Time’s Up:
Learn Rules for September UDI Deadline

June 9, 2015

Presenters:
Haley Lentz    Account Executive, Life Sciences
Gary Saner    Sr. Manager, Information Solutions - Life Sciences

In collaboration with Joe Hage and the LinkedIn Medical Devices Group
Agenda

- Reed Tech Company Profile
- FDA UDI / GUDID Refresher
- UDI/GUDID Lessons Learned
- Reed Tech GUDID Submission Solution Overview
- Q&A
Questions

Please send questions during the session to “Staff” via webinar “Chat”
Reed Tech Company Profile
Reed Tech – Company Profile

A recognized leader in providing solutions for content and lifecycle management

- Over 50 years of experience; founded in 1961
- Part of LexisNexis and Reed Elsevier
- Over 900 employees
- Sole contractor processing patents for USPTO
- Provider of regulatory data management and submission solutions to the Life Sciences industry

ISO Certified since 1998 (9001:2008)
HL7 Member since 2005
GS1 Solution Partner

Philadelphia Headquarters
Horsham, PA, USA
Washington D.C. Operations
Alexandria, VA, USA
European Office
Leiden, Netherlands
SPL* Preparation, Submission, and Lifecycle Management for Drug Establishment Registration and Drug Product Labeling/Listing

• Over 850 Pharma Customers
  - Small (1 label) to large (200+ labels) companies
  - 4 of the 5 largest pharma manufacturers in the world
  - Over 70 companies in over 25 countries outside the U.S.

• Most Experienced SPL Service Provider in the Industry
  - Since 2005 SPL mandate
  - Experts in CDER, CBER, and CVM Drug SPLs (LCR, ER, SID, LL, DSD, LDR)
  - Data Transformation & Validation; SPL Build & Lifecycle Mgm’t

• FDA Electronic Submissions Gateway (ESG) Service
  - Highest volume submitter of pharma SPLs
  - Over 450 companies

* SPL= Structural Product Labeling, HL7 XML standard adopted by FDA for submission of medical product information
SPL Preparation, Submission, and Lifecycle Management for Medical Device product publication in FDA’s GUDID

• Over 45 Medical Device Customers
  - Small (1 record) to large (250,000 records) manufacturers
  - 1 of the 3 largest Medical Device manufacturers in the world
  - 5 manufacturers have international users

• Experienced 3rd Party Submitter to the GUDID
  - 100% acceptance (comprehensive pre-submission quality check)
  - As of 28 Oct 2014, Reed Tech submitted ~34% of the total SPL records submitted to GUDID
  - Current contracts to submit over 500,000 additional SPLs
  - FDA ESG AS2 connection for automated, bulk SPL submissions
  - 21 CFR Part 11 compliant system for data processing/mgmt

• Roadmap to Support International UDID Submissions
  - Expanded/different data sets of IMDRF and regional UDID attributes
  - Build/submit UDI data per regional UDID specifications
FDA UDI / GUDID Refresher

Please send questions during the session to “Staff” via webinar “Chat”
FDA UDI Regulation Overview

Label
- UDI (Device Id + Production Id) on Device Label & Pkg
- UDI in human-readable plain-text and Automatic Id and Data Capture (AIDC) technology (e.g., 1D/2D barcode, RFID)
- Date Format YYYY-MM-DD (e.g., 2013-09-24) (except AIDC date must use Issuing Agency date format)

Direct Marking (DM)
- Permanently mark UDI on multiple use and reprocessed devices

FDA Global UDI Database (GUDID)
- Submit DI and device attributes to GUDID (NLM provides public portal, “AccessGUDID,” to FDA GUDID)

Reporting – include UDI as available

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Definitions

- **UDI** = Device Identifier + Production Identifier(s) = DI + PI(s)
- **GUDID Data** = DI (not PI) + Device Attributes = 55 Submitted Fields
FDA Label/GUDID Data

GUDID Data (directly)

CompuHyper GlobalMed®

Unique Medical Device

Brand Name

GMDN Description

Device Count

Production Identifier: Expiration Date

Production Identifier: Manufacturing Date

Storage & Handling Information

Device ID

Production IDs

Qty: 1 each
Size: 20mm x 12.5mm

REF Z1234

Size

Catalog Number

Unique Device Identifier (DI & PI)

Production Identifier: Serial Number

Production Identifier: Lot Number

Single Use

GUDID Data (needs coding)

CompuHyper GlobalMed, LTD
101 Innovation Drive.
New Sales, MD 20599-0100

CompuHyper GlobalMed, LTD
XXX-867-5309 (USA)
XXX-555-3226 (Outside USA)
http://www.compuhypergm.com

Labeller Name & Physical Address

Customer Contact Information

Reference: FDA webinar
“Ready For GUDID” 2015-01-14

www.ReedTech.com
1) FDA UDI Final Rule published 2013-09-24
2) I/LS/LS = Implantable, Life-supporting, and Life-sustaining devices
3) Direct Marking required on multiple-use and reprocessed devices
UDI/GUDID Lessons Learned

Please send questions during the session to “Staff” via webinar “Chat”
12 Step UDI/GUDID Plan

**UDI Prep**
1. Create UDI Governance Team
2. Research/Identify FDA UDI Requirements for Your Products
3. Evaluate Your Situation and Applicable Exemptions/Extensions
4. Define and Implement UDI Labeling Plan

**GUDID Prep**
5. Evaluate, Select, and Implement GUDID Solution
6. Create FDA Accounts (GUDID, ESG)
7. Collect Source GUDID Data
8. Normalize and Validate Source GUDID Data

**Production**
9. Submit GUDID Data to FDA
10. Process ACK Messages
11. Initiate & Maintain Data and System
12. International Readiness

http://www.medicaldevicesgroup.net/webinar/UDI-2015/
GUDID Submission Methods

Medical Device Manufacturer (MFR)

GUDID Submission Data

Manual Data Entry

FDA GUDID Web Interface

Admin

Software Buy / Build / Upgrade

Admin

Hosted Software (SaaS)

Admin

Outsourced Service

FDA GUDID

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<table>
<thead>
<tr>
<th>Submission Method</th>
<th>Description/Comments</th>
<th>Technology Cost</th>
<th>Operations Cost</th>
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<tbody>
<tr>
<td>FDA GUDID Web Interface</td>
<td>• You (or third party) enter data directly into the FDA GUDID</td>
<td>• “No” software cost</td>
<td>• Your admin, data entry, &amp; QA labor</td>
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<tr>
<td></td>
<td>• Best suited for low volume</td>
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<td></td>
<td>• Transcription error concern</td>
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<td></td>
<td>• Limited international reuse</td>
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<tr>
<td>Internal Software</td>
<td>• Buy / build / upgrade software (ERP, PLM, MDM, Labeling or other) to collect data</td>
<td>• “Own” software (buy/build/upgrade, install, validate, train, maintain)</td>
<td>• Your admin &amp; operations labor</td>
</tr>
<tr>
<td></td>
<td>and build SPLs</td>
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<tr>
<td></td>
<td>• Submit SPLs to FDA via the ESG (AS2)</td>
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<td></td>
</tr>
<tr>
<td>Hosted Software (Software as a Service)</td>
<td>• Use external software to collect data, build, and submit SPLs to FDA via the ESG</td>
<td>• “Rent” software</td>
<td>• Your admin &amp; operations labor</td>
</tr>
<tr>
<td></td>
<td>• High volume submissions</td>
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<td></td>
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<tr>
<td>Outsourced Service</td>
<td>• External provider accepts your data, builds, and submits SPLs to FDA via the ESG</td>
<td>• “Rent” software</td>
<td>• “No” internal Admin &amp; operations labor</td>
</tr>
<tr>
<td></td>
<td>on your behalf</td>
<td></td>
<td>• Service cost</td>
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# FDA GUDID Data Attributes

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<tr>
<th>Identification</th>
<th>Regulatory</th>
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<th>Characteristics</th>
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<td>Pri DI Issuing Agency</td>
<td>Publish Date</td>
<td>Device Count</td>
<td>Single Use (Y/N)</td>
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<tr>
<td>Primary DI #</td>
<td>Distribution End Date</td>
<td>Unit of Use DI #</td>
<td>Combo Product (Y/N)</td>
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<tr>
<td>Brand Name</td>
<td>Distribution Status*</td>
<td>Kit (Y/N)</td>
<td>HCT/P (Y/N)</td>
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<tr>
<td>Version/Model #</td>
<td>Premrkt Exempt (Y/N)</td>
<td>Pkg DI #</td>
<td>Contains Rubber (Y/N)</td>
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<tr>
<td>Catalog #</td>
<td>Premrkt Submission #</td>
<td>Pkg Quantity</td>
<td>Not Made with Rubber (Y/N)</td>
</tr>
<tr>
<td>Device Description</td>
<td>Supplement #</td>
<td>Pkg Contains DI #</td>
<td>MRI Safety Info</td>
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<tr>
<td>Sec DI Issuing Agency</td>
<td>FDA Listing #</td>
<td>Pkg Type</td>
<td>Size Type</td>
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<tr>
<td>Secondary DI #</td>
<td>Product Code</td>
<td>Pkg Discontinue Date</td>
<td>Size Value</td>
</tr>
<tr>
<td>DM Exempt (Y/N)</td>
<td>Product Code Name*</td>
<td>Pkg Status*</td>
<td>Size Unit</td>
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<td>DM DI Different (Y/N)</td>
<td>GMDN Code</td>
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<td>Size Text</td>
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<td>DM DI #</td>
<td>GMDN Name*</td>
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<td>Storage &amp; Handling Type</td>
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<td>GMDN Definition*</td>
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<td>S&amp;H Low value</td>
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<td>Rx (Y/N)</td>
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<td>OTC (Y/N)</td>
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<td>Serial # (Y/N)</td>
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<td>Mfg Date (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Expiration Date (Y/N)</td>
<td></td>
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<tr>
<td>Donation Id # (Y/N)</td>
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</tbody>
</table>

55 Submitted by Labeler
(some can have multiple values)
7 Populated by FDA GUDID System

* Populated by FDA GUDID System
Normalize & Validate Source GUDID Data

- “Normalize” data to FDA GUDID specs
  - Follow **FDA Business Rules**. For example:
    - GS1 GTINs must be 14 numeric characters
    - Date Format must be YYYY-MM-DD
  - Where applicable, ensure values utilize **Controlled Vocabularies**. For example:
    - “cm” for Size Unit of Measure
    - “Cel” for Temperature (Degrees Celsius)
  - For **grouped data**, all necessary related fields must be populated. For example:
    - Clinically Relevant Size Type = Length
    - Clinically Relevant Size Value = 25
    - Clinically Relevant Size Unit = cm
  - For **dependent data**, all necessary related fields must be populated. For example:
    - If “Require Sterilization prior to use?” = “Yes,” then “Sterilization Method” must be populated

- **Validation of all content**: the key to accuracy for your SPL submissions to the FDA
  - “Problematic” Data Elements from our experience. For example:
    - Labeler DUNS Numbers
    - Device Identifiers assignment
    - GMDN or FDA Preferred Term Values
    - Packaging and Kit Configurations

Data Validation is a Reed Tech core competency ... we can help
Survey Results – Your GUDID Solution Preferences

Where are you in the UDI compliance process? (171 responses)

- Have not started: 22%
- Started Planning only: 43%
- Have implemented some...: 21%
- Have completed: 1%
- Not applicable: 13%

How are you planning on completing the GUDID submission requirement? (224 responses)

- FDA GUDID Web Interface: 31%
- Internally developed solution: 12%
- Purchased software: 4%
- Service provider: 13%
- Uncertain or Not Applicable: 40%

If you are submitting I/LS/LS UDI data to the FDA, and taking into consideration the September 24, 2015 deadline, when are you anticipating making your submissions? (159 responses)

- Started Already: 4%
- June: 5%
- July, August: 14%
- September: 4%
- Uncertain or Not Applicable: 72%

If you are submitting Class II UDI data to the FDA, and taking into consideration the September 24, 2016 deadline, when are you anticipating making your submissions? (165 responses)

- Already started: 8%
- Will start 4Q 2015: 18%
- Start Jan - May 2016: 21%
- Start Jun - Aug 2016: 4%
- Start Sep 2016: 48%
- Uncertain or not applicable: 1%

www.ReedTech.com
GUDID Submission Solution Overview
Life Sciences Portal (LSP-UDI)

Please send questions during the session to “Staff” via webinar “Chat”
Reed Tech GUDID Solution

Medical Device Manufacturer

- Collect GUDID Data
  - PLM
  - MDM
  - ERP
  - RA
  - Labeling

Transfer Data
- XLS
- XML
- TXT
- GDSN

Life Sciences Portal – UDI System

Import Data Files
- Validate
- Transform
- Merge
- Load

Prepare Data
- Edit or Reload
- Review
- Approve

Process Submission
- Build and Validate SPL
- Submit SPL
- Process Acknowledgment (ACK)

FDA (EC, HC, CFDA)

LSP – UDI Database

- UDI Data
- Custom Fields
- Data, SPL, & ACK File
- Reports, Audit Trail

Reports, Updates

Controlled Vocabulary

Industry Standards

MFR (SaaS) or Reed Tech (Outsourced) User

Commercial Data Pool

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Reed Tech UDI Solution Benefits

**Simple**
- Focused GUDID Submission Function

**Least Intrusive**
- Complements Current Systems & Data

**Saves Time**
- Fast Startup
- Data Merges & Transforms

**Cost Effective**
- Automated Bulk Submissions
- Saves IT Costs

**Flexible**
- SaaS/Outsourced Models
- Future OUS UDID

**21 CFR Part 11 Compliant**
- Audit Trail

Only **75 work days** until FDA I/LS/LS submissions are due! Reed Tech Solution can easily meet this deadline

www.ReedTech.com
Reed Tech Contact Information

Haley Lentz  Account Executive, Life Sciences
hlentz@reedtech.com

Andrew Pfeifer  Account Executive, Life Sciences
apfeifer@reedtech.com

Phone:  1-800-772-8368   or   +1-215-734-6536
Web:  www.ReedTech.com
Reference Material
Available from ReedTech.com:

- GUDID Readiness Kit
- Reed Tech GUDID Data Element List
- Multiple Options To Weigh For Moving A UDI Into FDA’s Database
  “The Gray Sheet” 6 January 2014
  [http://go.reedtech.com/gray-sheet-article-0](http://go.reedtech.com/gray-sheet-article-0)
- UDI Training Course (in collaboration with Lernia Training Solutions)

Available Upon Request:

- Sample GUDID Account Request Form
- Reed Tech GUDID Record Template
UDI Resources

FDA

- UDI “Home Page”
  - UDI Rule, GUID Guidance, Compliance Dates, Resources

- UDI Help Desk

- GUDID Information
  - Basics, Guidance, Account Request, GUDID Web Interface, HL7 SPL, GUDID Status

- GUDID Web Interface (Login)
  - https://gudid.fda.gov/gudid/

- CDRH Resources (FDA Presentations: GUDID overview, account setup, etc.)

IMDRF – www.imdrf.org

EC Medical Devices – http://ec.europa.eu/health/medical-devices
Global UDI Activities

- **International Medical Devices Regulatory Forum (IMDRF)**
  - Cornerstone of global medical device regulatory direction
  - Group of Medical Device Regulators (Australia, Brazil, Canada, China, EU, Japan, Russia, U.S.)

- **A single worldwide UDid is Not Expected**
  - Regional UDIDs are expected to contain core information and have varying regional content
    - “Convergence, not Harmonization”
  - EU UDI mandate possible in 2016?
# Global UDID Data Elements

<table>
<thead>
<tr>
<th>Data Element</th>
<th>FDA</th>
<th>IMDRF</th>
<th>EC</th>
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<tbody>
<tr>
<td><strong>Device Information</strong></td>
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<tr>
<td>Primary DI Issuing Agency</td>
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<tr>
<td>Unit of Use DI Number</td>
<td>FDA</td>
<td>IMDRF</td>
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<td>Labeler DUNS Number</td>
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<td>Company Name</td>
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<td>DI Record Publish Date</td>
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<td>Device Subject to DM, but Exempt?</td>
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<td>DM DI Number</td>
<td>FDA</td>
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<td><strong>Device Status</strong></td>
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<td>HCT/P?</td>
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<td>Kit?</td>
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<td>Combination Product?</td>
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<td><strong>Device Characteristics</strong></td>
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<td>For Single-Use?</td>
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<td>Lot or Batch Number Control?</td>
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<td>Manufacturing Date Control?</td>
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<td>Expiration Date Control?</td>
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<td>Device required to be labeled as conta</td>
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<tr>
<td>Device labeled as &quot;Not made with nat</td>
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<td>Prescription Use (Rx)?</td>
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<td>Over the Counter (OTC)?</td>
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<td>Storage and Handling Type</td>
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<td>S&amp;H Low Value</td>
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<td>Special Storage Conditions</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Device Packaged as sterile?</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Requires Sterilization Prior to Use?</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Authorized Representative's name</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Authorized Rep. contact information</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>SaMD version;</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Restricted number of reuses</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>URL for additional information</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Labeled as containing DEHP?</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
<tr>
<td>Critical warnings or contraindications</td>
<td>FDA</td>
<td>IMDRF</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL** 62 44 32
### Medical Device UDI Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AIDC</strong></td>
<td><strong>Automatic Id and Data Capture</strong> – technology used for automated product identification (typically 1D/2D barcode, RFID, near-field communication, etc.)</td>
</tr>
<tr>
<td><strong>DI</strong></td>
<td><strong>Device Identifier</strong> – static product identification (uniquely identifies company and product version)</td>
</tr>
<tr>
<td><strong>ESG</strong></td>
<td><strong>Electronic Submissions Gateway</strong> – FDA agency-wide secure solution for accepting electronic regulatory submissions in electronic, bulk format</td>
</tr>
<tr>
<td><strong>GUDID</strong></td>
<td><strong>FDA Global UDI Database</strong> – registry of Medical Device DI and attributes</td>
</tr>
<tr>
<td><strong>GS1</strong></td>
<td>GS1 – an international, not-for-profit association that develops global standards (e.g., Global Trade Item Number-GTIN and Application Identifiers-AI) to improve the efficiency and visibility of supply and demand chains across sectors; <a href="http://www.gs1us.org">www.gs1us.org</a></td>
</tr>
<tr>
<td><strong>Issuing Agency</strong></td>
<td>FDA approved agency (standard) used to represent Medical Device UDI (GS1, HIBCC, and ICCBBA)</td>
</tr>
<tr>
<td><strong>HIBCC</strong></td>
<td><strong>Health Industry Business Communications Council</strong> – a non-profit organization that develops electronic exchange standards (e.g., Health Industry Bar Code-HIBC) for health care trading partners; <a href="http://www.hibcc.org">www.hibcc.org</a></td>
</tr>
<tr>
<td><strong>HL7</strong></td>
<td><strong>Health Level Seven</strong> – standards developing organization providing international healthcare information system interoperability standards for the exchange, integration, sharing, and retrieval of information</td>
</tr>
<tr>
<td><strong>ICCBBA</strong></td>
<td><strong>International Council for Commonality in Blood Banking Automation</strong> – international standards organization (not-for-profit, nongovernmental) responsible for the ISBT 128 Standard (International Standard for Blood and Transplant); <a href="http://www.iccbba.org">www.iccbba.org</a></td>
</tr>
<tr>
<td><strong>PI</strong></td>
<td><strong>Production Identifier</strong> – dynamic manufacturing information (i.e. batch/lot #, serial #, mfg. date, expiration date, and HCT/P code)</td>
</tr>
<tr>
<td><strong>SPL</strong></td>
<td><strong>Structured Product Labeling</strong> – document markup standard (XML) approved by HL7 and adopted by FDA as a mechanism for exchanging product information</td>
</tr>
<tr>
<td><strong>UDI</strong></td>
<td><strong>Unique Device Identifier</strong> = <strong>Device Identifier (DI)</strong> + <strong>PI (Production Identifier)</strong> per approved Issuing Agency</td>
</tr>
<tr>
<td><strong>XML</strong></td>
<td><strong>Extensible Markup Language</strong> – markup language defining a set of rules for document encoding in both human and machine readable language.</td>
</tr>
</tbody>
</table>
Questions & Answers

Please send questions during the session to “Staff” via webinar “Chat”