UDI: Change is happening across the world

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GS1 – a global non-for profit standard organisation

- 1 million companies worldwide use GS1 standards
- 25 industries served across 150 countries
- 112 Member Organisations around the world
- 6 billion barcodes scanned more than 6 billion times per day globally
International Medical Device Regulators Forum

- Voluntary group of medical device regulators from around the world
- Goal: international medical device regulatory harmonisation and convergence
- Members: Australia, Brazil, Canada, China, EU, Japan, Russia, South Korea, Singapore, USA
- WHO and regional organisations as observers
UDI system and GS1 system

- **UDI system** as defined by IMDRF
- **GS1 system**

**UDI**
- DI (Static Data)
- PI (Dynamic Data)

**UDID**
- Static Data Elements
  - DI = Primary Access Key

**AIDC**
- Machine Readable Data Carrier
  - Linear Barcode
  - GS1 DataMatrix
  - RFID

**Steps**
- **Identify**
- **Share**
- **Capture**
# UDI in AIDC terms

<table>
<thead>
<tr>
<th>UDI regulatory requirements</th>
<th>GS1 standards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>UDI-DI</strong></th>
<th><strong>GTIN</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>UDI-PI</strong></th>
<th><strong>AI</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td><em>(if applicable)</em></td>
<td>- Expiration date AI(17) - e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>- Batch - lot AI(10) - e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>- Serial number AI(21) - e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

*Production identifier data will vary by medical device type and manufacturer current practice.*

<table>
<thead>
<tr>
<th><strong>UDI-DI + UDI-PI = UDI</strong></th>
<th><strong>GTIN or GTIN + AI(s) = UDI</strong></th>
</tr>
</thead>
</table>

The **HRI format** shall follow the rules of the UDI Issuing Agency
Anatomy of a GTIN, an example

GS1 Country Code for Portugal

Assigned by GS1 Global Office

Assigned by GS1 Portugal

Assigned by Brand Owner

GS1 Company Prefix

I = Indicator or “Zero Filler”

P = Item reference

C = Check digit

NOTE: GTIN-14 example
Composition of the GTIN (UDI-DI)

To calculate the GTIN check digit:

https://www.gs1.org/services/check-digit-calculator
UDI in AIDC terms

Packaging Levels:
The UDI should be in the AIDC data carriers (i.e. bar code symbol) and also in human-readable form on each applicable packaging level as defined by regulation.

Each designated packaging level that is a trade item must have its own DI (GTIN).

Logistics units are exempt.
UDI Example of label

H.E.L.P. Acetate Buffer pH 4.85

4 x 3000 ml

Device Identifier (DI)
- "Static" portion
- GTIN (product identifier)

Production Identifier (PI)
- "Dynamic" portion
- Application Identifiers (e.g. serial, lot number & expiry date)

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Reference documents

**GS1 General Specifications** – describes how GS1 keys & data carriers should be used
http://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications

**GS1 Healthcare GTIN Allocation Rules** – GTIN assignment in Healthcare with Healthcare specific examples
EU specificity: “Basic UDI-DI” for illustration only

Before or after the supply chain, where Basic UDI-DI (GMN) is needed (see next slide)

In the supply chain, where trade item ID (GTIN) is to order, deliver, or invoice

<table>
<thead>
<tr>
<th>Level</th>
<th>QTY</th>
<th>DI</th>
<th>UDI Unit of Use</th>
<th>Base Package DI</th>
<th>Package DI</th>
</tr>
</thead>
<tbody>
<tr>
<td>UoU UDI-DI</td>
<td>1</td>
<td>GTIN A</td>
<td>Base Package DI</td>
<td>Package DI</td>
<td></td>
</tr>
<tr>
<td>Base Pack</td>
<td>50</td>
<td>GTIN B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd</td>
<td>250</td>
<td>GTIN C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GS1 Global Model Number (GMN) v.2

- GS1 Company Prefix + alphanumeric manufacturers internal model reference

For regulated healthcare medical devices:
- **Updated** GMN standard to align on new requirements from the European Commission on Basic UDI-DI:
  - Addition of 2 check-characters (no special characters)
  - Length: max 25 characters (23+2)

- independent of packaging
- never used in a data carrier

Composition of the GMN (Basic UDI-DI)

To calculate the GMN check characters:

https://www.gs1.org/services/check-character-calculator
UDI Databases – USA and EU

Part that the U.S. FDA UDI system focuses on today...
Manufacturers are able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.
UDI: challenges...

Roles and Responsibility
(internally and with SC partners)

Enterprise-wide project

Data Quality and Data Management
... and opportunities

**Pursue a global UDI strategy**
- Use a globally unique system for identification
- Develop a Global Data Governance approach
- Connect to multiple data recipients (incl. UDI Databases)

**Gain business value from UDI**
- Build systems do more than check the UDI Regulatory box
- Leverage the UDI throughout the Supply /Patient Care Chain
- Create a win/win relationship with your customers on UDI data
Requirements for medical devices identification

And more coming…
The need to align on a global UDI framework

- UDI is very beneficial. It is crucial that regulators around the world align on the global framework - IMDRF Guidelines and ensure consistency when setting-up regional or national UDI system

This will ensure:
- highest levels of patient safety beyond borders
- harmonized identification systems for medical devices globally
Benefits for all Healthcare stakeholders

Manufacturers: patient safety, cost optimisation, data synchronization and process efficiency

Hospitals: patient safety, adequately identified medical devices and a single and integrated system of information management

Regulators: patient safety, higher levels of market surveillance, more efficient adverse event reports and quicker recall - also across borders
http://www.gs1.org/healthcare/udi
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