Standards Implementation

GS1 HUG Meeting, November 2005
Tom Werthwine

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To answer the question: “Is this true?”

If not, then, “why not?”

If true, then, “How far do we have yet to go?”
Standards Implementation Work Team

Objectives
- Define - Healthcare goes for GS1 Standards
- Measure - Implementation Baseline Online Survey
- Analyze - At GS1 HUG Princeton Meeting
- Improve - TBD
- Control - TBD
HUG Implementation Baseline Survey Results (summary)

David Buckley

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### Survey Conducted 10 to 25 November 2005

#### GS1 Healthcare User Group - Implementation Baseline

**MEDICAL DEVICES - For the PALLET package level, which bar code symbol(s) are used?**

- [ ] GS1 Datamatrix
- [ ] RSS (Reduce Space Symbology)
- [ ] RSS with Composite
- [ ] EAN/UPC (covers EAN-8, EAN-13, UPC-A & UPC-E)
- [ ] GS1-128 (previously known as UCC/EAN-128)
- [ ] ITF-14
- [ ] Datamatrix
- [ ] Code 39
- [ ] Code 128
- [ ] Other

**MEDICAL DEVICES - For the PALLET package level, what DATA do you encode in the bar code?**

- [ ] GTIN (e.g., AI 01)
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- [ ] Lot or Batch Number (e.g., AI 10)
- [ ] Serial Number (e.g., AI 21)
- [ ] SSCC (e.g., AI 00)
- [ ] HIBC primary UPN
- [ ] HIBC secondary
- [ ] National Registration Number (e.g., PZN in Germany)
- [ ] Other
16 replies, all results presented as averages

- SMITHS MEDICAL
- Pfizer
- Medtronic, Inc.
- Boston Scientific
- Cook
- B. Braun
- Hospira
- Terumo Europe N.V.

- Novartis Pharma AG
- ABBOTT
- GlaxoSmithKline
- BD (Becton Dickinson)
- Merck
- Alcon Laboratories, Inc.
- Pall Medical
- Becton Dickinson

NOTE: Results refined for Medical Devices & Pharma
The answers pertaining to the Pharmaceuticals are no because we only manufacture medical devices. The answers should be N/A, however the system would not allow anything but yes / no.

Your review might give wrong overall impression since a pharma-only company is also obliged to answer yes / no to medical device questions. Likewise are device manufacturers also obliged to answer yes/no to pharma questions, which could confuse the survey. Otherwise great survey, and I look forward to receive a copy of the result!

[We] do not produce or market pharmaceuticals, therefore please disregard all input related to pharmaceuticals.

We are a medical device manufacturer and don't provide pharmaceuticals, but bar coded however most shelf packs have GTIN's but it may or may not have secondary information. On the unit packaging, we try to GTIN bar code the package, but may don't have them due to space constraints.
Survey Design – KEY LEARNINGS

• Need more respondents - both inside and outside GS1 HUG membership

• Healthcare is not one market with two segments - Pharma and Med Device : Healthcare is diverse

• We need to target the survey to avoid confusion

• We need to cover other GS1 service offerings
MEDICAL DEVICES
For the UNIT OF USE package level, which bar code symbol(s) are used?

<table>
<thead>
<tr>
<th>GS1 Datamatrix</th>
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<tbody>
<tr>
<td>RSS (Reduce Space Symbology)</td>
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Total # of respondents 17.

MEDICAL DEVICES - For the UNIT OF USE package level, what DATA do you encode in the bar code?

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Total # of respondents 17.
MEDICAL DEVICES - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, which bar code symbology do you use?

- GS1 Datamatrix
- RSS (Reduce Space Symbology)
- RSS with Composite
- EAN/UPC (covers EAN-8, EAN-13, UPC-A & UPC-E)
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Total # of respondents: 17.

MEDICAL DEVICES - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, what DATA do you encode?

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- Other
# Medical Devices – SHIPPER or CASE

## MEDICAL DEVICES - For the SHIPPER or CASE package level, which bar code symbol(s) are used?

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Total # of respondents 17. Statistics based on...
**NOTE: Only five companies Bar Code Pallets**

### MEDICAL DEVICES - For the PALLETON package level, which bar code symbol(s) are used?

- **GS1 Datamatrix**
- **RSS (Reduce Space Symbology)**
- **RSS with Composite**
- **EAN/UPC (covers EAN-8, EAN-13, UPC-A & UPC-E)**
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- **ITF-14**

- **Datamatrix**
- **Code 39**
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- **Other**

Total # of respondents 17.  
Statistics

### MEDICAL DEVICES - For the PALLETON package level, what DATA do you encode in the bar code?

- **GTIN (e.g., AI 01)**
- **Expiration Date (e.g., AI 17)**
- **Lot or Batch Number (e.g., AI 10)**
- **Serial Number (e.g., AI 21)**
- **SSCC (e.g., AI 00)**
Medical Devices – KEY LEARNINGS

- The predominant bar code used is code 128
- The predominant data are GTINs
- HIBCC usage is still significant
- Only 5 respondents bar code pallets
- RSS has made no inroads
- Use of serial numbers lags behind use of lot / batch
Pharmaceuticals

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**Pharmaceuticals – Unit of Use**

**PHARMACEUTICALS - For the UNIT OF USE package level, which bar code symbol(s) are used?**

<table>
<thead>
<tr>
<th>Symbol(s)</th>
<th>Graphic Representation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS1 Datamatrix</td>
<td><img src="image" alt="GS1 Datamatrix Bar" /></td>
</tr>
<tr>
<td>RSS (Reduce Space Symbology)</td>
<td><img src="image" alt="RSS Bar" /></td>
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<td><img src="image" alt="Code 128 Bar" /></td>
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</tbody>
</table>

**View**

- Other

**Total # of respondents 17. Statistics based on 8 respondents.**

**PHARMACEUTICALS - For the UNIT OF USE package level, what DATA do you encode in the bar code?**

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<th>Graphic Representation</th>
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<tr>
<td>GTIN (e.g., A1 01)</td>
<td><img src="image" alt="GTIN Bar" /></td>
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<td><img src="image" alt="Expiration Date Bar" /></td>
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**View**

- Other
### Pharmaceuticals – SKU

**PHARMACEUTICALS - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, which bar code system do you use?**

<table>
<thead>
<tr>
<th>Bar Code System</th>
<th>Percentage</th>
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<tr>
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**Total # of respondents 17.**

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**View**

**Other**

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**PHARMACEUTICALS - For the STOCK KEEPING UNIT (SKU) / SHELF PACK package level, what DATA do you include in the bar code?**

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Pharmaceuticals – SHIPPER or CASE

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Total # of respondents 17, statistics based on 0 responses

PHARMACEUTICALS - For the SHIPPER or CASE package level, what DATA do you encode in the bar code?

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Total # of respondents 17, statistics based on 0 responses

100% (all nine of the pharma responses)
NOTE: Only four companies Bar Code Pallets

PHARMACEUTICALS - For the PALLET package level, which bar code symbol(s) are used?

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HIBCC primary UPN
Pharmaceuticals – KEY LEARNINGS

- RSS usage significant at unit of use level of packaging
- The predominant data are GTINs
- HIBCC usage minimal
- Only 4 respondents bar code pallets
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### RFID

#### RFID is used, or planned to be used, for which items:

<table>
<thead>
<tr>
<th>Item</th>
<th>Usage Today</th>
<th>Planned for Future</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices</td>
<td></td>
<td></td>
</tr>
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<td></td>
</tr>
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<td></td>
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</table>

Total # of respondents 17.

#### RFID - Is your company a member of EPC?

- Yes
- No (but plan to join in the future)
- No (and have no plan to join)

Total # of respondents 17.

#### RFID tags are used for which packaging levels in your company?

- Unit of use
- Stock Keeping Unit (SKU) / Shelf pack
- Shipper or case
- Pallet
- Other (please specify)

Total # of respondents 17.
• **NO – Seven**
• **YES – Nine:**
  • Japan
  • FDA and some individual European countries.
  • Bar Code designed to meet Regulatory requirement for each marketed country.
  • FDA
  • US- FDA
  • FDA EU EFPIA
  • EAN128 is used to provide regulatory tracing capability at LOT level and shelf pack.
  • We use US as baseline. Barcodes changed for specific markets. - Germany -Spain -Brazil -Chile -Italy -Australia -Canada
  • Italy, Japanese requirement to meet JFMDA rules.
• **Unsure how to answer – One:**
  • Regulations drive much of what we do. We must comply.
• We are at a very early stage with RFID and will not consider it for the large range of sterile, small, low cost product lines. For the unit of use there are many situations where there is not enough space to include the GS1-128, but we put it at the next level of labelling. We are being increasingly asked to provide a pealable bar code and for China dual (2 the same) bar codes, which will add to the product cost. We try wherever possible to have "global" packaging rather than country specific packaging.

• I answered the above on behalf of our US market. To try and do so for other markets would be difficult...

• Practices vary by country. My response was global and may not be very valuable for this survey

• We anticipate the need to bar code all unit packaging, however, some of our product's packaging is not conducive to bar codes and we may need to redesign our unit packaging to apply the bar code efficiently.
CONCLUSIVE KEY LEARNINGS

Target key segments and expand base of respondents

Identify key opportunities

The product itself e.g. surgical instruments?

Pallets - Is the survey skewed?

Serialized GTINs as a precursor to RFID?

Other GS1 offerings e.g. GLNs?
Where do we go from here?

Invitation - Moving Ahead session

Invitation - Surgical Marking session

Expand and refine survey

Target

- AdvaMed Members
- Eucomed Members
- PhRMA Members
- Others?
Contact details

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