The Global Language of Business

Global Standards Management Process

Healthcare GTIN Allocation Rules

Mission-specific working group

Call to Action

What business challenges are being solved?

The Healthcare GTIN Allocation Rules were developed over a decade ago. Since then implementation of GTINs globally in healthcare has increased significantly and has changed in both commercial and regulatory environments. This has led to the need for an update in order to stay relevant.

Additionally, the general GS1 GTIN Allocation Rules (now the "GS1 GTIN Management Standard") have been completely re-written. As a result, the text and terminology between the "GS1 GTIN Management Standard" and the "GS1 Healthcare GTIN Allocation Rules" needs to be reviewed for update and consistency where appropriate.

Regulators and trading partners rely on the robustness of the GS1 system; the GTIN and the Allocation Rules are at the core of this trust as well as sometimes directly referenced in regulations.

Background

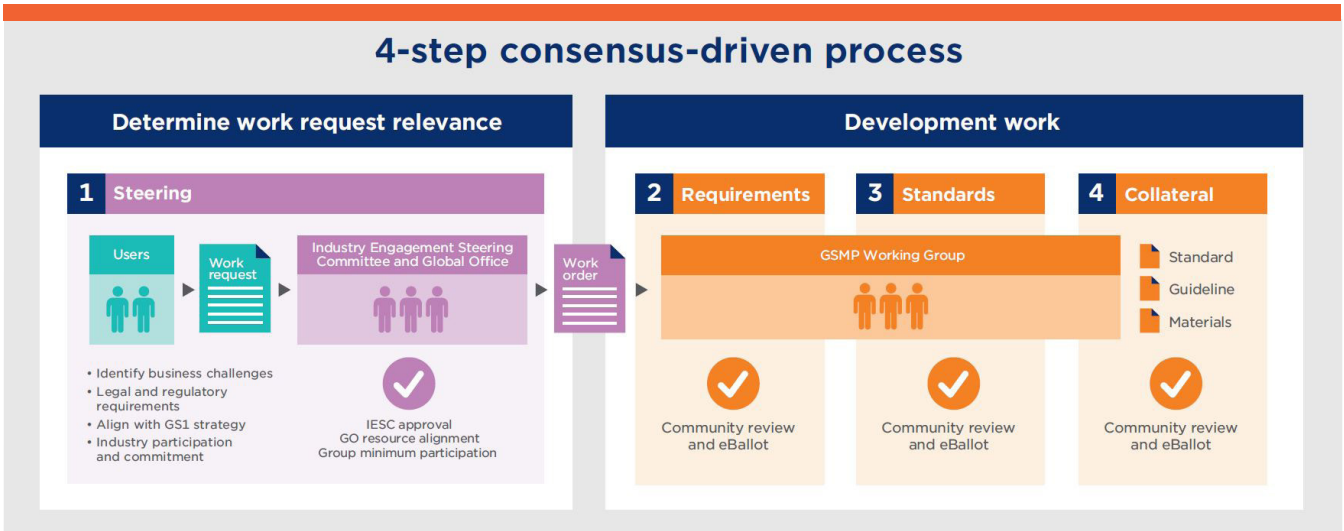
GS1 Healthcare has developed and promoted global industry standards to prevent medical errors, combat counterfeit products and improve supply chain efficiencies throughout the global healthcare industry.

The logic behind the need to change a GTIN is critically important to provide the information needed within the supporting systems that enable reliable identification, data capture and data sharing in the global healthcare industry in a consistent manner.

Since the development of the original Healthcare allocation rules over a decade ago new regulations, new business processes and new requirements have risen that require clarifications within the Healthcare GTIN Allocation Rules for it to maintain its value in the identification of items and in the broader implementation of GS1 standards in the healthcare industry.

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. A neutral participant, GS1 facilitates dialogue and the development of standards-based solutions among business and technical people. Industries represented include retail and consumer goods, fresh foods, healthcare, transport and logistics, governments and many more.

The revision will make the rules easier to use, and help companies better understand situations where healthcare specific rules apply.



Impact

Clarify the language in the Healthcare GTIN Allocation Rules so that they are easier to interpret and apply to today's business practices and support regulations. The intent is not to cause disruption but to document and better support the current state of business practices.

Review the allocation rules language and ensure consistency with the GTIN Management Standard where possible.

Ensure the allocation rules support the Clinical Trials standard once completed.

Working group objectives

1. Clarify the Healthcare GTIN Allocation Rules based on the implementation experience of the Pharmaceutical and Medical Device industries and regulation introduced since its initial creation.
2. Ensure the Healthcare GTIN Allocation Rules are aligned with the GTIN Management standard as much as possible without negatively impacting the specificity needed in healthcare. This work effort will not include revision or changes to the GTIN Management standard.
3. Ensure the Healthcare GTIN Allocation Rules support the Clinical Trials application standard, once completed.
4. The group may identify guidance materials need to support this work.

Who should join this working group?

Stakeholders of the healthcare industry representing the entire order to cash process, supply chain, clinical and medical procedures such as Manufacturers and distributors of Pharmaceutical products and Medical Devices, Hospitals and other care providers and MOs, GDSN Certified Data Pools and solution providers. They should have knowledge of:

- Product identification in healthcare, supply chain management, regulatory affairs and/or clinical procedure
- Hospital operations which require clear product identification practices including medical procedures, pharmacy product dispensing, procurement and supply chain operations
- Business or IT expertise in supply chain and logistics processes and systems

How will this working group operate?

This working group will follow GS1's standards development process:

- Participation Requirements - organisations who wish to participate in this GS1 Standards Development (GSMP) Working Groups must sign the GS1 IP Policy and the opt-in agreement for this work group. These policies help GS1 continue to offer neutral, open supply chain standards that can be implemented on a royalty-free basis.
- GSMP Process—the development of this work will follow the GSMP four step process.

Next Steps

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

Join the work group kick-off call on January 9

8:00 – 9:30 US ET via conference call

For questions please contact: Pete Alvarez at-peter.alvarez@gs1.org

GS1 AISBL
Blue Tower, Avenue Louise 326, BE 1050 Brussels, Belgium
T +32 (0)2 788 78 00 | **F** +32 (0)2 788 78 99 | **E** contactus@gs1.org
www.gs1.org