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
- UDI & GMDN Relationship
- New, Modified & Obsolete Terms
- Examples of 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:
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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 a plunger anti-sticking properties (internally precoated with con manually or by a syringe pump. This is a single-use device.</td>
</tr>
</tbody>
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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
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
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  - None of these words
- **In:** Words only in term

**Search Terms**

- **Record 1:** General-purpose syringe
  - Categories: 10 Single-use devices
  - **GMDN Code:**
  - **Definition:**

A sterile device that consists of a calibrated hollow barrel (cylindrical shape) used for delivery of fluids (e.g., medication) into, and/or withdraw fluids/gas from, a body cavity. 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 a single-use device.
Reveal the GMDN Code

Show results with one or more options

Search text: syringe general

For:
- All the words
- Any of the words
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- None of these words

In: Words only in term

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**
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**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

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      - CT1943 Syringes
Using Collective Terms to search

CT Quick Finder: Name/Code: syringe

Records 1-6 from 6

<table>
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<th>Code</th>
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<tbody>
<tr>
<td>CT1586</td>
<td>Dental syringes</td>
</tr>
<tr>
<td>CT1587</td>
<td>Dental syringes and associated devices</td>
</tr>
<tr>
<td>CT2281</td>
<td>Needleless valve-connectors</td>
</tr>
<tr>
<td>CT111</td>
<td>Syringe pumps</td>
</tr>
<tr>
<td>CT1943</td>
<td>Syringes</td>
</tr>
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<td>CT309</td>
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</tbody>
</table>

Search Results

15. Dental irrigation/aspiration syringe
16. Ear syringe
17. Embolization implant syringe
18. Gas/liquid chromatography syringe
19. General-purpose syringe
20. Hazardous fluid syringe
21. Heparin lock flush syringe, reprocessed
22. Heparin lock flush syringe, single-use
23. High performance liquid
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)
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 (FDA GUDID).

The UDID data could be distributed by:

- Public access website
- Bulk data download (e.g. Hospitals)
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier
(e.g. 12345678909874)
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
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
Thank you for listening

Any questions?

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