GS1 Healthcare White Paper Brief on UDI implementation

Global standards pave the way for Unique Device Identification (UDI)

EXECUTIVE SUMMARY

This paper is being released in advance of the UDI regulations to clarify questions the industry has raised and to provide implementation guidance. This paper will be updated with more specific and relevant information once the regulations become available.

Unique Device Identification is expected to improve patient safety and healthcare business processes; however, it will require significant investments by manufacturers, providers and other healthcare organisations. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.

The United States Food and Drug Administration (FDA), the European Commission and other regulators have made safety and integrity of the global Healthcare supply chain a strategic priority by proposing legislation for Unique Device Identification. The regulatory requirements for UDI, under development, propose to address today's supply chain issues involving identification of medical devices, inefficient and/or ineffective product recalls, incomplete adverse event reports, counterfeit products, and inefficient hospital supply chain processes.

This rapidly changing environment is forcing all healthcare supply chain stakeholders to adapt their business processes and systems to meet UDI requirements and to fully leverage the potential of UDI in the following ways:

- Suppliers will be required to assign a Unique Device Identifier to all of their medical devices. The UDI will be used as the "key" to device-related information stored in the regulators UDI public database and will ensure the unambiguous identification of a specific supplier's product. For some devices (depending on their risk class) manufacturing production-related identification will also be required on the product package and in the data carrier with the UDI, e.g., lot or serial number and expiry date.
- It is imperative that healthcare providers invest in IT systems and leverage the use of UDI information for electronic patient records, adverse event reporting, product recalls, inventory management, and other applications involving the need for positive identification of medical devices in order to fully realize the benefits of UDI.
- Solution providers need to develop the appropriate solutions for the industry in time to facilitate sector-wide implementation of UDI.

The successful implementation of UDI by all healthcare stakeholders from manufacturers to healthcare providers will depend on several factors, including:

- **Global Reach -** local deviations must be avoided and will have a negative impact on UDI.
- **Sector-wide Reach -** all stakeholders need to collaborate on the use of UDI to make a meaningful impact and to realize the full potential of UDI in the industry.
- **Risk-based Approach -** to be effective, the diversity of medical devices must be considered.
- **Standards-based Approach -** proprietary ways of capturing and exchanging information will also have a negative impact on implementations.

The GS1 System of standards provides a global framework to identify, capture and share healthcare product information, thereby enabling a worldwide implementation of UDI. To view this paper visit the GS1 Healthcare website at www.gs1.org/healthcare.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, please visit www.gs1.org/healthcare.