



# UDI

## Brief REPORT on the FDA project “Unique Device Identification”



Fig. 1: UDI header - source conference organizer Clarion Group Inc.

### Abstract

FDA reported Dec. 1, 2010 about the progress of the UDI project for Unique Device Identification. The Health Care Barcode - HIBC and GS1 bar code are the two unique data structures being prioritized for UDI under the scope of the global standard ISO/IEC 15459 Unique Identification. The UDI project is harmonized internationally in conjunction with the Global Harmonization Care Task Force – GHTF. National specific solutions will be considered. The legal regulation for UDI in the US is expected early 2011 but FDA is motivating the users not to wait. There is an FDA registry (data base) for medical devices in the planning stage. Serialization is not a mandatory issue yet but very desirable for users. Hospitals appreciate the efforts but would like to see even more support for in house tracking & tracing. The UDI conference was an ideal podium to learn about the FDA efforts and to discuss implementation issues. It presented pros and cons of straightforward coding with the help of HIBC or mapping to product identification with GS1 coding. UDI is a unique data concept independent of data carrier and technology, but conforming to ISO standards for world wide application. For users, uniqueness and data content is important, but there is not one specific structure. Labelers using alphanumeric product codes, as users of HIBC standards, are encouraged to extend the efforts of others using the full ISO specifications for delivering UDI right now

*Reed more in the chapters below.*

*Notes made by conference delegate*

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### **<sup>1</sup>The UDI conference**

The FDA UDI team, manufacturers, users from hospitals and representatives of health care associations met in Baltimore to discuss implementation of “Unique Device Identification – UDI” and its features. The target of the FDA and organizers was to inform participants about the project developments and to motivate them to initiate use of UDI. This program was presented to help medical device manufacturers, distributors, and hospitals prepare for implementing UDI. FDA's UDI System will transform disparate medical identification methods into a single device identification system that is consistent, unambiguous, standardized, and globally harmonized. The information included details on the proposed UDI regulation from the FDA. A tutorial was offered informing participants about basics of bar coding and RFID including data carriers and data structures.



*Fig. 2: The FDA UDI conference*

### **Food and Drug Administration - FDA**

The responsible FDA representative Jay Crowley reported in detail about targets and content of the proposed FDA regulation and its implementation. “Why UDI” was explained naming the following key points as reasons:

- Safety and effectiveness
- Post market surveillance
- Quality of care
- Patient safety
- Traceability

The basis for UDI implementation is the globally accepted standards, specifically ISO/IEC 15459 Unique Identification and GS1 and HIBC as the primary implementations. Mr. Crowley discussed where the starting point shall be for just the unique device identification, in terms of “what is it” and “who is responsible”. Relevant options should be defined such as expiration date, lot and serial number. For the near future vision, it was made clear that UDI shall become the key for the life cycle management of a product, including additional capabilities, such as anti-counterfeiting. Today's wording is open enough for smooth integration: “The unique identifier shall adequately identify the device through the distribution and usage process, and may include information on the lot or serial number.” As guidance for development and application of UDI clear statements were made:

- Develop UDI according to ISO/IEC 15459 [GS1, HIBC]
- Unique UDI applied to all levels of packaging, down to lowest level (patient use/unit of dose)
- No specific technology would be identified (technology neutral)
- Direct Part Marking (DPM) for some devices where feasible (e.g. reusable/re-sterilized devices, long-term implants)

UDI is relevant for any medical device, such as implants, instruments, dental products, etc. and for any packaging level. If the manufacturer would decide that this is feasible to use UDI, than Direct Part Marking would apply for primary products as well. In essence the FDA will manage the business rules and the planned FDA's UDI registry, but the information content shall be managed by manufacturers and service providers.

<sup>1</sup><http://www.udiconference.com/agenda.html>

### Implementation plan

Prior to implementation (issuance/publication) of the UDI requirements the FDA developed an implementation plan effective after having set the starting point by the government and release of the final rule. The timing is based on pre-designated risk classes:

- class III – 12 month
- class II – 36 month
- class I – 60 month

For follow up of the developments, see [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance)

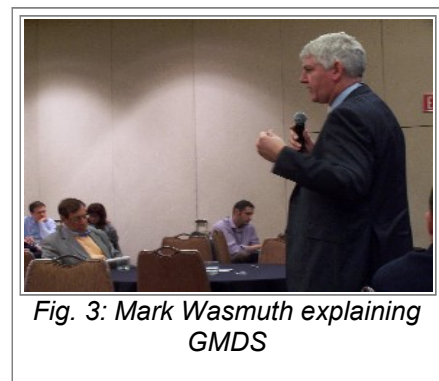


Fig. 3: Mark Wasmuth explaining GMDS

### UDI Database Development

The UDI Database in planning will use the “Device Identifier Type/Code [GS1, HIBC] as access key and include fields for model/brand names references, Unit of measure, contents known, labeled allergen (e. g. latex), FDA premarket authorization and listing number, classification, etc. Control is seen by Lot and/or Serial no. and Exp. Date.

Global Medical Device Nomenclature – GMDN supplies the classification code and terms for the devices. For electronic data communication the HL7 SPL r5 team will provide a model for UDI GHTF (Global Harmonization Task Force) data elements to transmit as a HL7 message.

### Global Medical Device Nomenclature – GMDN

The medical device nomenclature is reported as widely used. There are about 20.000 terms in the database today. There is a continuous maintenance for entry of new terms. The representative of GMDN Mark Wasmuth, Oxford, answered questions how to access the GMDN database and why FDA is requesting use of GMDN. (For further information to GMDN, see [www.gmdnagency.com/](http://www.gmdnagency.com/))

### Participants of the UDI project worldwide

It was reported that the UDI initiative is shared by the Global Harmonization Task Force (GHTF) and its world wide network which includes the *Asian Harmonization Working Party* (AHWP). The latest joint <sup>2</sup>document on the world wide UDI system was published Nov.22, 2010.



Fig. 4: Global Harmonization Task Force Emblem, source GHTF

### GHX – supporting UDI open and neutral

The speaker of GHX, provider for communication solutions, Ms. MJ Wylie concluded that for E-commerce and patient safety – data integrity is a must. GHX contributes by supplying a communication platform. It was stated that the guiding principle is to be open and neutral for processing the common standards supported by FDA and GHTF. The GHX services can help to translate the UDI standard for e-commerce connecting the physical product flow with the flow of data.

### Podium discussions – UDI advantages only

Members of the health care supply chain had the chance to meet together on the podium discussing the UDI project and its benefit for manufacturer, distributor and hospital. In essence, disadvantages of UDI did not come up, just advantages were discussed and how to implement it. For some of the hospital representatives, the UDI project looks just like a initial way to optimize processes in a hospital as well but not the only solution. It was pointed out that securing the patient would take much more effort than just to read a unique bar code from a product.

<sup>2</sup>[www.ghtf.org/ahwg/ahwg-proposed.html](http://www.ghtf.org/ahwg/ahwg-proposed.html)

As an example the HIBC Provider standard was mentioned and ANSI/HIBC 3.0 Positive Identification for patient safety, part 1: Medication Delivery. It defines and describes automatic data collection and transmission around the bed side medication process by the help of infusion pumps. The FDA initiative was seen as stopping at goods entry but does not cover such internal processes yet. Nevertheless any initiative to focus on uniqueness was appreciated, where UDI is seen as a support for this. Having all incoming products marked uniquely (one hospital reported about 70% are), is a good motivation for hospital IT personnel to mark and scan all other moving items (within the hospital) . This practice helps the hospital move closer to the vision of a step by step total auto-ID solution.

### **UDI Exhibition**

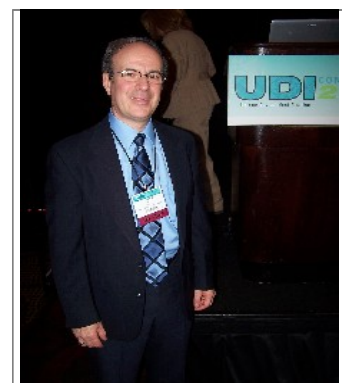
Exhibitors showed labeling solutions, direct part marking software tools and communication platforms. It was obvious that UDI is not a technology problem because unique product and package marking is state of the art regardless if data substructures are used such as GS1, HIBC or the migrating ASC structure according to ISO/IEC 15418. The solution providers offered the most convenient solutions for both the manufacturer as well as for the hospital, where distributors in the middle may benefit from UDI as well. Interesting enough, the focus was on Data Matrix (ISO/IEC 16022) as the data carrier. Even if RFID is one of the options for UDI, it has not entered in product marking yet, as previously predicted. This still may come.

### **Conclusion**

UDI is on path for increasing safety and efficiency. This is a world wide movement to a higher quality of supply logistics and care. Specifically hospitals expressed that they very much appreciate quick and total implementation. The UDI initiative will surely speed up the optimization process. Any supplier of medical devices is asked to join in implementing UDI. Today their decision is voluntary, tomorrow by law. Anyway, UDI is the base for any system aiming for error free data collection and documentation.

### **Outlook**

Where the UDI conference touched some very practical issues, other groups are already working on add ons and further developments. So the national standardization teams under the umbrella of ISO are busy preparing the next generation of scanning devices: the mobile phones. With them and the assistance of the telecommunication network it will be possible to scan a UDI and to check for information about it via network. This capability will be available, regardless of AutoID technology but Data Matrix, QR Code and RFID will, off course, play a major role. If a UDI is serialized once, than by help of the ISO project "Mobile Item Identification & Management (MIIM – the ISO/IEC 2917x series of standards)", it will be possible to trace a product back to the supplier or to a database where related information has been stored. Anti-Counterfeiting is one of the drivers for the projects of ISO/IEC JTC 1/SC 31/WG 6.



*Fig. 5: Robert Fox: "Look at the Technology behind UDI"*

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*Encl.: Annex Selection of relevant standards for implementing UDI*



## **Annex**

### **Selection of relevant standards for implementing UDI**

ISO/IEC 15418 GS1 Application Identifiers and ASC Data Identifiers

ISO/IEC 15459 Unique Identification, Part s1 to 6

ISO/IEC 29162 Guidelines for using ADC Media (Barcode & RFID)

ISO/IEC 29143 Air Interface Specification for Mobile Interrogators

ISO 22742 Linear bar code and two-dimensional symbols for product packaging

ISO 28219 Labeling and direct product marking with linear bar code and 2d- symbols

ISO 17366 Supply chain applications of RFID – Product packaging

ISO 17367 Supply chain applications of RFID – Product tagging.

DIN 66401 Unique Identification Mark

GS1 Global Specifications

ANSI/HIBC 1.3 Provider Application Standard

ANSI/HIBC 2.3 Supplier Standard

ANSI/HIBC 3.0 Positive Identification for Patient Safety; Part 1: Medication Delivery

*- and for the near future:*

ISO/IEC 29172-29179 Mobile Item Identification and Management (MIIM)

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