The webinar will begin shortly

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Toll Number (US/Canada): 1-650-479-3208
Event access code: 664 535 159
Welcome

Justine Freisleben
Senior Director,
Industry Relations
HDMA
Before we get started...

• Today’s webinar is being recorded.
• All participant lines are muted.
• Presentation and audio-replay will be made available by Monday, May 23.
This webinar is for information and educational purposes only.

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Q&A: Submit Your Questions

1. Type your question into the Q&A box located on the right-hand side of your screen.

2. Click the SEND button to submit your question.
Sponsored by
2016 Quick Start Guide: Revisions

Below is a summarized list of the significant changes from the previous 2014 version of the HDMA Quick Start Guide. Revisions include:

- The addition of a recommendation for a wrap-around case label.
- A change in the placement of the 2D GS1 DataMatrix symbol on the case label to the outer edges of the label, away from the carton edge.
- Updates to the information encoded in the 2D GS1 DataMatrix symbol.
- New guidance on inner pack labels.
- Inclusion of recommendation to use a SSCC for partial cases.
Panelists

Chuck Biss, Senior Director, AIDC Healthcare, GS1

Kay Gard, Senior Operations Manager, Product Distribution, Genentech Inc.

Mark Karhoff, Program Manager, U.S. Serialization, Genentech Inc.

Matt Sample, Senior Director, Secure Supply Chain, AmerisourceBergen Corporation
Who / what is GS1...

International... Not-for-profit... “SDO”
110+ Member Organisations
Over one million user companies
(from SME to global companies)
Member driven
150 countries served; 20 different domains
2,500 people helping us
Over 6 billion transactions a day
GS1 Healthcare - committed community of globally engaged stakeholders...

...and there are many more companies working with GS1 at a local level
To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.
GS1 - global and local

**GS1 Global Office**
Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

**GS1 Member Organisations ("MOs")**
Local offices in 110+ countries around the globe. Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

**HDMA** is **BOTH** a GS1 Global Healthcare member and a GS1 US member... ensuring both for Global and Local participation!
A lot achieved, with more to do...

- **2005**: GS1 signs memorandums of understanding with both HL7 and ICCBBA.
- **2006**: NEHTA in Australia endorses use of GS1 standards.
- **2007**: European Medical Devices Directive released.
- **2008**: Argentinian National Traceability system uses GS1 standards.
- **2009**: WHO preferred vaccine characteristics include presence of barcode that should conform to GS1 standards.
- **2010**: 99% of medical devices supply in Japan identified with a GTIN.
- **2011**: Canadian and CPSI endorse the adoption of GS1 standards.
- **2013**: Danish minister states “all Danish hospitals in the future have to use GS1 standards.”
- **2014**: GS1 confirmed as the first accredited issuing agency for the US FDA UDI rule.
- **2015**: Healthcare GTINs in GDSN exceed 1 million (33% end growth in 1 year).

**2016 & beyond**
EVERY item has ONE set of key identification data carried in ONE data carrier able to be scanned by EVERYONE at every key process step...
Why we are “here”...

GS1 Healthcare direction & drive...
- Global, harmonized, approach
- Develop & promote globally applicable healthcare standards
- Consistent interpretation & application of the GS1 General Specifications, without diversion

GS1 supported the “Quick Start” review with...
- GS1 General Specifications interpretation
  - Consistent GS1 terminology use
  - Identification & Marking clarifications
  - GTIN, GTIN Allocation, SSCC understanding
  - Packaging hierarchy identification
  - Data carrier (barcode) selection criteria
  - Verification - print & data quality
Supply chain efficiency...

and **ultimately**...

**PATIENT SAFETY!**
For more information...

www.gs1.org/healthcare

www.gs1.org/healthcare/standards
Overview
Genentech Label Development and Changes

- **Initiate**: Roche-Genentech initiated serialization efforts through a global and a connected US serialization program focused on building capabilities

- **Operationalize**: Recently these programs transitioned to deployment programs with more focus on customer impact

- **Optimize**: In parallel a focus has been placed on developing maintenance and production change management procedures with sustaining groups

**Packaging Notes**:
- Sellable unit level packaging has been managed by packaging artworks and engineering teams at plants throughout

- Tertiary packaging was owned by the Serialization programs but a new global forum that includes representatives from key stakeholders in each region has been established
Overview

Addressing the Revised Guidance

- **Central Forum:** Our internal global forum has been meeting regularly to review any guidance updates or feedback from customers.

- **2D Barcode Position on Case:** The change to move the 2D barcode on corner wrap case away from the corner is being implemented at internal plants as a change request.

- **CMO:** Plants are approaching conversion and proceeding with previous guidance to avoid further delay. Change request will be handled after conversion to address updated guidance.

- **SSCC Barcode for Partial Case Labels:** Printing at packaging lines is currently not in functionality. Dependent on a future function in software at packaging sites.

- **Legacy Stock:** Expect to work through currently produced design as we use stock in 2017 but will need to monitor as above changes are complete.
## Related Lessons Learned in Serialization Programs

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMO Management</td>
<td>Contract manufacturing conversions are significantly more involved and have longer lead times due to the complexity.</td>
</tr>
<tr>
<td>Serialization Data Accuracy</td>
<td>Quality of aggregation takes monitoring and time to stabilize. Involve downstream parties and processes in testing for flow of data.</td>
</tr>
<tr>
<td>End to End Label Testing</td>
<td>Labels will vary across plants as it is dependent on many factors. It was necessary to build a central internal label testing process beyond existing manufacturing quality processes to test use of labels from packaging through distribution.</td>
</tr>
</tbody>
</table>
Questions?
HDMA Barcode Webinar
Serialized Labeling

May 19, 2016
Moving to a Serialized World
Impact of serialized product labeling

Not all labeling is created equal… data and industry standards are more complex for serialized labeling; more prone to errors

Technology is different… scanning a 1 dimension barcode vs. a 2 dimensional DataMatrix comes with additional challenges

Consistency is key… to ensure repeatable and efficient processes; need to reach constancy on case and each serialized labeling
Moving to a Serialized World
Converging to a standard
Moving to a Serialized World

Product labeling: Good examples

Encoded to GS1 Standards
Human readable (HR) close to 2D →
Clear identification of HRI

Sealed “Each”
Eliminates potential returns issue
Moving to a Serialized World

Product labeling: Room for improvement

Incorrectly coded barcodes
Barcodes falling off (adulterer product)
Missing Human Readable (HRI)

What the heck is a UID?
(yes.. It’s the serial number)

Incorrectly coded barcodes
Using NDC instead of GTIN
Moving to a Serialized World

Product labeling: Room for improvement

GS1 Compliant 2D DataMatrix
Readable by iPhone application… but not $2500 scanners

<table>
<thead>
<tr>
<th>Quality Parameter</th>
<th>Result</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbol Grade</td>
<td></td>
<td>F</td>
</tr>
<tr>
<td>Cell Modulation</td>
<td></td>
<td>F</td>
</tr>
<tr>
<td>Fixed Pattern Damage</td>
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<td>F</td>
</tr>
<tr>
<td>Reference Decode</td>
<td></td>
<td>F</td>
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<td>Axial Non-Uniformity</td>
<td>+0.009</td>
<td>A</td>
</tr>
<tr>
<td>Unused Error Correction</td>
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<tr>
<td>Grid Non-Uniformity</td>
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<td>Cell Growth (CGH)</td>
<td>+16.388 mils</td>
<td></td>
</tr>
<tr>
<td>Cell Growth (CGV)</td>
<td>+16.020 mils</td>
<td></td>
</tr>
</tbody>
</table>

Need to ensure proper grading and quality inspection of 2D barcodes at the point of packaging
Moving to a Serialized World
Lessons learned from AmerisourceBergen’s serialization pilot

Serialized data in vulnerable position on packaging

Proposed HDMA Label Guidance Revision
Moving to a Serialized World
Lessons learned from AmerisourceBergen's serialization pilot

Which label do we scan??

100% Compliant Labels
Can’t Scan… Reflective Glare
Moving to a Serialized World

Other opportunities

- Barcode Quality and Verification
  - Ensure downstream, consistent, readability

- Serialized Pallet Labeling
  - Constantly identify *which* SSCC label to scan

- Partial Product Cases
  - Labeling of last batch partial case/bundle/inner-pack; use of SSCC

- Mixed Product Cases
  - Consistent labeling of non-pallet logistics containers
Where knowledge, reach and partnership shape healthcare delivery.
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Save the Date

Traceability Seminar

November 9 – 11, 2016 | Washington, DC

http://www.healthcaredistribution.org/events
Thank you to our sponsor
Contact HDMA

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Thank you