Case Studies: Sharing Lessons Learned

Panel:
Dennis Black, Director, e-Business, BD
Megan Brandt, VP Quality & Regulatory Affairs, Cardiovascular Systems, Inc.
David Reed, VP Operations, Cook Medical
Esther Carbon, Sr. Manager, Global Regulatory Labeling, RTI Surgical, Inc.
Panel Topics:
• Overview of current UDI Programs
• Challenges
• Benefits realized to date
• Where are you headed now?
Case Studies: Sharing Lessons Learned

2016-04-18

Dennis Black, BD
BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance cellular studies and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, optimize respiratory care and support the management of diabetes. The company partners with organizations around the world to address some of the most challenging global health issues. BD has more than 45,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. For more information on BD, please visit www.bd.com.
From a UDI Perspective:
- Class III
- Class II Life Sustaining
- Class II
- Class I

Products Include:
- Capital Equipment
- Disposable Products
- In Vitro Diagnostics
- Surgical Equipment
- Products sold at retail
Use of Data Standards:

Pre-2000
- Began working with GS1 predecessor in 1972
- Gained experience using GS1 standards in retail
- Multiple standards
- Fully aligned use of GS1 standards for ERP implementation

Post-2000
- Supply Chain integration of data standards
- Continuous effort to implement additional standards and processes
- Breakthroughs on commercial integration processes

All of this product identification work preceded FDA’s UDI rule
UDI Efforts Include:

Initial UDI Work:
- Reviewing applicable UDI data, GTIN assignment, and labels to conduct a gap analysis
- Internal education on UDI Requirements
- Confirming understanding of FDA UDI Rule
- Verifying Non-US Requirements & IMDRF guidance
- Forming UDI Team

Current Efforts:
- Revising ERP and Other System to Store UDI Data
- Revising policies, procedures and processes to comply with UDI
- Retooling/Printing Processes/Reassigning GTINs if necessary
- Label revision process
- Populating UDID
- Revising commercial processes

*We are moving from the voluntary adoption of data standards to compliance with a regulation.*
Case Studies: Sharing Lessons Learned

2016-04-18

Megan M. Brandt
Cardiovascular Systems, Inc.
CSI is devoted to developing and commercializing innovative solutions for treating both peripheral arterial disease (PAD) and coronary artery disease (CAD).

- Orbital Atherectomy Systems
Key Activities

- Establishment of Cross Functional Team & SME
- Barcode Vendor Selection
- Device Prioritization
- Quality System Process Impact
- Customer Notification
- Training
CASE STUDIES:
Sharing Lessons Learned

April 18, 2016

David Reed, Cook Medical
Cook Medical Overview

- 8 manufacturing companies
- 10 clinical divisions
- Coverage in 135 countries
- 16,000 SKUs
Cook Medical Circa 1999
The Steps We Took

- Recognized that we needed a standard product language
- Consolidated our global product catalog
- Chose a standard and assigned GTINs to all of our products
- Labeled inventory with GTINs
- Published data to GDSN
Implementing a Global Standard

1999
376,000 SKUs representing 20,000 parts

2001
Created global Cook product database

2003
 Implemented GS1 standards on labels (GTIN-14 and other Al’s)

2005
 Created Cook Americas customer service center (CMI)

2012
Validated and aligned packaging level indicators on labels
Published attributes to GDSN
Transacting with GTINs

FUTURE
Working towards full UDI compliance
Piloting GS1 standards’ use in Cook Manufacturing Supply Chain

UDIconference.com
Cook Medical Today
Case Studies: Sharing Lessons Learned
April 18, 2016

Esther Carbon, Sr. Mgr. Global Regulatory Labeling
RTI Surgical, Inc.
• Leading global surgical implant company

• Provides surgeons with biologic, metal, and synthetic implants as well as instruments

• Implants used in sports medicine, general surgery, spine, orthopedic, trauma, dental and cardiothoracic procedures.

• Headquartered in Alachua, Fla.
  • Additional U.S. locations (5)
  • International locations (4)
Role in UDI implementation

- Coordinator
- External agency contact – industry groups
- Project manager/ Labeling SME
UDI Challenges and Lessons Learned
UDI Challenges Include:

- Lack of label space
- Eliminating NDC/NHRIC Codes
- Aligning UDI Implementation with customer needs
- Market preferences for AIDC markings
- Interpretations of Issuing Agency Specifications (Myths and Internal Needs)
- Internal education and alignment
- Eliminating barcodes that are integrated with existing equipment
- Alignment of validation processes
UDI Challenges Include:

• Who is the labeler?

• Ensuring US UDI program doesn’t conflict with non-US requirements

• Trading partner requests that conflict with UDI requirements

• Direct part marking

• Date format: 8 digits on package vs 6 digits in barcode

• Ensuring alignment throughout the organization

• Communicating UDI changes
UDI Challenge: Label Space

CompuHyper GlobalMed®
Ultra Implantable™
Fictitious Medical Device
2.25 mm x 8 mm

Slide 23
UDI Challenge: NDC/NHRIC/HRI in Retail

* See FDA Document: Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices (Draft Guidance for Industry and Food and Drug Administration Staff)
UDI Strategy

- Device Classification
- Device Manufacturer
  - Who is the labeler?
  - Build GUDID Assessment into Supplier Quality System
- Device vs. Accessory
- Reusable Devices
- UDI Packaging Configurations
  - Multi-Packs vs. Single
Labels

• Barcode Selection
  – GS1, HIBBIC, ICCBA
• Expiration Date - YYYY-MM-DD
• Linear vs. 2D
• Label Verification/Validation
  – GS1 Verification - Barcode size & layout (Readability Zone)
  – CSI Validation - Fixed, variable from ERP to Label
• Challenges
  – Fitting bar code on current label stock
  – Changed label die cut to fit GTIN
  – Reduced number of peel off stickers
Internal Processes

- ERP Updates
  - GTIN—Standard Functionality
  - UDI—GTIN, Expiration Date, Lot
    - Customized Change

- Quality System Impact Assessment
  - Design Control
  - Complaints/MDR
  - ECO
  - Supplier Request for Change
  - Incoming Inspection (Supplied Finished Devices)
  - Return Goods Authorizations
GUDID

– Understanding field requirements and terms
– Editing rules
  • New GTIN vs. Update
– Post-Publishing Editing
  • What fields can be changed once published to the GUDID?
Key Takeaways

• Start Early
• Functional Team
  – Quality, Operations, Engineering, IT, Customer Service, Regulatory, Marketing
• Quality System Integration
• Training
• Leverage Available Resources
  – FDA guidance
• Ask Questions
GS1 Standard vs. UDI

**Data standard**: A common language for trading partners to use about products that pass through the supply chain.

<table>
<thead>
<tr>
<th>SAME DATA. DIFFERENT NAMES.</th>
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<tbody>
<tr>
<td>UDI</td>
</tr>
<tr>
<td>Unique Device Identification</td>
</tr>
<tr>
<td>DI</td>
</tr>
<tr>
<td>Device Identifier</td>
</tr>
<tr>
<td>PI</td>
</tr>
<tr>
<td>Product Identifier</td>
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<tr>
<td><em>(if applicable)</em></td>
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*Product identifier data will vary by medical device type and manufacturer current practice.*

| DI + PI = UDI | GTIN or GTIN + AI(s) = UDI |
Challenges

1. Varying global logistics of products and impact of UDI labeling changes
2. Impact of labeling changes to support UDI on global regulatory submissions
3. Underestimating the resource load of data review
4. Legal/contractual, regulatory and other implications of another “person-in-charge”, the labeler
5. Impact of UDI decisions on global business – e.g., selecting GS1 vs HIBCC
6. Cost of UDI implementation
7. Groups of products for which UDI was not considered e.g., non-sterile implants
   (success of industry groups in addressing major issues)
Benefits Realized to Date
Benefits Realized to Date:

• The UDI rule is sparking conversations on healthcare provider adoption
• Other countries seem to be aligning to FDA UDI rule
• Generally, UDI is aligned with customer tracking needs
• UDI Rule is aligned with most supply chain use of the standards
Benefits
Value in healthcare is a function of quality, efficiency, safety, and cost.
Improved Patient Safety

• Identifies: Right product, right patient, right time
• Is scanned at the bedside
• Helps prevent medication errors
• Combats counterfeit products
• Facilitates recalls

Image source: http://www.gs1eg.org/Sectors-Healthcare-100.htm
Improved Operational Efficiency

Electronic Transaction sets:
• No Human Intervention
• Purchase Order
• PO Confirmation
• Invoice
• Payment

Accuracy:
• Correct Product
• Correct Location
• Correct Quantity
• Correct Price

Timeliness:
• Delivered On Time
• Inventory Visibility
• Purchase History Visibility
UDI / GTIN is Just A Number
Improved Patient Safety

- Identifies: Right product, right patient, right time
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Image source: http://www.gs1eg.org/Sectors-Healthcare-100.htm
Benefits

1. Global product data standardization and management
2. Understanding logistical considerations for each product (intra-company as well as at end-user)
3. Process has set foundation for other improvements
Where are you headed now?
Where are you headed now?

Current Work:
• Still have much implementation work for Class 2 and Class 1
• Involved with several GS1 Work Teams
• Resolution of NHRIC/NDC Resolution
• General Process & ERP Refinement
• GUDID Submissions
• Commercial integration

Future Work:
• Non-US UDI/Data Standards Work
• Ensure sustainability of UDI processes
Looking to the Future

- Healthcare Provider Awareness / Adoption
- EHR Integration
- Patients / Caregivers Awareness
- MDEpiNET – RAPID Project
Plan Forward

- Improve global product data management with new tools and processes
- Transition UDI management from a centralized team to responsibilities by subject area (five-year plan)
- Improve barcode and other data capture methodologies
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