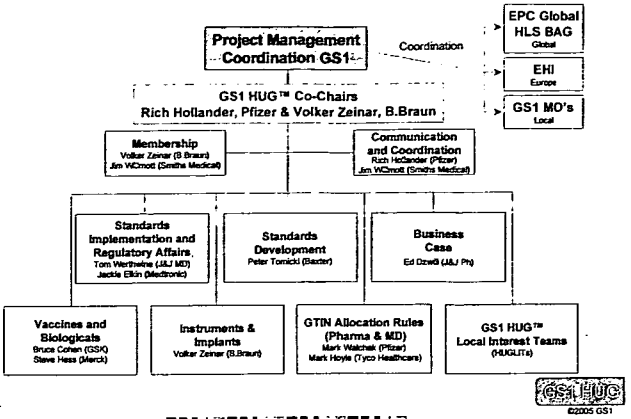
HUG Members

AEXXDIS
Alcon Laboratories
Amgen
Astra Zeneca
Baxter
BD
Boehringer Ingelheim
Boston Scientific
B.Braun
Cephalon
Cook
3M
GSK
Hospira
Johnson & Johnson Pharma
Johnson & Johnson Medical Device
Medtronic
Merck
Merck Germany
Novartis
Olympus
Pall Medical
Pfizer
Pharm Data
Premier
Smiths Medical
St. Jude
Terumo
Tyco
University Hospital Dijon
University Hospital Lyon
Wyeth
NACDS
EGA
Eucomed
Public Health Agency of Canada
NHS-CfH

Members from Pharma- and Medical device industry as well as from Associations and Regulatory Bodies

GS1 HUG

GS1 HUG™ Organisation



GS1 HUG

GS1 HUG™ Work Teams

Membership Volker Zeinar (B.Braun) Jim Wilmott (Smiths Medical)	Communication and Coordination Rich Hollander (Pfizer) Jim Wilmott (Smiths Medical)	Standards Implementation and Regulatory Affairs Tom Werthwine (J&J MD) Jackie Elkin (Medtronic)	Standards Development Peter Tomicki (Baxter)	Business Case Ed Dzwill (J&J Ph)
▪ identify & prioritise groups of supply chain stakeholders ▪ organize enlargement, including other stakeholders	▪ build communication and coordination infrastructure ▪ lead & organize internal / external communications ▪ web-site, press releases, newsletters ...	▪ research baselines of implemented standards ▪ develop global guidelines ▪ organize industry around a single position regarding future regulations ***'speak with one global voice'*** ▪ research baselines of legal requirements ▪ keep contacts to regulatory bodies	▪ review standards development process ▪ produce standards development strategy ▪ research industry & regulatory baseline for future healthcare standards development ▪ Recommendation and participation in GS1-GSMP optimization for healthcare	▪ develop business case to demonstrate the benefits of using a global standard ▪ best practice

GS1 HUG

GS1 HUG™ Work Teams

Vaccines and Biologicals Bruce Cohen (GSK) Steve Hess (Merck)	Instruments & Implants Volker Zeinar (B.Braun)	GTIN Allocation Rules (Pharma & MD) Mark Walchak (Pfizer) Mark Hoyle (Tyco Healthcare)	GS1 HUG™ Local Interest Teams (HUGLITe)
▪ develop a global standard and increase adoption across the supply chain ▪ aimed at improving patient safety and reducing medication errors	▪ analyse the necessity of marking instruments and implants ▪ process descriptions ▪ industry baselines ▪ technical framework / obstacles ▪ end user recommendations	▪ provide worldwide guidelines for GTIN assignment for pharmaceutical and medical devices ▪ lobby, via HUG and other stakeholders, for elimination of country specific divergences in GTIN allocation	▪ created to support local initiatives or investigate local requirements as required ▪ Supported by HUG members ▪ Promote and support local implementation

GS1 HUG

GS1's Brand Architecture

Guiding Principles

Collaborate Across GS1

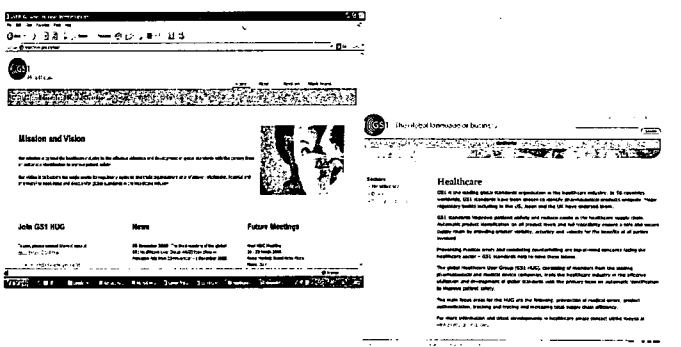
- HUG Members Participate on Other Work Groups within GS1 as Appropriate
  - Provide Feedback Mechanism with Other Work Groups and GS1 Organizations that Support the Development of Auto ID or eCommerce Standards
- Leverage Synergies with EPCglobal's HLS BAG for Activities focusing on RFID
  - HUG Leadership to Participate in EPCglobal Tri-Chair Monthly Meetings
- Communicate Regulatory Activity and Communication throughout GS1
  - RFID/EPC Discussions:
    - The HLS BAG Tri-chairs have Primary Responsibility for RFID Activities in the US via EPCglobal (Elizabeth Board)
    - HUG will include the HLS BAG Tri-chairs in Regulatory Discussions with Other Markets

Striving for Global Alignment

Stay Focused on Business Objective, Use and Practicality

- What role does auto-ID play in solving the objective?
  - What is the data structure required?
  - Define the data then choose the data carrier
  - Move away from national coding systems
- What are the use requirements?
  - Granularity? Lot or Serial
  - Volume? Transactions
  - Mixed or Homogeneous Packages?
  - Line of Site or non Line of Site?
- What are the technical challenges?
  - Dosage form, Package Level and/or Package Type
  - Do we need to print the codes in-line or can we use preprinted components?
  - Practical? Technically Possible but with What Quality and Cost
- What to do?
  - Strive for Global Alignment through Global Guidelines
  - Promote and implement worldwide

GS1 and HUG Websites



www.gs1.org/hug

Next Meetings of the GS1 HUG

19th to 21st September 2006
London

www.gs1.org/hug/

GS1 HUG

Questions?

Rich Hollander

rich.hollander@pfizer.com

The global language of business

1 - 1ページを印刷 して、
完了後に「次へ進む」ボタンをクリックしてください。 次へ進む

nwa.com check-in.

BOARDING PASS 1

Name:	**AKIYAMA/MASANORIMR**	Coach Class
Frequent flyer Nbr:	KEBJ04871103	Confirmation: **OYNJ7W**
E-Ticket Nbr:	0744308767507	Request:
Seat: 32-A	Gate: F14 Please confirm gate assignment	**Seat: 32-A**
Date: **15JUN2006**		
Flight: **NW 784**		
Depart: **Mpls/St. Paul, MN**	3:35PM	
Arrive: Boston, MA	7:36PM	

ノースウエスト航空予約番号はOYNJ7W です。

国際線をご利用の場合は、出発時刻の1時間前までにパスポート・データを読み取らせていただく必要があります。空港のセルフサービス・チェックイン機でパスポートのバーコードを読み込ませるか、あるいはノースウエスト航空係員にお申し出ください。

予約内容の詳細およびE-チケットの支払明細書(TSR)は、nwa.co.jp の予約確認画面からご参照いただけます。

お預けになる手荷物をお持ちのお客さまは、出発予定時刻の2時間前までに空港にお越しいただくことをお勧めします。 お預けになる手荷物に関するご案内は、nwa.co.jp よりご確認いただけます。

ご予定の変更により搭乗いただけない場合は、必ず出発予定時刻の前までに予約センターまでご連絡ください。ご出発時は、必ず出発予定時刻の30分前(米国内線の場合は、15分前)までに搭乗ゲートへお越しください。所定の時刻までにおいでいただけない場合は、予約をキャンセルさせていただく場合もございます。

次へ進む

VACCINES

Company	Lot Numbers				Serial Numbers				
	largest lot	numeric	alpha - numeric	association to serial #	meaningful	random	centralised	de-centralised	numeric
Berna Biotech (mfgr)	200,000	numeric		no		random	centralised		numeric
Australian Hospital	60	numeric		no		random		de-centralised	numeric
GS1 Croatia (wholesaler)	not greater than 12 characters		alpha-numeric	no					
Baxter	200,00		alpha-numeric	yes	meaningful			decentralised	numeric
Sanofi-Aventis	1,000,000		alpha-numeric	yes		random	centralised	decentralised	numeric
Merck	6 million tablets 1 million package units		alpha-numeric	no		random	centralised	decentralised	
GSK (mfgr and distributor)	1,000,000		alpha-numeric			random			

	Impact to Change		Questions: How many serial nos. would your company need if:		
alpha-numeric	yes	no	a) They assigned one serial number to every product "instance" they produced, independent of the packaging level or channel it was sold to.	b) They assigned one serial number to every product "instance" they produced, independent of the packaging level, but only for healthcare products	c) They assigned one serial umber to every product "instance" for their highest volume healthcare product.
	yes				
	yes				
	yes				
	yes		2 Billion/yr globally	2 Billion/yr globally	1 Billion/yr globally
		no			
alpha-numeric	yes				
alpha-numeric		no	A bit less than one billion for a one year period.	xxx because GSK Bio produces only vaccines	

Participants list HUG Conference 13 - 15 June Minneapolis, MN			
ID	Full_name	Organisation	Title
1	Jill Buss	3M	Manager, Package Engineering
2	Monica M. Kryzer	3M Company	Supply Chain Manager
3	Jeffrey Secunda	AdvaMed	Mr.
4	Gunther Lamparter	Aesculap AG & Co. KG	Director Service Systems
5	Mark Rutkiewicz	AGA Medical	QA Director
6	Grant Hodgkins	Alcon Laboratories, Inc.	Mr.
7	Vladimir Gusev	Amgen	Engineer II / Brand Protection
8	Volker Zeinar	B. Braun Group	Mr.
9	Peter Tomicki	Baxter	Mr
10	Thomas Cooley	Brigham & Women\'s Hospital	Assistant Director, Pharmacy
11	Mike Meakin	DHL - Exel Supply Chain	Quality Director
12	Ms. Kathleen Garvin	DoD	DoD Medical PM Data Sync
13	Jay Crowley	FDA	Mr.
14	David Racine	FDA/CDRH	Sr. Program Management Officer
15	Suzy Borgschulte	GlaxoSmithKline	RFID Business Analyst
16	Ed Dzwill	GPSG - Johnson & Johnson	Manager Package Technology
17	David Buckley	GS1 Global Office	Mr.
18	Michel van der Heijden	GS1 Global Office	Mr.
19	Barbara Dorner	GS1 Austria	Business Development Manager
20	Scott Gray	GS1 Global Office	Mr.
21	Eduardo Rodriguez Pinto	GS1 Chile	Mr
22	Valerie Marchand	GS1 France	Mrs.
23	Peter J. Alvarez	GS1 GDSN, Inc.	Senior Director
24	Michaela Haehn	GS1 Germany	Senior Project Manager
25	Ulrike Kreysa	GS1 Global Office	Group Manager Healthcare Solut
26	Yasuo Kurosawa	GS1 Japan	Deputy General Manager
27	Gary Hartley	GS1 New Zealand	Mr
28	John Roberts	GS1 US	Director
29	Bernard Hogan	GS1 US	SVP- CTO
30	Yamato Miyahara	GS1 Japan	Special Reseacher
31	D. Bruce Cohen	GSK	Technical Director
32	Brett Novak	Hospira Worldwide	Marketing Manager
33	Eric D. Strong	Hospira, Inc.	Packaging Engineer
34	Massimiliano Molinari	J&J - Pharma	GTO, Packaging Engineer
35	Mike Rose	Johnson & Johnson	Mr
36	Thomas Werthwine	Johnson & Johnson	Manager
37	Gary A Clement	Kimberly-Clark	Mr
38	Ron Bone	McKesson	Sr. VP Distribution Support
39	Ted Ng	McKesson Corp	Director
40	Barb Ruble	Medtronic, Inc	Director, Master Data Governan
41	Jackie Rae Elkin	Medtronic, Inc.	Ms.
42	Steve Hess	Merck & Co., Inc,.	Exec Dir Packaging Tech
43	Bruce Anderson	Ministry of Health - NZ	Dr
44	Masanori Akiyama	MIT Sloan School of Management	Visiting Professor
45	M. Diane Arico	Novartis Pharmaceuticals Corp	US Proj Mgr, Anti-Counterfeit
46	Masakazu Gotanda	Olympus Medical systems	General manager
47	Naomi Sekino	Olympus Medical systems	Manager
48	Mark Walchak	Pfizer	Senior Manager- Pack Tech
49	Rich Hollander	Pfizer	Mr.

50	Daphne Allen	PMP News	Editor
51	Joseph Pleasant	Premier Inc.	CIO
52	Patsy Johnson	Roche Diagnostics	eCommerce Principal
53	Alberto Sanna	San Raffaele Scientific Instit	Dr
54	Jim Willmott	Smiths Medical	Mr
55	Mark Hoyle	Tyco Healthcare	Mr
56	Ilisa Bernstein	U.S. FDA	Director of Pharmacy Affairs

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

Griffin Auditorium
Medtronic CRM West Campus
7000 Central Ave NE Minneapolis, MN 55432

If you have any questions or need further directions, Medtronic's main number is **1-763-514-4000**.

Directions from the DEPOT:

- Start out going NORTHWEST on S 3RD ST/3RD ST S toward 2ND AVE S.
- Continue to follow 3RD ST S.
- Take I-94 W / US-52 N. Merge onto I-694 E
- Take the MN-65 S / CENTRAL AVE exit- EXIT 38A.
- Turn LEFT onto CENTRAL AVE NE / MN-65 N.
- Continue to follow MN-65 N.
- Turn RIGHT onto MISSISSIPPI STREET.
- Turn LEFT onto CENTRAL AVE NE / CR-6 / CR-35.
- Continue to follow CENTRAL AVE NE / CR-35.

Directions from the AIRPORT:

- Exit the airport on Airport Road (East bound).
- Take the Hwy 55/ Mendota exit.
- Continue to follow the Hwy 55 West signs.
- Hwy 55 will merge into Hwy 62.
- Follow Hwy 62 to I-35W North.
- At the I-694 exit, take the West bound lane.
- Go West on I-694 to MN-65 S/CENTRAL AVE exit – EXIT 38A.
- Turn RIGHT onto CENTRAL AVE NE / MN-65 N.
- Continue to follow MN-65 N.
- Turn RIGHT onto MISSISSIPPI STREET.
- Turn LEFT onto CENTRAL AVE NE / CR-6 / CR-35.
- Continue to follow CENTRAL AVE NE / CR-35.

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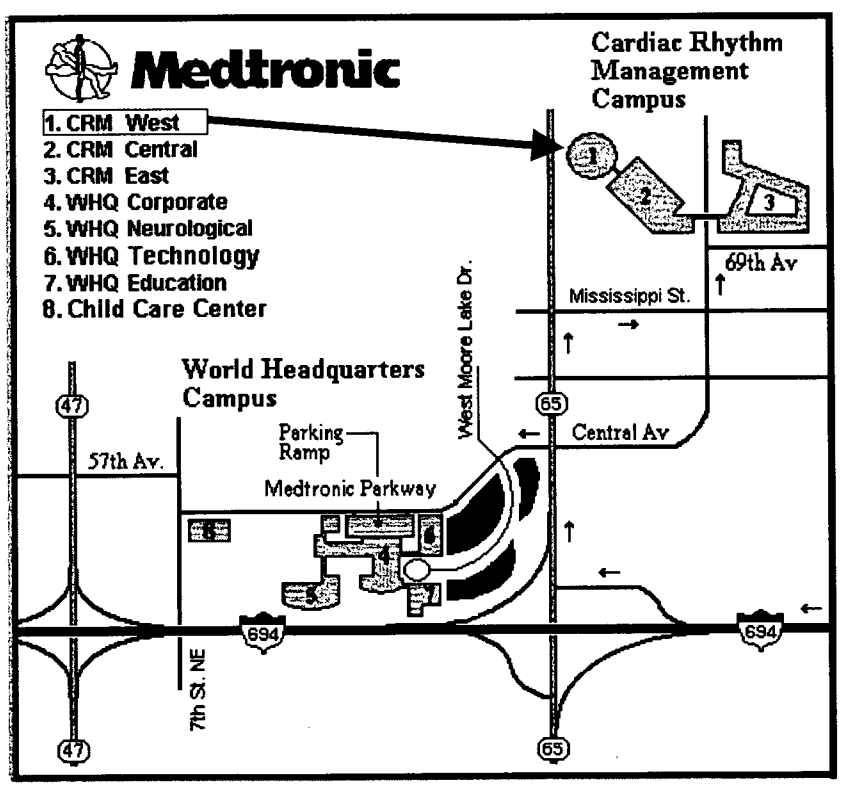
Alleviating Pain · Restoring Health · Extending Life

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



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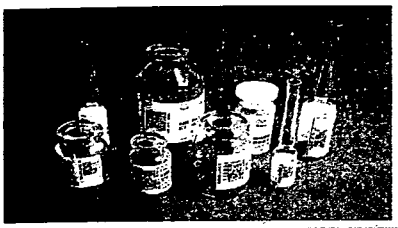
Alleviating Pain · Restoring Health · Extending Life



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

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 ethical drugs (In hospital use).
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)

(Note 6)

Type of ethical drug	Product code	Expiration date	Manufacturing No. or code
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 to be indicated (3) Logistics (outer) package unit

Additional data

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

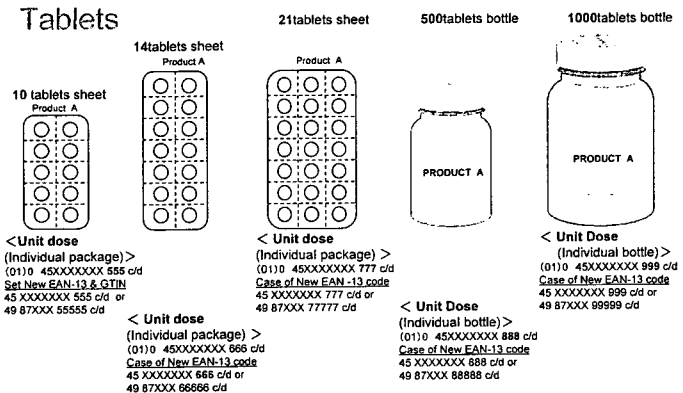
Type of ethical drug	Product code	Expiration date	Manufacturing No. or code	Quantity (Note 5)
Specific biological products	◎	◎	◎	◎
Biological products (excluding specific biological products)	◎	◎	◎	◎
Oral medicine (excluding biological products)	○	○	○	○
Injection (excluding biological products)	○	○	○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

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

Note of labeling items and data

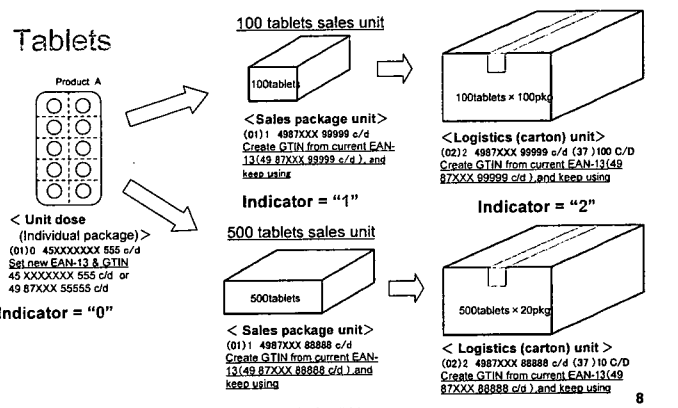
(Note 1)
"◎" means those which shall be indicated (essential indication), and "○" means those which are not necessarily indicated (voluntary indication).
(Note 2)
The formulation package unit refers to the smallest unit of the package of drugs marketed by marketing business license holders; i.e. a PTP 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

Tablets



Unit dose Indicator = "0"

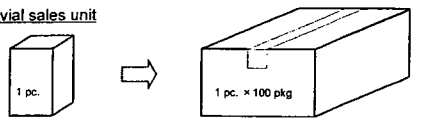
Tablets



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

Vials

1 vial sales unit



< 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"

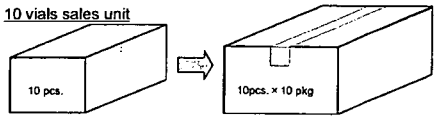
< Sales package unit>
(01)1 4987XXX 22222 c/d
Create GTIN from current EAN-13(49 87XXX 22222 c/d), and keep using

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"

10 vials sales unit

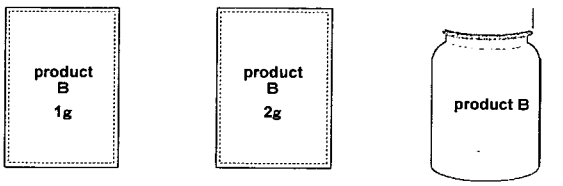


< Sales package unit >
(01)1 4987XXX 33333 c/d
Create GTIN from current EAN-13(49 87XXX 33333 c/d), and keep using

< 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

Powder Medicine (granule・powder)

1g Powder pack | 2g Powder pack | 500g powder bottle



< 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

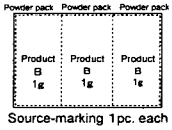
Unit dose indicator = "0"

Powder Medicine (granule・powder)

Powder pack

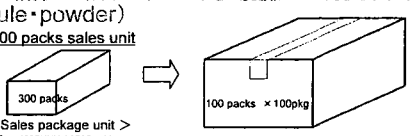
< Unit dose (1 pack each)>
(01)0 45XXXXXXX 123 c/d
Set new EAN-13 & GTIN
45 XXXXXXX 123 c/d or
49 87XXX 12345 c/d

Indicator = "0"



Source-marking 1pc. each

100 packs sales unit



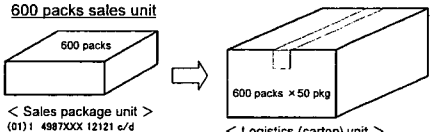
< Sales package unit >
(01)1 4987XXX 98765 c/d
Create GTIN from current EAN-13(49 87XXX 98765 c/d), and keep using

Indicator = "1"

< 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



< Sales package unit >
(01)1 4987XXX 12121 c/d
Create GTIN from current EAN-13(49 87XXX 12121 c/d), and keep using

< Logistics (carton) unit >
(02)2 4987XXX 12121 c/d (37)50
Create GTIN from current EAN-13 (4987XXX 12121 c/d), and keep using

Source-marking label example

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

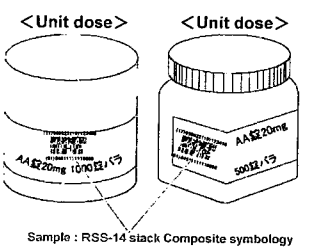
(01)14987111111111
(17)050822(10)123456

4 987111 111114

<Unit dose>
GTIN : 04511111110008

RSS-14 stack Composite symbology
OR
RSS limited Composite symbology

(17)050822(10)123456
(01)04511111110008



Sample : RSS-14 stack Composite symbology

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*
Current Marking	Unit dose *Marking none*	Sales unit EAN-13 EAN-13: 4987111111114	Logistics unit ITF-14 14987111123459 GTIN: 14987111123459

Parallel Marking 5 years

13

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

Appendix

Label samples,

Laser direct marking,

Scanners,

Verification system,

14

Label samples

RSS stacked Composite symbology

OR

RSS limited Composite symbology

Drug treatment label (In hospital issue)

Ampoule label

Ampoule label

Inner package label

Vaccine label

Inner package label

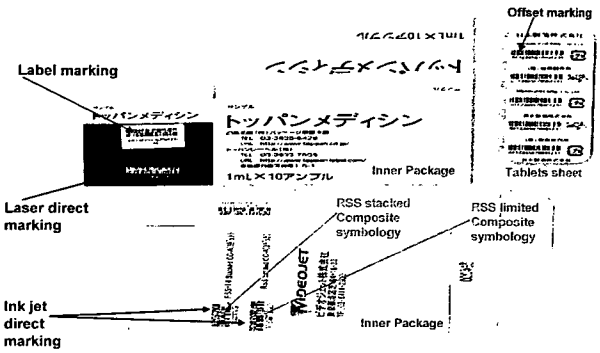
15

Tablet sheet marking samples in packaging line

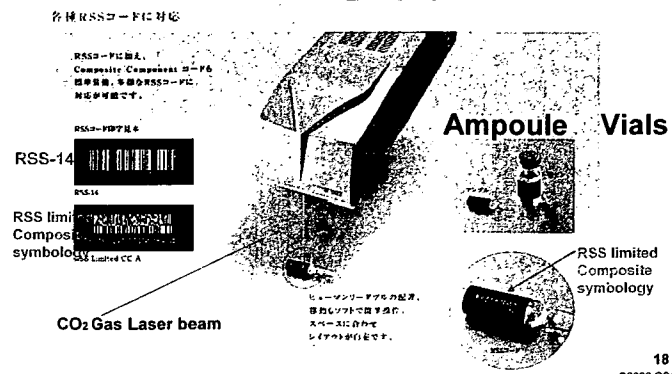
(Aluminium coting films)

16

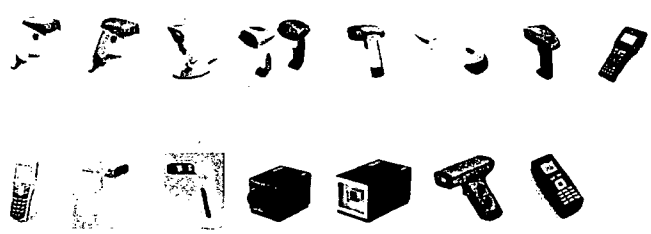
The inner package samples



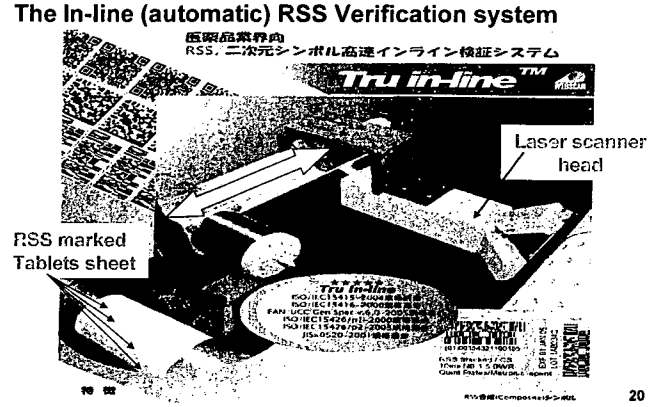
The Laser direct marking equipment (label-less marking)



The RSS / Composite Scanners (Handheld & Fixed Mount)



The In-line (automatic) RSS Verification system



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The global language of business

GTIN Allocation Team

Minneapolis, June 2006

Mark Walchak/Mark Hoyle/Project Leaders

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

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

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

Table of Contents – Top Level

ToC 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

Topic 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

Topic 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

Topic 4: Regulation

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)

Topic 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)

Topic 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?

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

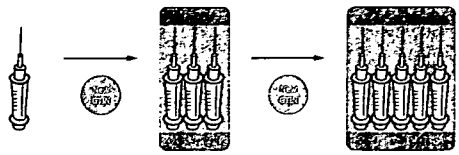
http://www.gs1.org/hug/work_teams/gtin_allocation/

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)

We are making good progress

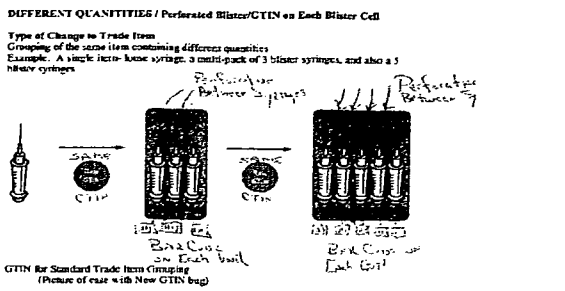
Packaging Levels

Each packaging level needs a different GTIN



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

But still a lot of work to do?



2) www.gs1.org/gmmiles

- 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

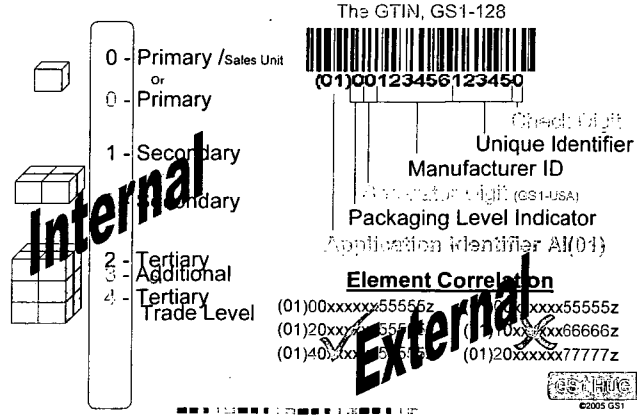
Areas of Concerns and Resolution

- 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)).

3) GTIN Allocation for Healthcare

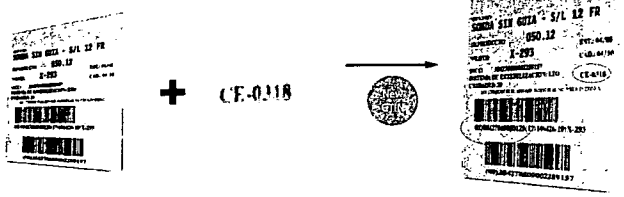
- GTIN Allocation Rules – Basic Top Level Principles
  e.g. Package Level Indicators
  Internal or External Affect
- GTIN Allocation Rules – Basic to Complex Devices / Kits
  - Application
  - When is a Package not a Package?
- GTIN Allocation Rule Concepts
  What Signifies a Change?
  - Commercial Variance,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

Top Level Principles



Top Level Principles

CE



4) Complex Devices

Three Component Parts

Ventilator

1. GUI
2. Primary Unit
3. Battery

} Independent Serial Numbers } Master Serial Number AI(21)

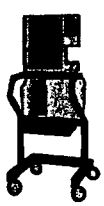
New GTIN ?

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!

Complex Devices

Configuration



- Software Options

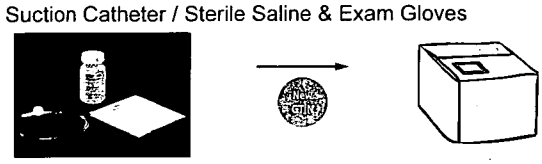
1. Installable Options (CD Rom / Modem / Internet Download)
2. Activated Options (Authorisation Code)

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.

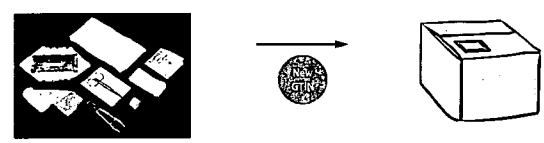
Kits - GTIN Allocation

Combinations of Independent Trade Items Each Having a Separate GTIN

Suction Catheter / Sterile Saline & Exam Gloves



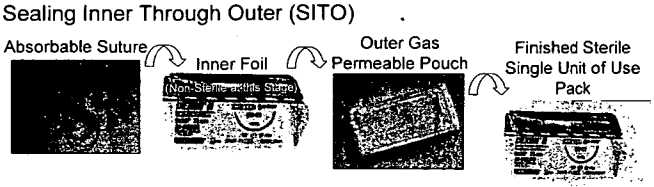
Swabs, Gauze sponge, Forceps, Scissors etc.

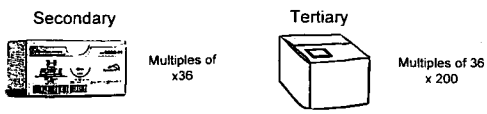


When is a Package Inner/Packaging Level

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?

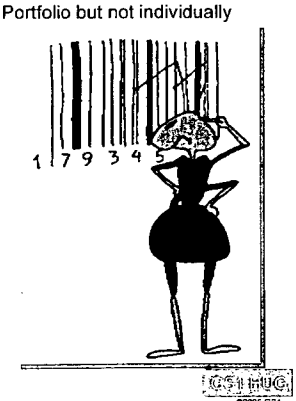
5) Within Scope of Our Next Steps

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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The global language of business

GS1 HUG – Global Healthcare User Group
Minneapolis, Minnesota, USA – 12 – 13 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.

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 Neurologica, 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.

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 WG III 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 synchronization in many international markets.

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

6:30 Cocktails & Networking Dinner - The Depot

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).

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 responsabilities. 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 Abbott 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

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 drove 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