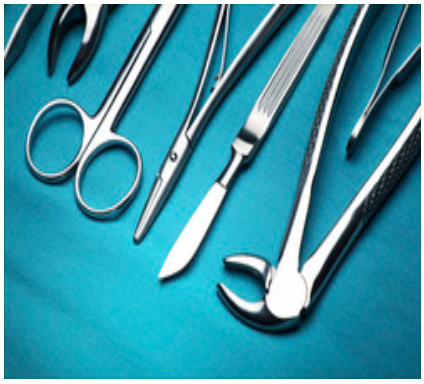
The Global Language of Business

Global Standards Management Process

GS1 Global Model Number Standard - UPDATE

Mission-specific work group

Call to Action



What business challenges are being solved?

GS1 must update the Global Model Number (GMN) Standard in order to include the NEW requirements from the European Union (EU) Commission on the structure and the definition of the Basic Unique Device Identifier – Device Identifier (Basic UDI-DI).

Additionally, the updated version of the GMN Standard must be approved at the latest by 15 May 2019, for GS1 to meet the deadline for final accreditation as UDI (Unique Device Identification) Issuing Entity in Europe.

Background

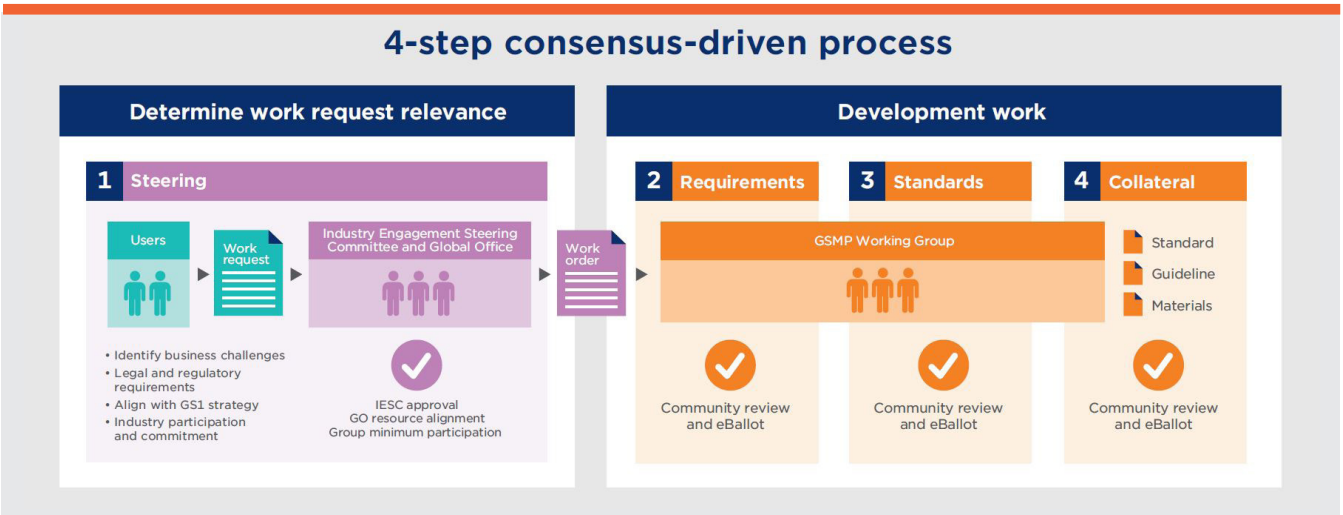
The EU Regulations introduce a new identifier – the "Basic UDI-DI" (Basic Unique Device Identifier – Device Identifier) which refers to the identifier of a device model/family. This identifier is not required in the IMDRF and in the US FDA UDI systems.

GS1 is one of the UDI issuing entities provisionally designated by the European Commission and must be able to meet the selection criteria to be considered for final designation as a UDI issuing entity for the EU. The Commission's selection criteria included providing a solution to implement the "Basic UDI-DI" according to their specification/requirements. In September 2017, GS1 developed a new identifier (i.e.. Global Model Number – GMN) designed to meet the needs of the "Basic UDI-DI" and be flexible enough to be leveraged in additional industries.

On 30 November 2018, NEW requirements were adopted by the European Medical Device Coordination Group that were unknown when the EU Commission initially required the development of the relevant Standard to support the implementation of the Basic UDI-DI. These requirements are not part of the EU Regulations and will be included in guidance documents from the EU Commission to be released later.

This work effort is to meet the new requirements for the Global Model Number which are to ensure the highest level of data quality.

The GSMP is a community-based forum for businesses facing similar problems to work together and develop standards-based solutions to address them. Active GSMP participants represent industries ranging from retail and consumer goods to fresh foods, healthcare, transport and logistics, government and more—a healthy mix of business and technical people from nearly 60 countries.



Impact

If GS1 does not update the relevant identifier, our status as a UDI issuing entity for Europe will be at risk. If GS1 should decide not to provide a solution, medical device manufacturers around the world who are supplying the European market, will not be permitted to use GS1 standards to identify their products anymore.

Working group objectives

The proposed update to the GMN Standard is to meet these new requirements that are meant to ensure the highest level of data quality in EUDAMED (European Database for Medical Devices):

1. Leveraging a check-digit, to raise the confidence that there are no errors in the GMN and to use it as one of the validation rules in the EU Medical Devices DataBase.
2. Limiting the length of the GMN, to maximum 25 characters to reduce the possibility for errors in the GMN.
3. The removal of the Basic UDI-DI definition from our GMN Standard.

Who should join this working group?

In addition to members of the original work group, GS1 is looking for broad participation since all stakeholders involved in the supply chain for medical devices will be affected by the new regulation. Due to the pressing urgency of the development there is no doubt that industry will come together to develop this update as they did very successful when creating the original GS1 key.

Suggested but not required skill-sets, both business and technical (public policy and regulatory affairs, expertise in traceability systems, etc.)

- Solid understanding of the GS1 system of standards.
- Knowledge of regulatory affairs, particularly EU related and public policy.
- Familiarity with medical device design, registration and manufacturing practices.
- Involvement in the distribution and administration of medical devices.
- Understanding of the global healthcare direction of identification.

How will the working group operate?

This working group will follow the GS1 Global Standards Management Process:

- **Define business requirements—**collect input from the industry, MOs and hospital communities relative to the GMN Standard update.
- **Refine and develop rules—**experts draft GMN Standard update and present it to industry, MOs and hospitals for approval.
- **Ratify and publish—**standards are approved by the standards development community, ratified by GS1 governance bodies and published.

Next Steps

- Working Group kick-off: **05-February, 2019**

For more information and to join the group, visit:
https://www.gs1.org/standards/development-work-groups#GMN

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