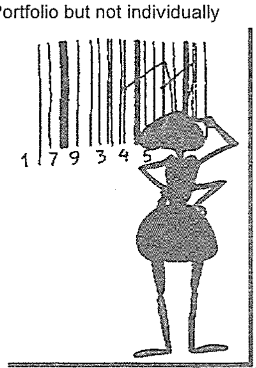
5) Within Scope or Out? Next Steps

Items Transacted Inside the Healthcare Portfolio but not individually Regarded as OTC, Rx or MD.

- Medical Device Service Kit
- Spare Parts
- Manuals
- IFU's (paper)
- IFU's on CD
- etc.



Define Our Rules!

Workshop Tomorrow, Clear Objectives: Open Participation Encouraged - Thank You

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HUG

Contact Details

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The global language of business

GS1 HUG™ Global Healthcare User Group
Minneapolis, Minnesota, USA, 13 – 15 June 2006

13 June 2006

9:00 – 9:30 Registration

9:30 Opening and Introduction

Welcome – GS1 Global Office – *Michel van der Heijden, CFO*

Michel van der Heijden is CFO for GS1.
Michel brings with him a wealth of extensive global management experience in international business activities, particular in the Healthcare Industry. His professional career spans work and knowledge in international finance, information systems, human resources and turn-around management. Michel spent 20 years with Johnson & Johnson, heading local and regional CFO functions in the companies Pharmaceutical, Consumer Goods and Medical Device units. He also spent 3 years with Novartis (Pharma) in Switzerland as the global CFO for Primary Care and has lived and worked in 6 countries, namely Belgium, the Netherlands, Mexico, US, Greece and Switzerland.

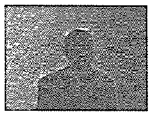
Greeting – *Dr. Susan Alpert, Medtronic, Inc*
Susan Alpert, Ph.D., M.D. was named Senior Vice President - Chief Quality and Regulatory Officer in 2005 She is responsible for all Medtronic quality, regulatory and clinical compliance efforts including overseeing health policy and payment.

Dr. Alpert joined Medtronic in July 2003 as Vice President Regulatory Affairs and Compliance from C.R. Bard, Inc., where she was Vice President of Regulatory Sciences. Dr. Alpert is on the board of the Food Drug Law Institute (FDLI), a forum for the FDA and the legal, business, academic and consumer communities to exchange perspectives on public policy, law and regulation relating to products subject to FDA jurisdiction. Dr. Alpert also serves on the board of the Medical Technology Leadership Forum (MTLF), an educational organization headquartered in Washington, D.C., focused on policy makers, the general public, and the media regarding critical issues affecting the development and adoption of advanced medical technology. In addition, Dr. Alpert serves on the board of the Women Business Leaders (WBL), an organization of women leaders in the health care sector. She is also President-elect of the Regulatory Affairs Professional Society.

Before joining Bard, Dr. Alpert served at the FDA where she held a variety of positions in the Centers dealing with drugs, devices and radiological health, and foods, including six years as the Director of the Office of Device Evaluation. She is a microbiologist and pediatrician with a specialty in infectious diseases and has practical experience in laboratory research and clinical trials.

Dr. Alpert completed her undergraduate degree at Barnard College, Columbia University in New York City and holds an M.S. and Ph D. in Biomedical Sciences from New York University. She received her M.D. from the University of Miami (Florida) and completed her clinical training at Montefiore Medical Center in the Bronx, New York and at Children's National Medical Center in Washington, D.C.

10:25 The HUG – Mission and Vision – *R. Hollander, Pfizer, HUG Co-Chair*



Rich Hollander is Senior Director of Packaging Services for Pfizer's Global Manufacturing group. His responsibilities include package design and development activities supporting the Animal Health, Consumer Healthcare and Human Health businesses as well as the development and implementation of global packaging initiatives.
Outside of Pfizer Rich has been an active leader on various committees, work groups and task groups aimed at addressing issues within pharmaceutical packaging. He is the former chair of the Institute of Packaging Professionals' Drug and Pharmaceutical Packaging Committee, PhRMA's Packaging Work Group, the USP Project Team on Packaging Storage and Distribution and the Product Quality Research Institute's Container Closure Work Group. Rich continues to be an active member in these groups.

***10:15 – 10:45 GS1 BarCodes,** Scott Gray: A Beep Can Save Lives*

Scott Gray has worked for GS1 for ten years and serves as the BarCodes Business Manager for GS1 Global Office. In this role, Scott works with marketing, customer service, development, and solutions areas, with EPC, eCom, and GDSN, and Member Organizations to ensure the BarCodes Business meets industry needs and is aligned with industry priorities. This role includes product management of GS1 BarCodes as well as the GS1 Identification System.
Prior to his current role, Mr. Gray held a number of positions inside GS1 Global and GS1 US in standards management and product development. Most recently, he was responsible for community management within GS1's standards area as GSMP Business Process Team Leader. Prior to that he was involved in merging GS1 bar code and identification standards at a global level, authored ISO standards on digital imaging, developed Web-based knowledge products, and developed educational programs. He is an experienced facilitator for, and promoter of, major GS1 initiatives. Before joining GS1, Mr. Gray spent during 15 years in the printing and packaging industry. He held various production, sales, and marketing management positions during that time and developed product lines associated with GS1 Standards.

10:45 – 11:00 Coffee break

11:00 – 1:00 The HUG Work Teams – Update

Communication & Coordination – *Jim Willmott, Smiths Medical*

Jim Willmott is the Group Labelling Manager for Smiths Medical, a part of Smiths Group plc. His responsibilities include the development of, and ensuring compliance to, corporate identity guidelines for packaging, labelling and instructions for use, used by the manufacturing sites worldwide. This encompasses regulatory, legal and language requirements for all medical devices sold in all markets. In addition, Jim is also responsible for the labelling artwork creation, for key products lines sold in Japan, using primarily MAC computers and applications.

Jim joined Smiths Medical in June 2002, having previously worked for other leading medical device manufacturers, in both Regulatory Affairs and Marketing positions. He was based in Germany and Japan before returning to the UK to join Smiths Medical. He is also a member of several committees and task forces within trade associations and standards authorities (e.g. ABHI, Eucomed, BSI & CEN).

Standards Implementation/ Regulatory Affairs - *Tom Werthwine, Johnson & Johnson MD & Jackie Elkin, Medtronic*

Tom Werthwine has over 25 years experience in the medical device industry. His background includes regulatory affairs, research & development, and marketing. Tom is currently with the Johnson & Johnson Global Supply Chain Group. In addition to being a member of the GS1 Healthcare Users Group, Tom is an active member of the AIM Global Healthcare Action Group, the EPCglobal Healthcare and Life science Business Action Group, and the Health Industry Business Communications Council. Tom holds a B.A. from Penn State University.

Jackie Elkin has been working in the medical device sector for more than 18 years. Currently, Jackie holds the position of Regulatory Compliance Manager for Medtronic, Inc Corporate Regulatory Compliance. Her responsibilities include the development and implementation of global policy and standards around Standard Product Identification for Medtronic products and services. In this role, she is also responsible for managing product identification applications and associated governance teams to ensure Medtronic distributed products are in compliance with established Corporate Quality and Regulatory Affairs Policy.

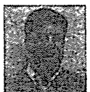
Standards Development – *Peter Tomicki, Baxter*

Peter Tomicki has been a global project manager in Baxter Healthcare's Corporate R&D group focusing on supply chain and packaging technology for 5 years. In his role he is responsible for implementing global projects from strategy to launch, including corporate and industry standardization and representing Baxter and/or the healthcare industry in industry associations, regulatory agencies, clinical groups, GS1, EPCglobal, GHX and others.

Business Case – *Ed Dzwill, Johnson & Johnson Pharma*

Ed Dzwill is Manager Package Development for the Global Pharmaceutical Supply Group since February 2002. GPSG provides supply chain management to Johnson & Johnson's Pharmaceutical sales and marketing companies, Ortho-McNeil Pharmaceutials Inc, Ortho Women's Health and Urology, Janssen Ortho-McNeil Primary Care, Ortho-McNeil Neurologics, Alza, Tibotec, Ortho Neutrogena, Vistakon Pharmaceuticals, and Ortho Biologics. His responsibilities include package design and development activities as well as involvement in global packaging initiatives in Bar Codes and RFID.

Vaccines & Biologicals – *Stephen Hess, Merck and Bruce Cohen, GSK*



Stephen Hess joined Merck in 1987 supporting the animal health packaging business. Since then he has worked in various Human health and vaccine packaging related positions including International and Domestic responsibilities. He is currently the Executive Director of packaging technology for Merck and Co., Inc.
Prior to joining Merck, Stephen worked at Purdue Pharma and Olin Chemical in packaging related functions. He graduated from Michigan State University with a BS in Packaging in 1980.

Bruce Cohen has been involved in pharmaceutical packaging for over 30 years. He has held positions at Alcon Laboratories, BBL, Boehringer Mannheim Diagnostics, Sterling Drug Inc , Glaxo Inc. and now GlaxoSmithKline. In his current position, he is responsible for the design, development and evaluation and specifying of all new materials, packaging components and new graphic designs related to the manufacturing of all GlaxoSmithKline Rx products sold in or exported from the USA. He is also the US Pharma Business representative on the GSK RFID Collaboration Team.
He has a degree in Package Engineering from Michigan State University and holds several patents on component designs. He is a member and past chairman of the Drug & Pharmaceutical Packaging Committee of IoPP, past chairman of the PhRMA Bar Code Technical Committee. Currently he chairs the PhRMA Paperless Labelling Task Force as well as being a member of the Packaging Work Group.

1:00 – 2:00 Lunch

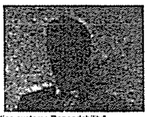
2:00 – 3:00 ***Tokyo Medical University** - Prof. Masanori Akiyama*

Prof. Masanori Akiyama is visiting professor at the Massachusetts Institute of Technology Sloan School of Management and the Tokyo Medical University as well as assistant professor at Keio University School of Medicine and the Hamamatsu University School of Medicine. After his M.D. degree at the university of Tokushima he was working in the fields of urology and pathology before concentrating more on the field of Medical Informatics. From 1999 to 2002 he held a position in the Ministry of Health and Welfare in the Department of National Hospitals policy medical treatment section. Afterwards he joined the National Institute of Public Health as associated professor.
Prof Masanori Akiyama is the director of the Japan association for medical informatics.

3:00 – 3:30 FDA – Dr. Ilisa Bernstein

3:30 – 4:00 Coffee break

***4:00 – 4:30 Scientific Institute Hospital San Raffaele, Italy** – Dr. Alberto Sanna*



Alberto Sanna graduated at Politecnico di Milano. He is involved in healthcare process re-engineering projects in FCSR since 1989.
From 1992 to 1996 he was assigned to the Information Technology department., where robotics experience merged with process analysis, Information System analysis, design and implementation. Since 1996 he is member of the European Standard Body CEN TC 251 Health Informatics WGIII Safety Security and Quality, as well as of the ISO TC 215 Health Informatics Commission
He was Project Coordinator of DRIVE (DRug In Virtual Enterprise) Project (5th EC Framework Programme), IST-12040. Since 2002 he is the head of the e-Services for Life and Health Unit and he is Professor at the Information Sciences University of Milano, of "Information systems Dependability".
Since January 2004 he is Project Coordinator of PIPS (Personalised Information Platform for life and health Services) Project, aiming to realize a multichannel platform to release services and information to the Citizen constantly updated and personalised.
Since 2004 he is also member of the Project Management FCSR team of Project PRIME (Privacy and Identity Management in Europe), an integrated project in the area of trust and security, aiming at the realization of a multi-sector and large scale-sustainable approach to privacy and identity management.

***4:30 – 5:00 GDSN – Global Data Synchronization** – Pete Alvarez*

Pete Alvarez is Senior Director of GS1 GDSN, Inc., the organization driving the Global Data Synchronization Network and the Global Registry. He is responsible for the business operations of the GDSN, including global expansion strategies. He joined the GS1 organisation in May 1999 and has held various positions of increasing responsibilities in disciplines such as technology, education, and marketing.

Prior to joining GS1, Pete worked for organizations such as National Semiconductor, Avery Dennison and Monarch Marking Systems among others. His 25 year career includes experience in bar coding, printing, adhesive coating technologies, RFID and data synchronisation in many international markets.

5:00 - Summary of the day, preparation for the work teams

6:30 Cocktails & Networking Dinner - The Depot

14 June 2006

NOTE - Rather than parking at Medtronic CRM-West lot, for this day only - please park in the CRM-Central lot (which is the lot you drive through to get to the West for Tuesday and Thursday). After parking in the CRM-Central lot please cross the street and enter the visitor's entrance of CRM-East where the breakout sessions will be held.

Moving ahead in the Work Teams

The breakout sessions will be lead by the Work Team leaders and enable further progress in the work of the teams.

Morning session 9:00 – 12:30:

Vaccines & Biologics (Skyway A)
Instruments & Implants (Skyway B)
GTIN-Allocation Rules (Skyway C)

12:30 – 2:00 - Lunch

Afternoon session 2:00 – 5:30:

Standard-Implementation/Regulatory Affairs (Skyway A)
Standard-Development (Skyway B)
Business Case (Skyway C)

Coffee breaks determined by work team leaders

GS1 HUG

15 June 2006

9:00 Report back to plenary from Work Teams

10:00 – 10:45 Premier, *Joe Pleasant*

Joseph M. (Joe) Pleasant is CIO and Senior Vice President of Premier, Inc., the largest healthcare alliance in the United States, with an estimated annual purchasing volume in excess of $25 billion and more than 200 Healthcare systems that own or operate some 650 institutions. Premier also has affiliations with another 900 hospitals.

Prior to being appointed to his current position as CIO and Senior Vice President in charge of Premier's Information Systems, Mr. Pleasant served as Chief Administrative Officer of SunHealth, Inc., one of Premier's predecessor organizations. During his 25 years with SunHealth, Mr. Pleasant held numerous positions that included senior management consultant, relationship manager for owners in Virginia, West Virginia and Maryland, senior Human Resources executive and CIO.

In his current position as CIO, Mr. Pleasant oversees Premier's information systems infrastructure that includes legacy, enterprise, and web enabled offerings.

Mr. Pleasant is past Chairman and a founding member of the Coalition for Healthcare eStandards (CHeS), a fellow member of HIMSS, and a founding member of CHIME. Mr. Pleasant is involved in national efforts to improve the Healthcare supply chain and serves on Board of Directors of both the National Alliance for Healthcare Information Technology (NAHIT) and GS1 and is a member of the Health Industry Distributors Association's Supply Chain Advisory Council. Mr Pleasant is past President of the North Carolina Chapter of HIMSS and chaired HIMSS's 2006 Annual Conference Education Committee. A cum laude graduate of N.C. State University in Engineering, Mr. Pleasant holds a Masters of Business Administration degree from the University of North Carolina

10:45 – 11:15 Coffee break

11:15 - 11:45 EPCglobal – the Healthcare and Life Sciences Business Action Group (HLS BAG) - *Mike Rose, Johnson & Johnson, RFID/EPCglobal Value Chain & Ron Bone, McKesson*

Mike Rose has worked for Johnson & Johnson for over 30 years.
Mike was appointed Vice President, RFID/EPC Global Value Chain with responsibility for Johnson & Johnson's RFID/EPC strategy. Mike's key responsibilities include
- Working with Johnson & Johnson's operating units and their customers to assess the impact of RFID on business processes, information and enabling technology,
- Overseeing J&J's RFID Incubator Fund to stimulate innovation through RFID, and
- Collaborating with industry associations, regulatory agencies and external standard setting organizations to establish the future direction of RFID/EPC

Mike is a member of EPCglobal's Board of Governors Mike is a tri-chair of EPCglobal's Healthcare and LifeSciences Business Action Group, and is member of EPCglobal's Business Steering Committee.

GS1 HUG

Prior to his current assignment, Mike was most recently the Chief Information Officer for Ortho Biotech. In his career, Mike has held various positions of responsibility across Information Management and Discovery Research
Mike graduated from La Salle University with a BA in Biology, and received an MSE in Computer Science from the University of Pennsylvania.

Ron Bone is Senior Vice-President of Distribution Support at McKesson Pharmaceutical, San Francisco. In his role he is responsible for RFID & CSOS, the SAP Buy Side Business Owner and Field Distribution Network Standardization. He works since 33 years with McKesson Corp in areas of operations, sales and financial management.
Ron is member of the EPCglobal - Business Steering Committee and Tri-Chair of the Healthcare and Life Sciences Business Action Group as well as Member of Industry Relations Committee of the Healthcare Distribution Management Association (HDMA).

11:45 – 12:15 Brigham and Women's Hospital, *Tom Cooley*

Tom Cooley, RPh, MBA, is Assistant Director, Department of Pharmacy Services, Brigham and Women's Hospital, Boston, MA. He is responsible for the department's information technology development and services, Investigational Drug Service, O.R. Pharmacy Service and Medication Safety
Tom has contributed to the development and implementation of several information systems at BWH, introducing POE, adult and neonatal intensive care Pharmacy systems, the recent eMAR initiative, and the incorporation of bar code technology in the medication use process at BWH.

12:15 – 12:45 GS1 Chile, *Eduardo Rodriguez*

Eduardo Rodriguez is the New Market Development Manager at GS1 Chile and responsible for the development of new GS1 Standards Applications, RFID/EPC projects, alliances with key technology partners and HUG support and development.
As project and operation manager he also leads the data synchronisation service, training, Development Bank projects and the first pilot projects for public health use of standards with 5 hospitals and 40 laboratories.
Eduardo worked before in multiple industries like steel, telecommunication, and informatics and has also consulting experience.
He holds a university degree in industrial engineering and computer science.

12:45 – 2:00 Lunch

GS1 HUG

2:00 – 2:15 GS1 Japan, *Yasuo Kurosawa:*
The Status of Medical Standardizing in Japan

2:15 – 2:45 Advanced Medical Technology Association – AdvaMed, *Jeff Secunda, Associate Vice President Technology & Regulatory Affairs*

Jeffrey Secunda is Associate Vice President of Technology & Regulatory Affairs for the Advanced Medical Technology Association (AdvaMed). Among his primary responsibilities at AdvaMed, Secunda is the staff liaison to the Auto-ID Working Group. Prior to joining AdvaMed, Secunda worked with the FDA regulatory affairs consulting firm Shotwell & Carr. He was Vice President of R&D for a medical sensor firm in Texas from 1996 to 2003. In addition, Secunda has more than 20 years' experience in senior-level biomedical engineering posts at some of the most prestigious health facilities in the country, including Massachusetts General Hospital and Children's Hospital in Boston where he was the Director of Biomedical Engineering from 1982 to 1995. Secunda was also an Adjunct Assistant Professor of Biomedical Engineering at the Boston University School of Engineering. Secunda holds several medical device patents and has served on the Board of Directors of AAMI and ACCE. Born in Boston, Massachusetts, he earned an M.S. in Biomedical Engineering from Boston University, and an M.B.A. from the University of Massachusetts.

2:45 HUG Standard Development, *Peter Tomicki: Proposed HUG Recommendations for US FDA Review of 21 CFR Parts 201, 606, 610*

3:00 Discussion – Summary – Next steps – Date of Next Conference

3:15 Closure of meeting

GS1 HUG

GS1 HUG™ Global Healthcare User Group
MINNEAPOLIS, MINNESOTA, USA, 13 – 15 JUNE 2006

Preliminary Agenda for the 4th HUG Conference

13 June 2006

9:30 Opening and Introduction

Welcome – *GS1 HUG™*
Greeting – *Medtronic, Inc.*
The HUG – Mission and Vision – *Rich Hollander, HUG Co-Chair, Pfizer*
The future governance model of the HUG

The HUG Work Teams – Update

Communication & Coordination / Membership – *Jim Willmott, Smiths Medical*
Standards Implementation/ Regulatory Affairs - *Tom Werthwine, Johnson & Johnson MD & Jackie R. Elkin, Medtronic*
Standards Development – *Peter Tomicki, Baxter*
Business Case – *Ed Dzwill, Johnson & Johnson Pharma*
Vaccines & Biologicals – *Stephen Hess, Merck and Bruce Cohen, GSK*
GTIN Allocation Rules – *Mark Walchak, Pfizer and Mark Hoyle, Tyco*
Instruments & Implants – *Volker Zeiner, B.Braun*

Patient Safety and Automatic Identification

***GS1 BarCodes, Scott Gray:** A Beep Can Save Lives*

Prof. Masanori Akiyama, *Tokyo Medical University,* *Dept of Medical Informatics, MD,PhD@MIT Sloan, Visiting Professor Massachusetts Institute of Technology Sloan School of Management Center for eBusiness*

Brigham and Women's*

Veterans Affairs Medical Centers*

Rush -Presbytarian Hospital*

Johns Hopkins*

Networking Dinner

* tbc

GS1 HUG

14 June 2006

Moving ahead in the Work Teams

The breakout sessions will be lead by the Work Team leaders and enable further progress in the work of the teams.

Morning:

Vaccines & Biologics / Instruments & Implants / GTIN-Allocation Rules

Afternoon:

Standard-Implementation/Regulatory Affairs / Standard-Development / Business Case

15 June 2006

Report back to plenary from Work Teams

Premier, Joe Pleasant

EPCglobal – the Healthcare and Life Sciences Business Action Group (HLS BAG)

Advanced Medical Technology Association – AdvaMed, Jeff Secunda, Associate Vice President Technology & Regulatory Affairs*

LifeScience Alley*

Healthcare Distribution Management Association - HDMA*

Discussion – Summary – Next steps – Date of Next Conference

* tbc

GS1 HUG

GS1 HUG™ Global Healthcare User Group
Elancourt/Paris, France, 20 – 22 September 2006

20 September 2006

From 8:30 onwards: Registration

Introduction

9:00 – 10:30 Training on GS1 Standards – BarCodes, eCom, GDSN and EPCglobal, GS1 HUG™ Basics

David Buckley is a 10 year veteran of GS1. In that time he has occupied various roles in the development and implementation support of GS1 standards. In his current role, Mr Buckley's main responsibilities are focused on assisting GS1 Member Organisations with tools that support the consistent implementation of standards with particular emphasis on the GTIN Allocation Rules and Helpdesk web systems. Mr Buckley also provides the secretariat to the ISO working group in the area of Bar Code data content.

Upon completion of his degree in Economics, from the University of Loughborough, Mr Buckley joined the graduate programme of the Xerox Corporation in his native England. During this time he worked primarily on quality and product nationalisation. Xerox further supported his MBA studies which were awarded in 1994.

Within the HUG work programme, Mr Buckley has provide GS1 Staff support to the Work Team 'GTIN Allocation Rules' for Healthcare, led by Mark Walchak (Pfizer) and Mark Hoyle (Tyco Healthcare) and the Bar Code Implementation in Healthcare Baseline survey.

For Sally Herbert, please see GDSN and Classification

Erik Sundermann is currently the EPC Implementation Support Manager for GS1. As such, he supports the GS1 Member Organizations in their efforts to implement and promote EPC in their local markets.

Before joining GS1, he worked for more than 4 years as a senior supply chain management consultant with PriceWaterhouseCoopers and IBM, where he was involved in all aspects of RFID/EPC projects.

Erik holds a Ph.D. in computer science from the University of Ghent, Belgium and a Master in Supply Chain Management from the Vlerick Management School, Belgium.

10:30 – 11:00 Coffee break

GS1 HUG

11:00 Opening and Introduction

Welcome – *Pierre Georget, GS1 France*

Aged 50, Pierre Georget has a great deal of experience in retail distribution. He joined the EAN France team 19 years ago, where his responsibilities have continually increased over the years.

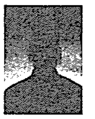
A university graduate, Pierre Georget has a Master in Economics Science (Paris X) – specialising in Econometrics – as well as degrees in philosophy and law.

As Technical Director from 1995 to 2000, he had responsibility for standards for electronic exchanges and AIDC, he was in charge of the French EDI Value Added Network, Allegro. He initiated the national network of electronic catalogues, GDSnet.fr and the global repository GEPIR. He was appointed CEO in 2004

He held several responsibilities within major standard organisations both at national and international level. At the United Nations, he was Chairman of the Edifact Working Group (UN/CEFACT/EWG). In France he was chairman of the standardisation committee for EDI and XML (EDIFRANCE), and of the standardisation committee for AIDC (including RFID). He is a member of the COS TIC, strategic committee for information and communication technology at the French standardisation body – AFNOR.

He is a member of the GS1 GDSN Board of Director and of the GS1 Advisory Committee.

Greeting – *Michael Linney, Tyco Healthcare*



2006 - **Tyco Healthcare / Vice President Logistics EMEA**
2002 - 2006: **Tyco Healthcare / European Distribution Director General**
1998 - 2002: **Exel / France Distribution Director - Marks & Spencer**
1995 - 1998: **TDG Logistics / Distribution General Manager - ICI Paints in UK, France & Benelux**
1993 - 1995: **TDG Logistics / Contract Manager - Halfords**
1988 - 1993: **TDG Logistics / Shift Manager - Pedigree Petfoods.**

The HUG – Mission and Vision – The new Structure and Roadmap – *Rich Hollander, Pfizer and Peter Tomicki, Baxter*

Rich Hollander is Senior Director of Packaging Services for Pfizer Inc.'s Global Manufacturing group. His responsibilities include package design and development activities supporting the Animal Health, Consumer Healthcare and Human Health businesses as well as the development and implementation of global packaging strategies. Rich received his Bachelor's Degree in Mathematics from Rutgers University in 1985 and his Masters Degree in Industrial Engineering from the Georgia Institute of Technology in 1987. He worked as a consultant with Andersen Consulting from 1988 until 1990 focusing in manufacturing information management systems. He joined Pfizer in 1990 as an Industrial Engineer and in 1992 became Manager of Package Engineering. Since then Rich's responsibilities have grown to include all areas of package design and development for Pfizer. Outside of Pfizer Rich has been an active leader on various committees, work groups and task groups aimed at addressing issues within pharmaceutical packaging. Rich currently co-chairs the GS1 Global Healthcare User Group and is the former chair of the Product Quality Research Institute's Packaging Work Group, USP Project Team on Packaging, Storage and Distribution, Institute of Packaging Professional's Drug and Pharmaceutical Packaging Committee and PhRMA's Packaging Work Group. He continues to be an active member on all of these work groups.

GS1 HUG

For Peter Tomicki, please see GSMP for Healthcare

The HUG Governance – *GS1 Global Office – Michel van der Heijden*

Michel van der Heijden is CFO for GS1. His responsibilities include Finance and Administration, Strategic Alliances and New Sectors.

Michel brings with him a wealth of extensive global management experience in international business activities, particular in the Healthcare Industry. His professional career spans work and knowledge in international finance, information systems, human resources and turn-around management. Michel spent 20 years with Johnson & Johnson, heading local and regional CFO functions in the companies Pharmaceutical, Consumer Goods and Medical Device units. He also spent 3 years with Novartis (Pharma) in Switzerland as the global CFO for Primary Care and has lived and worked in 6 countries, namely Belgium, the Netherlands, Mexico, US, Greece and Switzerland.

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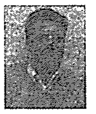
GS1 HUG

Vaccines & Biologicals – *Stephen Hess, Merck*



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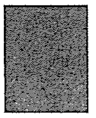
Prior to joining Merck, Stephen worked at Purdue Pharma and Olin Chemical in packaging related functions. He graduated from Michigan State University with a BS in Packaging in 1980.

GTIN Allocation Rules – *Mark Walchak, Pfizer & Mark Hoyle, Tyco Healthcare*



Mark Walchak is Senior Manager of Global Packaging Technology at Pfizer. His area of responsibilities includes; consumer health, human health and animal health. Mark is active in the bar coding and anti-counterfeiting areas. Mark also is a member of the International Federation of Animal Health's Global Traceability Core Team.
Mark joined Pfizer in 2004 after having worked for 30 years in the healthcare and consumer goods area.

Mark Hoyle has a broad and varied experience across a number of industries but has concentrated within pharmaceutical and medical device manufacturing for the last 12 years. He is today focused with Tyco Healthcare as the leader for European Packaging.

In his present role he is responsible for global strategy development and implementation for product identification, complemented with a background in automation and controls.

Prior to joining Tyco Healthcare, at the beginning of 2005, Mark has worked as Process Development Group Manager for Ocular Sciences Inc. with key responsibilities for product launch of their daily disposable contact lens range. Prior to his six years with OSI he has worked as a Systems Validation Engineer for Glaxo, staying very involved with developing technologies and their introduction to the healthcare industry.

GSMP for Healthcare – *Peter Tomicki, Baxter*

Peter Tomicki has been a global project manager in Baxter Healthcare's Corporate R&D group, focusing on supply chain and packaging technology, for 5 years. In his role he is responsible for implementing global projects from strategy to launch, including corporate and industry standardization and representing Baxter and/or the healthcare industry in industry associations, regulatory agencies, clinical groups, GS1, EPCglobal, GHX and others.

GS1 HUG

Instruments & Implants – *Volker Zeinar, B.Braun*

Volker Zeinar is responsible for the global coordination of bar code / auto-id affairs in the B.Braun Group. This concerns company internal projects, customer projects as well as contacts to healthcare associations and standardization organizations.

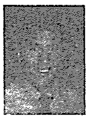
Volker has been involved in the development and application of GS1 standards for almost 20 years, not only in healthcare, but also in the consumer market and the engineering industry. Amongst others he was responsible for IT projects at the trade group REWE in Cologne and at the steel manufacturer Thyssen Industry.

Prior to his engagement as freelancer for B.Braun, since January 2003, Volker has worked as Consultant for the B.Braun subsidiary 'Diomedes Health Care Consultants' with focus on the optimization of logistics processes in hospitals.

His knowledge in logistics, informatics and healthcare processes is an ideal prerequisite to work on global standards regarding product identification and communication for the healthcare industry. Volker currently co-chairs the GS1 Global Healthcare User Group.

12:30 – 13:30 Lunch

Unique Device Identification – *Jay Crowley, FDA*



Jay Crowley is Senior Advisor for Patient Safety in FDA's Center for Devices and Radiological Health. Jay is interested in developing new methods and techniques to identify, analyze, and understand problems occurring from medical device use within the healthcare environment. He has been working at FDA for nearly 20 years in a variety of positions. Jay holds degrees in Risk Analysis and Engineering.

CNDG (Conférence nationale des directeurs généraux) – *Pascal Mariotti*, University Hospital of Lyon .

Born in 1965 Pascal has a diploma of the l'Institut d'études politiques in Grenoble, followed by the education to Hospital Director at the National School of Public Health in Rennes. He is now the responsible purchasing and logistic manager for the university hospitals of Nantes, Bordeaux and Montpellier. Additionally he also has responsibilities for the civil Hospital of Lyon and is Délégué général of the GCS UNI.H.A (Appellation provisoire). In this context he also coordinates the National Commission of Purchasing and Logistic Managers of the French University Hospitals.

EFPIA (European Federation of Pharmaceutical Industries and Associations) – *Graham S. Smith, Astra Zeneca*

Graham is Project Director for AstraZeneca's European Supply Chain Programme, based in Brussels. At these meetings he will be representing European Federation of Pharmaceutical Industries and Associations (EFPIA), where he is Chairman of both the Distribution Ad Hoc Group and Coding Group.

Graham has extensive experience of both the pharmaceutical and medical devices industries and supply chains, currently with over five years experience at AstraZeneca and previously with Abbott Laboratories for over eight years. Prior to this Graham worked in consumer electronics and a variety of manufacturing companies in the UK. He has a degree in Manufacturing and is a member of the Institute of Operations Managers.

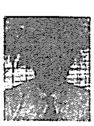
GS1 HUG

Eucomed (The Voice of the Medical Technology Industry in Europe) – *Mike Kreuzer, Supply Chain and e-Business Task Force (ETF)*

Michael Kreuzer is the Technical and Regulatory director of ABHI (Association of British Healthcare Industries). In addition, he is also the chairman of the Eucomed E-business and supply chain management task force (ETF) as well as the Association Secretaries Council, a role which brings him into close contact with the various national medical technology associations in Europe. The current focus of the Eucomed ETF group is bar coding and auto identification capture technologies.

15:30 – 16:00 Coffee break

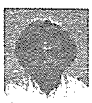
Wholesaler experience in France - *Jean-Luc Maurat*



Jean-Luc Maurat has over 25 years experience in purchasing and logistics in various fields as motor, food, human health, animal health industries and DIY distribution. In 2001, he joined Asept InMed (subsidiary of the Medi-Globe group - and formerly of the Teleflex group - manufacturer and distributor of medical devices), as Supply Chain Manager.

Jean-Luc has implemented a WMS using GS1 standards and co-operates with suppliers, transporters and customers in GS1/EAN 128 introduction. He works additionally as logistics consultant and teaches Warehousing Management at Toulouse Business School and Master. Jean-Luc is also President of the South West Logistics Club (CLSO) He graduated from Toulouse Business Scholl in 1980 and CPA (Executive MBA) in 1993.

Blood derivate supply chain in the hospital - how to maximise full traceability - *Bernard Dieu, CHU Rouen*



Bernard is Chief of the Pharmacy Department at the University Hospital Rouen. As a Doctor in Pharmacy, he developed most of his carrier at the University Hospital Rouen, a multi-site Hospital in Normandy with about 2,500 beds and a turnover of €45 billions for its pharmacy. Bernard is very engaged in developing best practices in the Hospital Pharmacy.

IFAH (International Federation for Animal health) – Decision for Standards and Implementation - *Jean Claude Muller, Merial*

Jean Claude Muller is Director of Global Supply Chain Support in Merial. After an engineering career, he joined Merial 20 years ago and fulfilled several assignments. He served as engineering projects leader in several countries in the world to set up biological production facilities, then as plant Director where he accumulated deep packaging experience. His current assignment led him to organize, set up and manage the worldwide supply chain information system of Merial and support Merial Supply Chain as far as IS technology is concerned. He is also currently Chairman of the Traceability Team of the International Federation for Animal Health (IFAH).

17:00 Departure of bus to Louvre
18:00 Louvre visit: Guided tour "Step inside the Da Vinci Code"
20:00 Informal Dinner in the city centre of Paris
This is a privately organized event costing approximately €40, to be paid on the day.

21 September 2006

9:00 – 17:00 Moving ahead in the Work Teams on the topics:

Morning: Business Case, followed by GTIN Allocation Rules – in parallel with Instruments & Implants

12:30 – 14:00 - Lunch

Afternoon: Introduction and kick-off for new work teams – Auto ID Data and Serialization

Coffee breaks determined by Work Team leaders

Evening Networking Dinner Cruise on the Seine - sponsored by GS1 France

22 September 2006

9:00 EPCglobal – Health Life Science Business Action Group (HLS BAG) – *Chris Adcock, President EPCglobal*

Chris Adcock is president of EPCglobal Inc™, the global organization leading the drive to standardize and commercialize the Electronic Product Code (EPC). As president of EPCglobal, Mr. Adcock will lead the global, multi-industry adoption of the EPCglobal Network™ and related EPC technology.
Mr. Adcock has a proven track record of leadership within the fast-moving Consumer Goods industry. He has held a series of senior management positions in Europe with The Gillette Company, a global market leader in several consumer product categories. His most recent position was General Manager of the Nordic Region for the Gillette Company. A native of the United Kingdom, Mr. Adcock's career to date has been focused on both marketing and customer management and has included extensive experience of international markets, working in parts of Europe, the Middle East and East Africa. He has successfully developed and implemented strategies aimed at growing market share, reducing costs, and improving ways to service multi-national customers. Between 2001 and 2004 he held the position of Chairman of the AIM Trade and Industry Committee. AIM is the global trade association, serving more than 900 members in 43 countries, dedicated to accelerating the growth and use of Automatic Identification and Data Capture (ADIC) technologies around the world. Mr. Adcock holds an MBA from Cranfield University in the UK.

10:00 RFID on Medical Devices – *Janice Kite, Johnson & Johnson*

Janice is eBusiness Manager for Johnson & Johnson's UK 18 Medical Device & Diagnostics companies. Her career has mainly been spent in the IT industry spanning the areas of European Project Management, Business Analysis, Customer Service Management and Process Benchmarking. She moved into the healthcare sector eleven years ago when she joined Johnson & Johnson as Customer Service Manager.
Her current role serves both internal and external customers (UK healthcare market), in the areas of eCommerce and eMarketing developing and implementing solutions, processes, policy, compliance and standards as well as monitoring eBusiness trends and emerging technologies.
Janice has recently completed an MBA with Henley Management College; her dissertation is the subject of her presentation.

10:30 – 11:00 Coffee break

11:00 The Spanish Healthcare Market – *Carlos Torme, GS1 Spain*
(Details available at the conference)

11:30 – 12:00 GDSN and classification – an overview – *Sally Herbert, President GS1 GDSN*

Sally Herbert is President of GS1 GDSN, the organization driving the Global Data Synchronization Network and the Global Registry. She joined GS1 in March 2005, with the commercial and operational charters for leading, and executing upon, the defined direction of the GDSN Roadmap. Sally also has responsibility for the Global Product Classification (GPC) process.

Sally has a demonstrated track record of balancing technology development, customer service and marketing within U.S. and international markets. She has successfully formulated strategies for business growth, cost reduction, and serving the needs of a global, varied retail and manufacturing customer base. Before joining GS1, Sally held the post of Chief Operating Officer for the World Wide Retail Exchange (WWRE). She joined the Exchange in November 2001, and had global responsibility for the consistent delivery of products and services to the members of the Exchange. In addition to managing the development of technology, she facilitated member relationships from sales to product implementation and ongoing support through the application of value-added services. Sally also held leadership positions with IBM, MCI WorldCom and the U.S. Air Force Reserve.

Sally Herbert holds a BSBA in Marketing and an MBA in Information Systems.

12:00 – 12:30 Diversity of Classification systems – *Maurice Ventura, Cladimed*

Maurice Ventura is hospital pharmacist with a diploma of the l'Institut d'Administration des Entreprises de Paris (IAE). He has worked 16 years as hospital pharmacist in the Hospitalier à l'Assistance Publique – Hôpitaux de Paris, and the last seven years as purchasing director, being also responsible for the product information and related databases. In this function he maintained a database of 150,000 healthcare products (medical devices, drugs and laboratory consumables). Since October 2005 responsible of Pôle Acquisition de Données at VIDAL for the administration of a database supporting software for hospitals and public pharmacies. Maurice is also President of the French Association for the classification of medical devices (CLADIMED). He works additionally as healthcare consultant for public hospitals.

12:30 – 13:30 Lunch

13:30 – 14:30 Report back to plenary from Work Teams

15:00 Discussion – Summary – Next steps – Date of Next Conference

15:15 Closure of meeting

15:30 Bus back to Paris/Airport

25 September 2006

GS1 France organised visit to the University Hospital of Dijon. Further details available upon request.

GS1 HUG

GS1 HUG™ Global Healthcare User Group
Paris, France 20 – 22 September 2006

Draft Agenda for the 5th HUG Conference

20 September 2006

from 8:30 onwards: Registration

Introduction

9:00 – 10:30 Training on GS1 Standards – BarCodes, eCom, GDSN and EPCglobal, GS1 HUG™ Basics

10:30 – 11:00 Coffee break

11:00 Opening and Introduction

Welcome – *Pierre Georget, GS1 France*
Greeting – *Tyco Healthcare.*
The HUG – Mission and Vision – The new governance model and roadmap

The HUG Work Teams – Update

Communication & Coordination – *Jim Willmott, Smiths Medical*
Standards Implementation/ Regulatory Affairs - *Tom Werthwine, Johnson & Johnson MD & Jackie R. Elkin, Medtronic*
Standards Development – *Peter Tomicki, Baxter*
Business Case – *Ed Dzwill, Johnson & Johnson Pharma*
Vaccines & Biologicals – *Stephen Hess, Merck & Bruce Cohen, GSK*
GTIN Allocation Rules – *Mark Walchak, Pfizer and Mark Hoyle, Tyco Healthcare*
Instruments & Implants – *Volker Zeinar, B.Braun*

12:30 – 13:30 Lunch

AFSSAPS (Agence francaise de securite sanitaire de produits de sante) - tbc
CNDG (Conférence nationale des directeurs généraux) – *Philippe Domy, DG CHU Amiens*
EFPIA (European Federation of Pharmaceutical Industries and Associations) – *Graham S. Smith, Astra Zeneca*
Eucomed (The Voice of the Medical Technology Industry in Europe) - tbc

GS1 HUG

15:30 – 16:00 Coffee break

Wholesaler experience in France - *Jean-Luc Maurat*
CHU Rouen – Handling of blood derivate products - tbc
IFAH (International Federation for Animal health) – Decision for Standards and Implementation – *Jean Claude Muller, Merial*

17:00 Departure of bus to Louvre
18:00 Louvre visit: Guided tour "Step Inside the Da Vinci Code"
20:00 Informal Dinner in the city centre of Paris

This is a privately organised event costing approximately 40 Euro, to be paid on the day.

21 September 2006

9:00 – 17:00 Moving ahead in the Work Teams on the topics: GTIN Allocation Rules – Application Identifiers – Serialization – Business Case – Instruments & Implants

12:30 – 14:00 - Lunch

Coffee breaks determined by work team leaders

In the evening: Networking Dinner Cruise on the Seine - sponsored by GS1 France

22 September 2006

9:00 EPCglobal – Health Life Science Business Action Group (HLS BAG)

10:00 RFID on medical devices – *Janice Kite, Johnson & Johnson*

10:30 – 11:00 Coffee break

11:00 - 11:45 The Australian catalogue of medicine – *NEHTA (National E-Health Transition Authority), Ken Nobbs, tbc*

11:45 – 12:00 GS1 Australia - tbc

12:00 – 12:30 Diversity of Classification systems – *Maurice Ventura, Cladimed*

12:30 – 13:30 Lunch

GS1 HUG

13:30 – 14:30 Report back to plenary from Work Teams

15:00 Discussion – Summary – Next steps – Date of Next Conference

15:15 Closure of meeting

15:30 Bus back to Paris/Airport

GS1 France has organized a visit to the university hospital in Dijon on the 25th September!

25 September 2006

10.00 – 10.30 Welcome

10.30 – 12.00 Presentation of the different projects running in the CHU Dijon

1. **Traceability of sterilization deliveries with bar codes**
2. **Traceability of sterilization deliveries with RFID tags**
3. **These two applications in order to confirm the hospitals can use both technologies**
4. **Traceability of clean and dirty textile containers with RFID tags with Geodis and GRPS readers**
5. **Traceability of patients with GLN and RFID tags**

12.00 – 13.30 Lunch at the cafeteria

13.30 – 15.30 Visit to the wards concerned with the projects

16.00 Train to Paris

18.00 Arrival at Paris Gare de Lyon

HUG

GS1 Global Healthcare User Group
GS1 HUG™
Governance Charter

Version	Date	Changes	Responsible
1.0	18.09.2006	Final version for LT Meeting in Paris	Ulrike Kreysa
1.1	26.09.2006	Feedback from LT discussion in Paris incorporated	Ulrike Kreysa
1.2	08.10.2006	Final document for LT vote with changes after comments from Mark, Peter and Jim	Ulrike Kreysa
1.3	11.10.2006	Inserted background about status of non-for-profit for GS1 and fees are used to cover HUG activities according to work plan. Voted on and approved by HUG Leadership Team	Ulrike Kreysa

1.0 Mission

To lead the healthcare industry to the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.

2.0 Vision

To become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) seeking input and direction for global standards in the healthcare industry.

3.0 Accountability

To the GS1 Management Board

4.0 Membership

4.1 Voting Membership Criteria

HUG Voting Members must be a member company of a GS1 member organization. Members can be manufacturers, wholesalers/distributors, GPO's, hospitals and pharmacies, logistics provider, doctors and nurses.
Voting members of the HUG contribute to the HUG activities and basic operational costs with an annual fee.
The HUG membership fee is Euro 3.500 per year. Conference fees will be different for voting HUG members and non-voting HUG members.
GS1 is a not for profit global standard organization. The GS1 global Healthcare User Group (GS1 HUG™) is a GS1 facilitated healthcare members group. GS1 HUG activities are self funded. These fees are collected and dispersed on a revenue neutral basis. The funds collected are to cover the costs of the meetings and activities of the GS1 HUG and other appropriate costs including a surplus account to cover anticipated costs. The fees and activities are determined by the Leadership Team annually and are adjusted based on the forecast activity.

Voting members have voting rights in the development of global standards and password-protected access to all documents. They can be candidates for the Leadership Team and the Co-Chair positions.

If a member misses three or more meetings/conferences, membership is considered inactive, that means that the voting rights are waived until the Leadership Team reinstates them.

4.2 Voting Criteria

More than one individual can represent voting member companies; however, each member company has only one (1) vote, even if they have multiple divisions.

Plenary decisions of the HUG, for example ratifying guidelines and Work Team results, will be taken by simple majority of the members that are entitled to vote, a quorum of 50% is necessary. Voting will be done by e-ballot.
GS1 supports and manages the decision process but has no voting privileges.

4.3 Non-voting Membership Criteria

Organizations with a keen interest in standards development and patient safety may support the GS1 global Healthcare User Group (GS1 HUG™) by participating in the Work Teams. Non voting members are eligible to become members of HUG Work Teams, attend HUG events, and have

limited access to documentation and work results. Associations, regulatory bodies and educational institutes can be non-voting members with no voting privileges.

Non-GS1 members can participate at conferences/meetings but cannot vote.

4.4 Healthcare Provider

Organizations and / or individuals who deliver healthcare to the patient are considered healthcare providers. Healthcare providers are encouraged to use the GS1 system and participate in the HUG.

4.5 Technology and Solution Providers

Technology and Solution Providers can participate in HUG Work Teams, only by invitation through the respective Work Team leaders, to provide technical input. Upon invitation of the Leadership Team, they can participate in HUG conferences/meetings as observers, without voting privileges.

5.0 Organizational Leadership

5.1 Leadership Team

The Leadership Team shall comprise of a minimum of seven (7) full members and a maximum of twelve (12) full members. Membership should be geographically balanced. Qualifications to serve as a Leadership Team member include subject matter expertise in the GS1 System and associated technologies. GS1 Member Organization representatives (maximum 3 – adequate to market activities) may also serve as additional non-voting Leadership Team members.

Roles and Responsibilities

The Leadership Team shall

- elect two Co-Chairs through nomination and consensus.
- develop and maintain the overall HUG strategy
- manage, finance, conference/meeting planning, public relations, membership and policy
- ensure geographic and supply chain stakeholder balance
- formulate individual positions of the HUG in response to regulatory, customer, and local standards initiatives.
- represent HUG membership to external groups and organizations with interests in standards and patient safety - GS1 representatives shall be engaged.
- create Work Teams to respond to, or drive, specific initiatives.
- ensure that Work Teams are adequately resourced.
- appoint Work Team leaders, review progress of the Work Teams on a regular basis and ensure that there is alignment between the Work Teams.
- ensure participation in the Global Standard Management Process (GSMP) by representing the HUG in GSMP and by using GSMP for any standards to be developed

Leadership Team members must be able to act as their organisations representative in key-decisions

The Leadership Team shall hold regular scheduled teleconferences to monitor progress, discuss issues and meet in person in conjunction with the HUG conferences. Further face-to-face meetings can be organised if necessary.

Limits of Authority

Decision-making is achieved through consensus, which is defined as approval without sustained opposition – a quorum of 50% is necessary.

Leadership Team Selection Process

A candidate to the Leadership Team must be engaged in GS1 Standards development efforts and should be able to promote the implementation of the developed global standards and best practices in their organizations and should therefore be able to provide linkage between their business and the GS1 HUG™. An election committee, consisting of HUG Co-Chairs and the GS1 Global Office, shall nominate candidates. Candidate confirmation is obtained by e-ballot of the membership.

Term Limits

Leadership Team members serve a one-year term which is renewable.

5.2 Co-Chair

The Leadership Team shall elect two Co-Chairs. The Co-Chairs should provide adequate representation from all healthcare sectors and an attempt should be made to keep a geographical balance.

Roles and Responsibilities

Co-Chairs shall:

- convene and preside at HUG conferences and meetings
- approve agendas proposed by the GS1 Group Manager Healthcare.
- facilitate the consensus process
- disseminate and monitor communications with membership
- assign duties as necessary to advance the work of the HUG
- report to the GS1 Management Board

Term Limits

Co-Chairs serve a term of 2 years with the possibility to be re-elected for another two years. Co-chair terms are staggered to ensure continuity. Co-Chairs must be able to act as a representative of their organisation in key decisions for the duration of their term. GS1 staff cannot serve as Co-chairs.

Limits of Authority

Decision-making is achieved through consensus with the Leadership Team, which is defined as approval without sustained opposition.

5.3 Work Team Participation

The HUG develops proposals for global standards through Work Teams.

Work Teams focus on specific business issues.

The working language is English.

HUG membership will review and approve, by majority vote, the results of the Work Teams before they enter the Global Standard Management Process (GSMP). The Work Teams champion the proposed standards through the GSMP.

5.4 Work Team Leaders

Work Teams are ideally co-chaired.

Leaders of the Work Teams are responsible for the progress of the team according to the scope and deliverables. They are also responsible for all administration of their team and will be supported in that task by staff from GS1.

5.5 Group Manager Healthcare

Roles and Responsibilities

- Facilitation of the HUG's decisions
- General Communication
- Reporting to GS1 Global Office (GO) Management
- Ensuring that HUG Leadership Team has sufficient support from GS1 staff
- Driving GS1 alignment with HUG goals and objectives

Term Limits

Group Manager Healthcare maintains the position as long as he / she remains in post.

6.0 Conferences and conferences procedures

There will be three conferences per year, the HUG Leadership Team determines time and place, but they should take place in different geographical regions. The agenda of the conferences are drafted by the Group Manager Healthcare and approved by the Leadership Team.

6.1 Conference fees

There are fees applicable for conferences; HUG voting members pay a reduced fee.
Speakers participate free of charge at the conferences, as well as regulatory bodies, GS1 staff and GS1 Member organisations.

The Leadership Team decides if the HUG will reimburse the travel costs for a speaker – there will be no remuneration for speakers.

6.2 Anti-Trust Statement

The GS1 Anti-Trust Statement must be brought to the attention of all participants at the beginning of each conference/meeting and teleconference.

6.3 Quorum

Leadership Team and Work Team decisions are not binding when a quorum is lacking at the time of the decision. GS1 GO shall maintain rosters of HUG, Leadership Team and Work Team membership. A quorum is defined as more than half of the registered roster.

6.4 Minutes

Where a quorum is present, minutes shall be taken and posted on the working area of the GS1 HUG™ website. The recording of minutes is a voluntary, rotating function of the members present.

7.0 Document Development Process

7.1 Document Types

Specific Responses regarding public policy

One or more Leadership Team members draft specific responses with subject matter support from the GS1 GO. The Leadership Team then reviews the proposed response. Substantive and editorial changes are suggested and approved by consensus. Review can be via a physical meeting, e-mail, teleconference or Webex, lead by the Work Team "Public Policy". The HUG will submit the response to the regulatory authorities either via the local GS1 Member Organisation or through the Group Manager Healthcare.

Position Papers

Any member of the HUG or a GS1 Member Organization can draft a position paper. Once drafted, the paper can be submitted to the HUG Leadership Team for adoption. Substantive and editorial changes are suggested and approved by consensus. Review and adoption can be via a physical meeting, e-mail, teleconference or Webex. Once the Leadership Team and originator reach agreement the position paper can be posted on and distributed via HUG website.

Press Releases

A press release is a succinct and timely announcement. Agreements among industry groups, regulatory bodies, key customers and companies' adoption of GS1 Standards, or a change in GS1 HUG Leadership are possible press release topics. As topics are presented to the GS1 HUG™ Leadership Team, they shall reach a consensus before forwarding to GS1 GO Marketing to draft and publish.

Version 1.3 Page 7 of 8 10/16/2006

8.0 Communications

Communication with associations and regulatory bodies is done through the Group Manager Healthcare at GS1 GO in alignment with the Leadership Team and according to the mission and work plan of the HUG.

GS1 provides the neutral platform for discussions between the healthcare industry and regulatory bodies.

The Support Team 'Communication and Coordination' is responsible for all marketing activities of the HUG, in alignment with the GS1 branding guidelines and the GS1 GO Marketing Team. GS1 GO maintains the HUG website (www.gs1.org/hug).
Communication, with regard to HUG global marketing activities, shall be the responsibility of the Leadership Team, in alignment with the GS1 branding guidelines and the GS1 GO Marketing Team. GS1 GO shall maintain the HUG website (www.gs1.org/hug).

For presentations to third parties GS1 HUG™ standard presentation templates shall be used.

Annex:

How to Use This Document – Document Conventions

MUST: This word, or the terms "REQUIRED" or "SHALL", means that the definition is an absolute requirement.
MUST NOT: This phrase, or the phrase "SHALL NOT", means that the definition is an absolute prohibition.
SHOULD: This word, or the adjective "RECOMMENDED", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
SHOULD NOT: This phrase, or the phrase "NOT RECOMMENDED", means that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
MAY: This word, or the adjective "OPTIONAL", means that an item is truly optional.

Version 1.3 Page 8 of 8 10/16/2006

Definitions for a better understanding of the business requirements description

Expression	Meaning
Container	hard pack for trays
Instrument	the item itself (means Item No)
Peel pack	one or a few instruments packed in a soft packs
Tray	could be packed in a soft or container way (equivalent : basket, corb)
Macro	Focus area : Ordering, delivery, goods receipt, stock/asset management
Micro	Focus area : CSSD processes, operating theatre processes
Loan	Focus area : Processes regarding products which are loaned from supplier side
Repair	Focus area : External repair processes
Recommended for process management	Not directly linked to patient safety, but necessary for appropriate process management
Unit level	The single instrument (means serialised)
Mandatory	Means that minimum one user described this as mandatory (could be a legal regulation). As a consequence this may not be considered as mandatory by all users
Optional	Means that minimum one user described this as "nice to have", to optimise patient safety, process managements, quality, etc

Surgical Instruments BR

AIDC DATA WORKTEAM Oct. 30th, 2006

Business Requirements Template : SURGICAL INSTRUMENTS

Note: To see comments click View & Comments; Click View & Comments again to hide comments.

Focus	No	Business Requirement (WHAT)	Rationale (WHY)	Mandatory/Optional	Status	IT remarks
macro	1	Instruments need GTINs	due to clear identification in eProcurement processes	Optional	Open	Optional, because few hospitals practice eProcurement
macro	2	At receipt at a hospital the person receiving the new instrument must be able to identify that actual instrument (Item No) by data capture of the information on its package	To link the ID of the instrument to an inventory, receipt process	Mandatory	Open	
macro/repair	3	At receipt at a hospital the person receiving the instrument must be able to identify if the instrument at unit level (Serial No) is the instrument ordered and is either a new instrument or a repaired instrument.	For inventory and instrument management purpose	Mandatory	Open	inclusive receipt of the goods
macro/loan	4	A tray must be able to be identified (Item No) as a loan tray if it is a loan tray to be returned	To assure accounting of loan trays.	Optional	Open	could be with the optical trade mark
macro/loan	5	A tray must be able to be identified (Item No) as a loan tray if it is a loan tray for long term use in this hospital	To assure accounting of loan tray	Optional	Open	could be with the optical trade mark
macro/repair	6	Instruments have to be identified at unit level (Serial No)	Must be able to scan the item to determine which set it belongs to	Optional	Open	
macro	7	Instruments have to be identified at unit level (Serial No)	Definition of the ownership of an instrument to another house	Optional	Open	
macro	8	Data capture must be possible at instrument/peel pack/tray level (Item No)	Cost allocation when processed for a third party.	Optional	Open	
micro	9	All instruments at unit level (Serial No) must be identifiable (not only the new ones, but also the existing ones).	To initiate or maintain the life cycle record of the instrument.	Mandatory/Optional	Open	Each instrument has to be identified according country specific regulation, but not all instrument belong to a risk category justifying this and not all instrument are today technically markable
micro	10	In France, Class III and Class II reusable instruments must be traceable.	This is a government regulation	Mandatory	Open	the last 5 patients by them the instrument at unit level (Serial No) has been used, have to be documented
micro	11	Instruments (Item No) have to be identified	When verifying the instruments functions, having access to functionality tests descriptions. For instruments made of multiple parts, instructions to "rebuild" the instrument. When handling the instrument, finding right cleaning, sterilisation, etc. instructions.	Optional	Open	
micro	12	Instruments have to be identified at unit level (Serial No)	Special tracking of high value and intensive maintenance instruments.	Optional	Open	
micro	13	Peel packs, tray & container have to be identified	To manage the journey of goods in the CSSD (planning purposes, informing users about scheduled availability, etc.)	Optional	Open	to be able to know where an item is during the CSSD cycle
micro	14	Tray at unit level (Serial No) has to be identified by entering the CSSD	To manage incoming trays and define the delivery time	Mandatory for process management	Open	ID of the tray to be read
micro	15	Instruments (linked to one patient) have to be identified before the cleaning process	A different cleaning (desinfection) process is necessary for instruments which have been used with a potentially infected patient (CJD disease)	Mandatory	Open	The process is driven at tray level + isolated instruments (peel packed)
micro	16	Cleaning process has to be identified	To associate the instruments at unit level (Serial No) to the cleaning cycle for traceability purposes	Mandatory	Open	

Surgical Instruments BR

AIDC DATA WORKTEAM Oct. 30th, 2006

Business Requirements Template : SURGICAL INSTRUMENTS

Note: To see comments click View & Comments; Click View & Comments again to hide comments.

Focus	No	Business Requirement (WHAT)	Rationale (WHY)	Mandatory/Optional	Status	IT remarks
micro	17	Instrument at unit level (Serial No) has to be identified before and/or after the cleaning process	To manage incoming instruments into the CSSD (before / after = depending on local rules; if the instruments are pre-cleaned at OR, then instruments at unit level (Serial No) can be read before cleaning at CSSD)	Recommended for process management	Open	most of the CSSD proceed by counting the instruments to find out if something is gone lost in a tray.
micro	18	Instrument, tray and container at unit level (Serial No) have to be identified at the assembling process	To secure the completeness of the tray included in the container. A help in the assembling process (can be used as education for new staff) and documentation of the completeness of this process.	Mandatory	Open	
micro	19	Instruments have to be identified at unit level (Serial No)	Limit instruments crossing between trays	Optional	Open	
micro	20	In a hospital data capture at unit level (Serial No) must happen as an instrument/peel pack/tray is being prepared.	To assure that traceability of the instrument/peel pack/tray can be established or maintained.	Mandatory	Open	to link the item, its handling and the prescribed processes
micro	21	Reusable instruments at unit level (Serial No) must be linked to their sterilization process.	To assure proper sterilization and life cycle of the instrument. And to reduce the transmission of disease.	Mandatory	Open	
micro	22	Sterilisation process has to be identified	To associate the container (and the included tray & instruments) to the sterilisation cycle (process)	Mandatory	Open	
micro	23	Sterilisation process has to be identified	To be able to validate all the peel packs and containers included in a sterilisation cycle	Mandatory	Open	
micro	24	After the sterilisation process, tray & container has to be identified	To be able to exclude a non-conform container from its sterilisation cycle	Mandatory	Open	
micro	25	In a hospital peel packs/trays' availability is checked before the operation.	To assure that all the necessary instruments/peel packs/trays are available for use.	Mandatory	Open	
micro	26	In a hospital the completeness of the available peel packs/trays is verifyed before the operation.	To assure that all the necessary instruments/peel packs/trays are there.	Mandatory	Open	means the instruments are being counted, not individually scanned
micro	27	In a hospital the completeness of the available instruments/peel packs/trays is verifyed after the operation.	Also to account for all instruments/peel packs/trays and to assure that nothing was left in a patient.	Mandatory	Open	this is the counterpart to Nr 26
micro	28	In a hospital data capture must happen in the operation room after the operation to identify all the peel pack/tray at unit level (Serial No) used in the operation.	To provide traceability of the instruments/peel packs/trays used in an operation and to link the use to the patient files.	Mandatory	Open	Serial No of the trays, peel packs and isolated instruments, based on assembling process
micro / repair	29	Instruments (Serial No) have to be identified at unit level	For vigilance purposes, this including maintenance tracking	Optional	Open	
micro/loan	30	A tray must be able to be identified at unit level (Serial No) as a loan tray if it is a loan tray	To link the tray ID to the patient file	Mandatory	Open	unique identification of the tray. The content of the tray is mostly not documented in the hospital IT system (due to efforts); this information is stored by the supplier.
micro/loan	31	A tray must be able to be identified (Serial No) as a loan tray if it is a loan tray for long term use in this hospital.	To link the tray ID to the patient file	mandatory	Open	the content of the tray could/should be documented in the hospital IT system

GS1 HUG

HUG/HLS Serialisation Work Team Feedback Session

Berlin 1 February 2007
Stephen Hess, Merck

The global language of business
www.gs1.org

Serialization Feedback Session

A Combined effort of GS1 HUG and HLS
Global focus
All Healthcare products

Please Welcome our New work team co – lead

Massimiliano Molinari J & J

Serialisation Work Team Core Team

We are looking for diverse participants that:

1) Represent the different roles in the supply chain, such as:
   - ✓ Manufacturers
   - ✓ Wholesalers
   - ✓ Retailers
   - ✓ GPOs
   - ✓ Hospitals
   - ✓ GS1 Member Organizations

2) Represent small, medium and/or large enterprises

3) Work locally and think globally

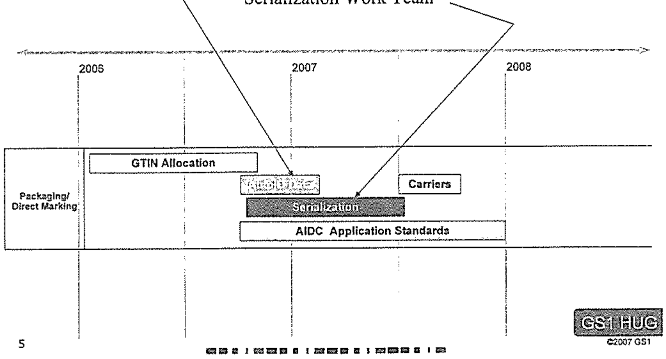
Serialization Work Team Current Members

- Abbott
- AdvaMed
- Aesculap
- Amgen
- Astra Zeneca
- Baxter
- Boston Scientific
- B.Braun
- Cardinal Health
- Cook
- FDA
- GSK
- HDMA
- Johnson & Johnson
- McKesson
- Medtronic
- Merck Germany
- Novartis
- Pfizer
- Purdue
- Roche
- Sanofi-Aventis
- St. Jude
- Tyco Healthcare
- Wyeth

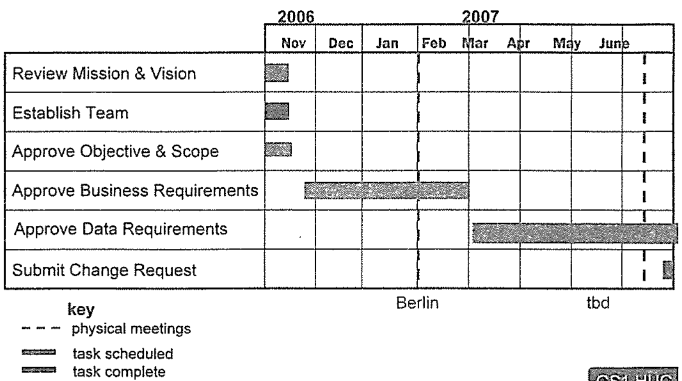
GS1 MO
- Australia
- Austria
- Canada
- China
- France
- Hungary
- Italy
- India
- Ireland
- Japan
- New Zealand
- Spain
- Switzerland
- UK
- USA

Introduction – Work Teams versus Roadmap

"AIDC Application Standards "



Serialization



Serialization

What's the interest in serialization?
To determine the global healthcare industry's size and structural requirements for specific data elements *(e.g., lot numbers, serial numbers)* to support patient safety and product authentication for healthcare products as defined by GS1 HUG below:

- Vaccines
- Biologics
- Therapeutic nutritional products
- Pharmaceutical
- Medical Devices (e.g., Instruments, Implants)

GS1 HUG

Scope
Serialization Work Team's Scope

The Serialization WT will review and document business and regulatory requirements for serialization by:

- Size (capacity needed)
  - All Healthcare
  - By product (GS1 HUG)
  - By product (GTIN)
  - By lot
  - By serial number
- Meaningful numbers versus randomization & affect on capacity
- Decentralization/centralization of allocation & affect on capacity
- Structure
  - Numeric length
  - Alpha-numeric length

GS1 HUG

Scope
Supply Chain Boundaries

Manufacture — Distribution — Care Facility

From: Finished Goods → To: End of Treatment

These are the boundaries

GS1 HUG

Business Requirements Example

Updated: January 17,2007
Pharmaceuticals

1	Manufacturers, Wholesalers, Repackers	[illegible]	[illegible]	Optional	Open	FDA - Counterfeit Drug Task Force Report - 2006, California Board of Pharmacy Draft Regulations	
2	Manufacturers, Wholesalers, Repackers	[illegible] "forever".	[illegible]	Optional	Open	HLS Serialization Task Force	The term "forever" needs to have established & agreed to boundaries — i.e. 20 years
3	Manufacturers, Wholesalers, Repackers	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	[illegible]
4	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
5	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
6	Manufacturers, Wholesalers, Repackers	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
7	Manufacturers, Wholesalers, Repackers	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force and GS1 Serialization Work Team	[illegible]
8	Manufacturers, Wholesalers, Repackers	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
9	All Supply Chain Stakeholders	[illegible]		Optional	Open	HLS Serialization Task Force	
10	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
11	Manufacturers, Wholesalers, Repackers	[illegible]		Optional	Open	HLS Serialization Task Force	Consistent with the Uniqueness requirement #2
12	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	[illegible]
13	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	[illegible]
14	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
15	All Supply Chain Stakeholders	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	
16	Manufacturers, Wholesalers, Repackers	[illegible]	[illegible]	Optional	Open	HLS Serialization Task Force	[illegible]

GS1 HUG

Current Phase – Gathering business requirements – Its not too late to contribute

My role in the supply chain is…

My business requirement is… (must relate to serialization and patient safety)

The rationale for this requirement is…

This requirement is mandatory or optional

The work team evaluates and documents status open/close

GS1 HUG

HUG/HLS Serialisation
Work Group - Questionnaire

The GS1 HUG/HLS Serialisation Work Group is distributing this questionnaire to assist in the development of business requirements with the goal of developing a global standard for the healthcare industry.

Answers to the questionnaire will help us determine the size (capacity) and structure needed to support serialization requirements.

1. I am a: _____ manufacturer, _____ distributor, _____ wholesaler, _____ hospital, _____ other:
   For this questionnaire our products are: _____ Vaccines, _____ Biologics, _____ Therapeutic Nutritional, _____ Pharmaceutical, _____ Medical devices: *instruments/implants*

If other please describe:

2. Our largest number of healthcare products in a lot* is _______________.
**for this survey lot and batch are considered identical in the external supply chain.*

3. Is your lot number structure numeric or alpha numeric?
   _____ numeric
   _____ alpha numeric

4. Is there ever an association with lot numbers in your serialization scheme?
   _____ yes
   _____ no

If yes, with what frequency. ____________________________

GS1 HUG