Global Medical Device Nomenclature (GMDN)

GMDN – A Requirement for UDI

Mark Wasmuth – CEO, GMDN Agency
What we will be discussing

- Why is the GMDN needed
- GMDN data structure
- How to find GMDN terms
- Unique Device Identification
- UDI & GMDN Relationship
- Examples of GMDN in use
- Questions?
Why the need for Device names?

Large variety of devices!
Why is consistent naming important?

- Medical Devices are traded internationally
- **Regulators** need to approve devices efficiently by identifying the product group and the related hazards / risks
- **Regulators** need to identify ‘systematic’ failures of medical devices
- **Hospitals** can identify the products they need and manage their inventory
Why was the GMDN needed?

Existing nomenclatures:
- ‘National’ systems (not suitable for international harmonisation) & Single language
- Unstructured / un-standardised
- Too vague / poor definitions
- Too rigid – difficult to include new technology
- Can’t keep up with volume of innovation
- Too many duplicates / overlaps
- Uncontrolled – no update method for users

Not meeting Regulator needs
What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- The international standard (ISO 15225) for naming Medical Devices
- Used by 65 national Medical Device Regulators - Backed by IMDRF
- Over 4000 Manufacturers worldwide
- Translated into 25 languages
- 22,000 Preferred Terms with Definitions
- Controlled distribution and updating
- International acceptance
Global acceptance?

- GHTF (now IMDRF) proposes GMDN for UDI
- EC proposes GMDN for the EUDAMED (market surveillance database)
- EUCOMED supports the use of GMDN in meeting the needs of European manufacturers
- EC has translated the GMDN into 20 languages
- WHO & MSF use GMDN in guidance for developing countries
- Collaboration Agreement with IHTSDO (Snomed CT)
- US FDA are using GMDN in the first national implementation of UDI
GMDN Term Structure

Each GMDN Term consists of 3 parts:

- **Term Name:** General-purpose syringe

- **Definition:** A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical

- **Code:** 47017
How can you find GMDN Codes?

www.gmdnagency.org
Searching for GMDN Terms

Show results with one or more options
Search text: syringe general
For:
- All the words
- GMDN Code(s)
- Any of the words
- Original Source Code(s)
- The exact phrase
- Translation Code(s)
- None of these words
In:
- Words only in term
Review the Results

Show results with one or more options

Search text: syringe general
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Search Terms

Records 1-1 from 1

<table>
<thead>
<tr>
<th>Term</th>
<th>Type</th>
<th>GMDN Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>General-purpose syringe</td>
<td></td>
<td></td>
<td>A sterile device that consists of a calibrated hollow barrel (cylindrical) and is used for the withdrawal or delivery of fluids or gases. It is typically used in medical and laboratory settings.</td>
</tr>
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How can you find GMDN Codes?

Show results with one or more options
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<td>A sterile device that consists of a calibrated hollow barrel (cylindrical) fluid (e.g., medication) into, and/or withdraw fluids/gas from it. At the distal end of the barrel is a male connector (typically a ‘hub’ of a hypodermic needle or an administration set). It is typically plunger anti-sticking properties (internally precoated with a smooth, non-stick surface) manually or by a syringe pump. This is a single-use device.</td>
</tr>
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<td>General-purpose syringe</td>
<td></td>
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More detail

Term Details
Product Identifier
Created 21/06/2007 14:08:18
Modified 11/02/2013 22:45:31

Term General-purpose syringe
Definition A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical applications. At the distal end of the barrel is a male connector (typically a Luer-lock type) for the attachment of the female connector (hub) of a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have plunger anti-sticking properties (internally precoated with compatible substances) allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.

Categories
10 Single-use devices

Collective Terms
- CT233 Surgical
- Device Materials
  - CT979 Inorganic materials
    - CT201 Synthetic polymers
      - CT179 Plastics
      - CT212 Silicone
      - CT180 Synthetic rubber
  - Device Power/Operation
    - CT326 Manually powered/operated
  - Device Sterility
    - CT336 Sterile
  - Device Use Frequency
    - CT981 Single use
- High-Level Device Groups
  - CT309 Syringes/Injectors and associated devices
    - CT1943 Syringes
Reveal the GMDN Code

![Image of search interface with search text: syringe general]

### Search Terms

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Collective Terms

GMDN uses **Collective Terms** to provide:

- Better navigation with variable hierarchies
- Compare common features:
  - Materials (Inert, Latex, Animal)
  - Invasiveness (Internal / External)
  - Sterility (Supplied Sterile / non-sterile)
  - Use Frequency (Single Use / Reusable)
  - Powered by (mains, battery, air, etc.)
- Flexible to meet future needs
Collective Terms

**Term Details**
Product Identifier
Created 21/06/2007 14:08:18
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**Term** General-purpose syringe
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Using Collective Terms to search

You have selected:
- High-Level Device Groups - CT309 Syringes/Injectors and associated devices
- CT1943 Syringes

CT Quick Finder: Name/Code: syringe

Search Results:
- Dental irrigation/aspiration syringe
- Far syringe
- Embolization implant syringe
- Gas/liquid chromatography syringe
- General-purpose syringe

Records 1-6 from 6

Code | Name
---|---
CT1586 | Dental syringes
CT1587 | Dental syringes and associated devices
CT2281 | Needleless valve-connectors
CT111 | Syringe pumps
CT1943 | Syringes
CT309 | Syringes/Injectors and associated devices

Records 1-6 from 6
What’s the process?

- Identify the GMDN Code for all of your products, from the GMDN database
- Provide the GMDN Code to your Customers / Distributors / Data Pools
- Use the GMDN Code to register your products with your MD Regulator
- Use with **Unique Device Identification** (UDI)
Unique Device Identification

- Pack / product marking of ‘unique’ identifier
- Marking also includes production identifiers (e.g. Batch No., Expiry Date, Serial No…)
- **Machine** readable (e.g. bar code) and human readable
- Linked to other product data in a database (e.g. make, model, etc.)

![Barcode Image]
The GMDN code is one of the 25 mandatory core data elements identified in the IMDRF ‘UDI System for Medical Devices’ draft Guidance Document.

Data for each device is provided by the manufacturer to the **UDI Database** (UDID).

The UDID data could be distributed by:
- Public access website
- Bulk data download (e.g. Hospitals)
UDI requires a Carrier & Hardware

- Product Label (Carrier)
  - Linear Bar Code
  - 2D Bar Code (more data)
  - RFID - Radio Frequency Identification (non-contact)

- Hardware to read labels
  - Bar code Reader
  - Image Scanner
  - RFID Scanner
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)

Hudson
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)

Generic Device Group - GMDN Term
(e.g. GMDN Code 47071)

Hudson
12345678909874

Brooks
19876543218976

Woods
32345678908765
When you can’t find a Term?

If you can’t find a GMDN Term for your product:

1. Ask us for assistance

2. Apply for a new Term:
   - On-line Request Application
   - Attach your product datasheet / pictures
   - We discuss the draft Term with you
   - Two week public comment period
   - Database updated daily
Modifying or Obsoleting Terms?

- We modify existing Terms
  - To increase the scope
  - Improve the definitions
- Make Terms Obsolete
  - To remove inadequate Terms
  - Reducing over time
- Notifications by email to Members
Example of GMDN & UDI for Regulation

- Post Market surveillance
  - Identify systematic (generic) product failure
  - Support rapid product recall

- Better Regulation
  - Speed up Pre-market approval
  - Identify products quickly
  - Detailed information on imports and exports
  - Quickly identify trends about new equipment use and problems
GMDN speeding up pre-market approval

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>Test Method</th>
<th>Date</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
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GMDN speeding up pre-market approval

New Applicant

<table>
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<tr>
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<tbody>
<tr>
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<tr>
<td>38501</td>
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<td>38501</td>
<td>Jones</td>
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</table>

Previously Approved Device
GMDN speeding up product recall

Product Failure

Regulator Device Register

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>UDI [GTIN]</th>
<th>Date</th>
<th>Recall</th>
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<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>2011</td>
<td>✓</td>
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GMDN speeding up product recall

Product Failure

Hudson

Regulator Device Register

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<td>✓</td>
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<tr>
<td>38501</td>
<td>Woods</td>
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<td>x</td>
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</tr>
<tr>
<td>38501</td>
<td>Brooks</td>
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<tr>
<td>38501</td>
<td>Jones</td>
<td>58746528415424</td>
<td>?</td>
<td></td>
</tr>
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</table>

Investigate this product too?
Example of GMDN & UDI in Hospitals

- **Asset Management**
  - Support equipment commissioning
  - Help identify equipment location
  - Support maintenance programmes

- **Inventory Control**
  - Reduce wastage
  - Translate product labels with poor descriptions
  - Improve stock control
Use the GMDN to find missing stock

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>UDI [GTIN]</th>
<th>Stock</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>1</td>
<td>Ward C</td>
</tr>
</tbody>
</table>

Hudson

(01)12345678909874

20 Needed in Ward C
Use the GMDN to find stock

<table>
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<tr>
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<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>1</td>
<td>Ward C</td>
</tr>
<tr>
<td>38501</td>
<td>Woods</td>
<td>32345678908765</td>
<td>2</td>
<td>Ward E</td>
</tr>
<tr>
<td>38501</td>
<td>Brooks</td>
<td>19876543218976</td>
<td>100</td>
<td>Ward H</td>
</tr>
</tbody>
</table>

20 Needed in Ward C

100 Located in Ward H
Nottingham University Hospital

- Clinical Engineering application
Thank you for listening

Any questions?

enquiries@gmdnagency.org

mark.wasmuth@gmdnagency.org