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
- Any of the words
- The exact phrase
- None of these words
In:
- Words only in term
Review the Results

Show results with one or more options

Search text: syringe general
For:
- All the words
- Any of the words
- The exact phrase
- None of these words
In: Words only in term

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 (cyl fluids (e.g., medication) into, and/or withdraw fluids/gas from At the distal end of the barrel is a male connector (typically a (hub) of a hypodermic needle or an administration set. It is t plunger anti-sticking properties (internally precoated with con manually or by a syringe pump. This is a single-use device.</td>
</tr>
</tbody>
</table>
How can you find GMDN Codes?

Show results with one or more options
Search text: syringe general
For:
- All the words
- Any of the words
- The exact phrase
- None of these words
In: Words only in term

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) used for injecting or withdrawal of fluids (e.g., medication) into, and/or withdraw fluids/gas from. At the distal end of the barrel is a male connector (typically a 10 ml syringe) and an administration set. It is typically used with plunger anti-sticking properties (internally coated) or manually. This is a single-use device.</td>
</tr>
</tbody>
</table>

G•M•D•N
More detail

<table>
<thead>
<tr>
<th>Term Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Identifier</strong></td>
</tr>
<tr>
<td>Created 21/06/2007 14:08:18</td>
</tr>
<tr>
<td>Modified 11/02/2013 22:45:31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>General-purpose syringe</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Single-use devices</td>
</tr>
</tbody>
</table>

**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

**Show results with one or more options**

Search text: syringe general

For:
- All the words
- Any of the words
- The exact phrase
- None of these words

In: Words only in term

**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>P</td>
<td>47017</td>
<td>A sterile device that consists of a calibrated hollow barrel (cylindrical container) into, and/or withdraw fluids/gas from, the barrel is a male connector (typically a Luer-lock type needle or an administration set. It is typically made of plastic (internally precoated with compatible substances) allowing single-use device.</td>
</tr>
</tbody>
</table>

G•M•D•N
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
- **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
  - 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
Using Collective Terms to search

[Image of search results for syringe, showing various types of syringes and codes]
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.)

Hudson

12345678909874
UDI Database

- 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)
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
\(\text{e.g. 12345678909874}\)

Generic Device Group - GMDN Term
\(\text{e.g. GMDN Code 47071}\)

- Hudson
  - Code: 12345678909874

- Brooks
  - Code: 19876543218976

- Woods
  - Code: 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>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GMDN speeding up pre-market approval

New Applicant

<table>
<thead>
<tr>
<th>Hudson</th>
</tr>
</thead>
</table>

Previously Approved Device

<table>
<thead>
<tr>
<th>Jones</th>
</tr>
</thead>
</table>

Regulator Device Register

<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>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38501</td>
<td>Woods</td>
<td>ISO 7886</td>
<td>2009</td>
<td>✔️</td>
</tr>
<tr>
<td>38501</td>
<td>Brooks</td>
<td>ISO 7886</td>
<td>2008</td>
<td>✔️</td>
</tr>
<tr>
<td>38501</td>
<td>Jones</td>
<td>ISO 7886</td>
<td>2010</td>
<td>✔️</td>
</tr>
</tbody>
</table>
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>
</tr>
</thead>
<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>2011</td>
<td>✓</td>
</tr>
</tbody>
</table>

Hudson
GMDN speeding up product recall

Product Failure

Investigate this product too?

Regulator Device Register

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>UDI [GTIN]</th>
<th>Date</th>
<th>Recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>2011</td>
<td>✓</td>
</tr>
<tr>
<td>38501</td>
<td>Woods</td>
<td>32345678908765</td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>38501</td>
<td>Brooks</td>
<td>19876543218976</td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>38501</td>
<td>Jones</td>
<td>58746528415424</td>
<td></td>
<td>?</td>
</tr>
</tbody>
</table>
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

G•M•D•N
Use the GMDN to find 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>
<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>

Stock Control Database

20 Needed in Ward C

100 Located in Ward H
Nottingham University Hospital

- Clinical Engineering application

![Image of Medusa software interface](image-url)
Thank you for listening

Any questions?

enquiries@gmdnagency.org

mark.wasmuth@gmdnagency.org