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Implementation of UDI In the Medical Device Industry

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Overview of Presentation

1. Industry Opportunities
2. US FDA Commitment to an Effective Implementation of UDI (Demonstrating the Importance of Guidance)
3. Lessons Learned
4. Remaining UDI Implementation Challenges
5. Foundational Elements Needed for a Successful Implementation of UDI
6. References

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UDI Opportunities for Industry

- FDA and EU Commission acknowledge the **importance of using the existing global standards for product identification** to **accommodate existing business systems and practices**, thereby avoiding the need to create supplementary systems and practices for Unique Device Identification.
- Implementation of Unique Device Identification in an AutoID format (bar code) on product packages will **enhance the healthcare providers ability to capture and record accurate product identifiers in business systems, processes to the point of patient care**.
- Many **manufacturers are already using the global product identification standards of the "issuing agencies"** for supply chain automation and efficiency.

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Commitment to an Effective Implementation

The Importance of Guidance

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Commitment to Successful UDI Implementation

- FDA has provided a **very collaborative environment** between industry and the agency to work through difficult implementation issues.
- FDA acknowledges UDI implementation **requires a learning process** as we cannot anticipation every situation given the diversity of device types, the magnitude and volume of device types.
- FDA has provided **multiple communication channels** for industry to ask questions, provide feedback, and work together.

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FDA Collaboration Efforts with Industry

- **Many public forums dating back to 2005** for UDI education and public comment on UDI
- **Bi-annual UDI conferences led by FDA** allows industry stakeholders to learn and help educate on UDI implementation
- GUDID **training and education webinars**
- GUDID **user group sessions**
- **FDA Help Desk Service** and resources to assist industry with implementation questions

- Provided an **Exception Process for Manufacturers** to apply for exceptions and/or alternative methods for marking UDI
- Provided additional **Guidance Documents** after the publishing of the rule to address issues or challenges that arise

UDI Guidance Provided by FDA as a Result of Collaboration and Adjudication Process

UDI GUIDANCE DOCUMENTS ISSUED by FDA
UDI Policy Regarding Compliance Dates for Class I and Unclassified Devices - January 16, 2018
Direct Marking of Devices: Guidance for Industry and Food and Drug Administration – November 17, 2017
FDA UDI Alternative: UDI-A170001 – Alternative for Existing Inventory **-** April 7, 2017
Enforcement Policy (extension) for NHRIC and **NDC** assigned to Devices: August 30, 2016
Form and Content of Unique Device Identifier (UDI): Draft Guidance for Industry & FDA Staff: July 25, 2016
Convenience Kits: Draft Guidance for Industry and Food and Drug Administration Staff: January 4, 2016
Database (GUDID): Data Submission Compliance Date of September 24, 2015 - Guidance for Industry and Food and Drug Administration Staff: August 14, 2015
Frequently Asked Questions, Vol. 1 - Guidance for Industry & Food and Drug Administration: August 20, 2014
Small Entity Compliance Guide: Guidance for Industry & Food and Drug Administration Staff: August 13, 2014
Database (GUDID): Guidance for Industry and Food and Drug Administration Staff: June 27, 2014
FDA's UDI LETTERS TO INDUSTRY
Letter of Intent to Extend Timelines for Class I and Unclassified Devices: June 2, 2017
Extension Letter to Rigid Gas Permeable Contact Lens Manufacturers: September 22, 2016
Extension Letter for Certain Class II devices (kits, repackaged, combination): September 6, 2016
Availability at Implant, Extending Inventory Depletion Timelines for Consigned Devices: March 22, 2016
Extension Letter to Soft Contact Lens Labelers: October 6, 2015
Letter to IOL Labelers re: GUDID Submissions: July 10, 2015
Extension Letter to Implant (non-sterile) Labelers: November 19, 2014
Extension Letter to Class III Contact Lens and Intraocular Lens Labelers: August 15, 2014

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Exceptions, Alternatives & Extensions in the Rule

- FDA UDI rule provides a mechanism to request exceptions, exemptions, alternatives and extensions of time for certain portions of the rule
- Enables manufactures to address implementation challenges in a positive and constructive manner

	October 2014	June 2015	April 2016	June 2017
GUDID Labeler Accounts	240	425	1275	4410
GUDID Records	33,000	75,000	570,000	1,440,277
Total Helpdesk Inquiries	4000+	8000+	16,400	30,836
Helpdesk Closure Rate	91%	95%	86%	97.9%

Compliments: Linda Sigg, Associate Director Informatics - FDA CDRH

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Lessons Learned

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Key Learnings

- Initial **Implementation Timeline should be at Least 2 Years**
  - IT systems design and process implementation considerations
  - Device labeling must be prepared as much as one year in advance of product release
  - Numerous implementation questions required clarity from FDA, which took more than one year
  - Phased approach based on risk classification
- Appropriate Role of the **Date of Manufacture in AIDC**
- **Managing through mergers and acquisitions**, as well as third party relationships (e.g. suppliers and distributors)
- **Multiple to Device Identifiers** (DI) assigned to one device according to issuing agency rules

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Exempt Devices Manufactured Prior to Effective Date

- UDI rules **should not apply to devices manufactured or labeled prior to the compliance dates of the rule**
  - Many devices have long shelf lives
  - Healthcare systems may rely on consignment inventory

- Locating, removing, storing, and/or reworking devices after the compliance date to either re-label or destroy is unproductive and could lead to product shortage

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Remaining Implementation Challenges

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Capital Equipment & Accessories

- Capital equipment may be challenging for some UDI application (MRI, CT, Xray, Mammography…)
  - Often these are configured specifically for customers – potentially hundreds of configurations
  - May have individual medical device components that make up the system
  - Many accessories apply to these devices, each often with their own UDIs
  - Requirements to apply UDI to “combinations of product” could be difficult to manage, confusing and lead to ambiguity

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Label Placement & Upgrades

- Labeling challenges
  - Accessibility to users – where on the device should the UDI label be applied? Capitol equipment → multiple components, often in different rooms make up a single device
  - Multiple UDI labels – which label(s) apply to the system
- Upgrades
  - Medical device upgrades (adding new clinical functionality versus providing a "patch") – results in multiple UDIs for a given medical device
  - Upgrades typically applied in the field → application of labeling in the field and by whom? OEM service representative, third-party service provider, customer?
  - Software – upgrades versus an update – need to consider when incremental UDIs need to be displayed instead of a whole new UDI (e.g. rip and replace)

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"Modular" equipment

- Medical device "systems" that are devised of multiple components that are interchangeable
  - Examples: patient monitoring systems, ultrasound w/probes
  - The complete, branded medical device has a UDI applied
  - UDI applied to individual medical device components
  - Which UDI is captured during service events and used in adverse event reporting?

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Labeling for Orthopedic Procedure Sets and Trays

- Background: Non-sterile orthopedic sets and trays do not have packages and labels and may contain hundreds of devices in a small space, making the labeling requirements very difficult or impossible
  - FDA provided an initial compliance date extension for implantable devices so that labeling approaches could be developed
- FDA has taken a flexible approach
  - Permit cross reference tools in the interim
  - Permit DI only when technologically infeasible

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Establishing Responsibility

Providing **clear definition of the entity responsible** for UDI is critically important

"Labeler"

vs.

"Manufacturer"

What is most important to the Regulators ?

A) Alignment with regulatory filing and device registration reporting responsibility?

B) Product branding assignment concept?

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Needed for Effective UDI Implementation

IMDRF Fundamental Concepts of a Globally Harmonized UDI System:

- The UDI and UDI Carrier are based on **global standards** without deviation
- The UDI applied to a medical device anywhere in the world should be able to be **used globally and to meet the UDI requirements** of its regulatory authority
- National / local identification numbers should **NOT be a substitute for UDI**
- Regulatory authorities **should not specify the procedure for modifying** the UDI standards
- The UDI Database (UDID) **core elements should not be modified**
- The UDID should use the Health Level Seven **International (HL7) Structured Product Label (SPL) and web based interface for data submission**
- **Every medical device needs to be identified by a UDI**, unless it is exempted

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General Consideration to Facilitate an Effective UDI Implementation

- ☑ Implementation Schedule
- ☑ Specification Availability
  - **Reference Table for UDI Data Elements:** (data type, structure, LOV, editing rules, conditional fields, cardinality rules … → *see FDA GUDID data reference table*
  - **UDI Data Exchange Instructions:** messaging structure, XML schema, content, vocabulary, validation rules …… → *see FDA HL7/SPL Implementation Specification.*
    - ✓ *Consider other data exchange options available, e.g., .xls upload, XML messaging standards for batch upload*
- ☑ Implementation Support
- ☑ UDI Adjudication Process for Issues & Requests for Alternatives.
- ☑ Guidance documents are timely

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Key Takeaways

Industry

- Early awareness and impact assessment
- Don't wait to implement
- Cross-functional involvement and support

Regulators

- Consistency – DI, database submissions
- Communication

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THANK YOU!

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