



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. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all Healthcare stakeholders worldwide.

- Healthcare providers will need to 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 related to positive identification of medical devices.
- Solution providers will need to develop the appropriate solutions for the industry in time to facilitate sector-wide implementation of UDI.

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

The successful implementation of UDI by all Healthcare stakeholders from manufacturers to Healthcare providers will depend on several factors, including the following.

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

- Suppliers will be required to assign a Unique Device Identifier to all of their medical devices, and to apply the UDI code in machine-readable format on the product label or directly on the product. The UDI will be used as the "key" to device-related information stored in the regulator's UDI public database and will ensure the unambiguous identification of a specific supplier's product. For some devices (depending on their risk classes and existing control mechanisms) manufacturing production-related UDI identification will also be required on the product package and in the data carrier, e.g., lot and expiry date or serial number.

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 realise the full potential of UDI in the industry.
Risk-based approach	To be effective and inclusive, the diversity of medical devices must be considered.
Standards-based approach	Leveraging open, global and user lead standards will maximize efficiency and consistency in product data capture and reporting. Open standards, such as GS1, provide a scalable framework for global interoperability and future improvements

The GS1 system of standards provides a global framework to identify, capture and share Healthcare product information, thereby enabling a consistent worldwide implementation of UDI.

THE CHALLENGE: UNAMBIGUOUS IDENTIFICATION OF MEDICAL DEVICES AND RAPID ACCESS TO DEVICE RELATED INFORMATION

"Current device identification is a mess. Different manufacturers use different standards in different ways if they use anything at all. Distributors apply their own. Hospitals apply their own. And we just sort of cascade into this series of events which means that we can't find devices."

Jay Crowley, Senior Adviser for patient safety at the U.S. Food and Drug Administration's (FDA) Centers for Devices and Radiological Health (CDRH) at the FDA UDI Public Workshop on February 12, 2009.



The lack of unambiguous identification of medical devices or the inaccessibility to critical device related information significantly impacts the Healthcare supply chain, patient safety and treatment processes.

- Did you know that it took eight hospitals in Hong Kong two weeks to find 30 patients affected by a recall of a hip replacement system?¹ Hospitals often have to rely upon recall databases using a variety of numbering schemes to identify products, making it difficult to match devices to patients.
- Did you know...that the Food & Drug Administration (FDA) in the US received 66,000 adverse event reports for medical devices in 2007, of which 60% lacked the lot number or other meaningful identifier?²
- Did you know... that the Department of Defense in the US discovered that Healthcare providers' product catalogues had problems matching the correct manufacturer name for 30% of the medical devices they had in their catalogue and that 20-25% lack the product brand name?³
- Did you know... that the part number '8630' in the product catalogue of a leading Group Purchasing Organization (GPO) in the US was linked to 9 different numbers from different distributors?⁴

The US Food and Drug Administration is required by the FDA Amendments Act of 2007 to 'promulgate regulations establishing a unique device identification system for medical devices...'. The FDA has worked closely with

industry stakeholders and standards organisations, such as GS1, to develop these requirements and expects to publish a Final Rule in 2012. The FDA has also worked with other regulatory bodies worldwide to drive harmonisation in UDI regulation and implementation. The International Medical Device Regulators' Forum (IMDRF), formerly known as the Global Harmonisation Task Force (GHTF), has established a dedicated Ad Hoc Working Group to provide guidelines and a model for global UDI implementations. The European Commission is also developing UDI requirements. The EU recast of the Medical Device Directives will incorporate Unique Device Identification. Many other countries are also considering implementation of UDI regulations.

Increase patient safety	<ul style="list-style-type: none"> • Enhance effective product recalls • Reduce medical errors • Tool for anti-counterfeiting strategies
Improve post-market surveillance	<ul style="list-style-type: none"> • Enhance effective adverse event reporting
Enhance capture of correct information	<ul style="list-style-type: none"> • Effectively capture product data to populate electronic health records
Enhance business process	<ul style="list-style-type: none"> • Improve supply chain processes, inventory management • Enhance eProcurement

THE OPPORTUNITY: UDI ACROSS BORDERS

The successful global implementation of UDI from manufacturers through to Healthcare providers will depend on several factors, including the following.

Global Reach

The IMDRF (a.k.a. GHTF) UDI Ad Hoc working group advocates a globally harmonised UDI system to achieve the true benefit of UDI for patient safety across borders.

"The UDI System is intended to provide a single, globally-accepted system for positive identification of medical devices. Health care professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a device, its key attributes. The UDID is a designated source for additional information. It is critical to note that the benefits of UDI can only accrue if all stakeholders, from the manufacturer through to healthcare providers and patients, use UDI throughout their system. Therefore, it is imperative that all stakeholders be educated about the development and use of a UDI System."⁵

Regional or local solutions and company internal processes fragment the global implementation of UDI

and are not scalable across geographic and jurisdictional borders. UDI provides a common global framework where local market requirements can still be met, but not at the expense of a global solution.

Sector-wide Reach

All supply chain stakeholders from manufacturers through to healthcare providers need to prepare for UDI. Suppliers typically will have to comply with regulatory requirements; however regulators often do not have the same authority over hospitals. Nevertheless, the intention is that all healthcare supply chain partners will need to collaborate and implement solutions to fully realise the benefits of UDI.

Risk-based Approach

Due to the extensive diversity of medical devices, a gradual risk-based approach to implementation is essential. Risk Classes are effectively used in regulatory jurisdictions for regulation and will likely be the basis for UDI implementation. For example, the US FDA will normally require compliance for Class III devices in one year after the final UDI ruling, Class II medical devices in three years, Class I medical devices up to five years.



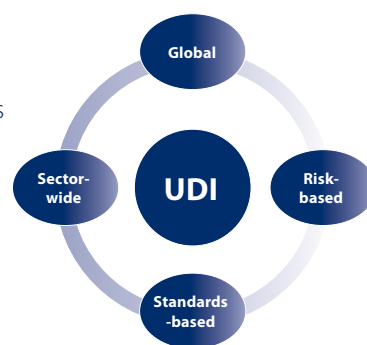
Standards-based approach

Using non-standard or proprietary means of capturing and exchanging information negatively affect data accuracy and process efficiency. Some organisations develop their own proprietary identification systems, electronic product catalogues or traceability systems, which are only functional within their own organisation. Others use locally developed systems that are only functional within the confines of a single sector or a single country. Standards provide a global harmonised and integrated framework to manage supply chain information.

The UDI System is intended to provide a single, globally-accepted system for positive identification of medical devices. Health care professionals and patients will no

longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a device, its key attributes. The UDID is a designated source for additional information.

It is critical to note that the benefits of UDI can only accrue if all stakeholders, from the manufacturer through to healthcare providers and patients, use UDI throughout their system. Therefore, it is imperative that all stakeholders be educated about the development and use of a UDI System.⁵



THE SOLUTION: THE UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM

“The fundamental concepts of a global UDI System include:

- The UDI and UDI Carrier are based on global standards
- A UDI applied to a medical device anywhere in the world should be able to be used globally to meet the UDI requirements of any regulatory authority
- National or local identification numbers should NOT be a substitute for UDI
- Regulatory Authorities should not specify how to modify these standards
- The UDI Database core elements should not be modified
- The UDI Database should use the HL7 SPL for data exchange⁵”

The Unique Device Identifier includes the “key” to device related information stored in a database, and ensures the unambiguous identification of a specific product. The GS1 solution for creating the device identifier of a UDI is the Global Trade Item Number (GTIN). The ‘dynamic’ portion of a UDI is a production identifier generated in manufacturing and includes expiry date, lot number or serial number (depending upon how the device is controlled) and is printed on the product label, see illustration below.



UDI with a GTIN, Expiry and Serial Number

Ideally, the UDI database would be a global network of regional databases communicating with each other and providing a single point-of-access. This model could allow data providers to load their master data once for all geographies and data recipients have access to master data of all their suppliers through one source. A similar model is already in use by manufacturers, distributors, GPOs and providers to share product data via the GS1 Global Data Synchronization Network (GDSN). The GDSN can be leveraged by manufacturers as a data feed to the UDI databases.

The Unique Device Identification system will:

- provide a single, globally accepted source for positive identification of medical devices.
- Adequately identify medical devices through distribution and use.
- provide rapid access to key attributes of the device from a dedicated database.
- simplify integration of information on device use into medical records.

The UDI initiative is expected to involve many different organisations.

- Regulators and (inter-) governmental bodies have already mandated or are expected to mandate unique identification of medical devices.
- Medical device manufacturers will need to comply with those regulations in order to market their products in those countries, but can also leverage UDI to optimise their business processes.

1. Hong Kong Hospital Authority - http://www.gs1.org/docs/healthcare/news_events/091110/4_Hong_Kong_Hospital_Authority_Wong.pdf

2. US FDA - http://www.gs1.org/docs/healthcare/case_studies/Case_study_US_FDA_UDI.pdf

3. US Department of Defense - http://www.gs1.org/docs/healthcare/news_events/060411/16_Harrington_DoD.pdf

4. Premier - http://www.gs1.org/docs/healthcare/news_events/060411/23_UDI%20Database%20Roundtable.pdf

5. GHTF Unique Device Identification (UDI) System for Medical Devices

<http://www.ghetf.org/ahwg/ahwg-final.html>

- Healthcare providers will need to have the necessary IT systems in place to leverage UDI information for electronic patient records, adverse event reporting, product recalls, the 'perfect order', inventory management, and other applications.
- Other Healthcare supply chain stakeholders, including Group Purchasing Organisations, distributors and wholesalers, will also need to accommodate and facilitate the use of UDI.
- Healthcare payers may also decide to leverage UDI for reimbursement purposes for certain medical devices.
- Solution providers and logistics providers will need to develop the appropriate solutions and services to

facilitate the implementation of UDI.

- The GS1 Global Data Synchronisation Network (GDSN), provides a single point of connection from anywhere in the world, via the GDSN-certified data pools which provide standards-based services to upload and retrieve device related information.
- GS1 Global Office will continue to facilitate the standards development process in which all stakeholder members can participate in developing requirements for global, neutral and user-driven standards.
- GS1 Member Organisations (MOs) support local stakeholders to leverage global standards for UDI implementation in their region.

GS1 SUPPORTS THE IMPLEMENTATION OF UDI

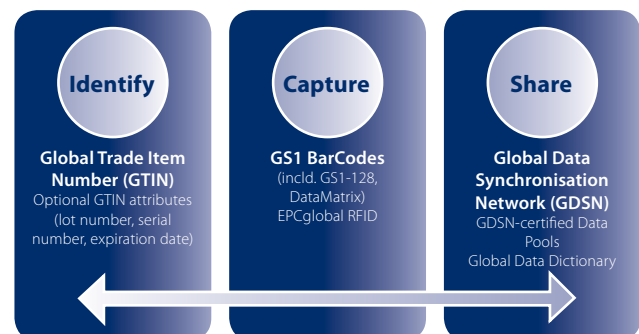
GS1 has over 100 GS1 Member Organisations and more than 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local situation.

GS1 has successfully managed communities of users from various sectors for over 30 years. GS1 Healthcare, the global Healthcare user group, has provided a neutral forum for the last six years for all Healthcare supply chain stakeholders to meet and develop the necessary standards. The Global Standards Management Process (GSMP) ensures a truly user-driven process to develop standards.

The GS1 system of standards enables all stakeholders to efficiently and effectively meet UDI requirements by ensuring interoperability and compatibility within an organisation, between organisations and across borders. A single standard will ultimately accelerate implementation and increase compliance to the UDI regulations.

- Global** – GS1 Standards ensure globally unique identification and enable cross-border compatibility of supply chain solutions.
- Robust** – Today, in various sectors, over 6 billion transactions per day are enabled by GS1 standards, demonstrating its robustness.
- Multi-sector** – Using the same standard to identify and trace Healthcare and non-Healthcare items ensures compatibility for Healthcare stakeholders sourcing a wide variety of items.
- User-generated** – GS1 Standards are built and maintained collaboratively by volunteers from across the world and representing every part of the supply chain.
- Scalable** – GS1 Standards meet the needs of a small rural hospital as well as a multi-national supplier. Many Healthcare manufacturers have already invested in the implementation of GS1 Standards and can leverage that for further roll out.

Standardised GS1 product identifiers, such as the Global Trade Item Number (GTIN) and GTIN-based serial numbers or lot numbers, provide unambiguous identification for both UDI and the supply chain leveraging a single investment in standardisation worldwide. Encoding the UDI in a GS1 bar code on a label enables the automatic reading of the identifier further reducing errors caused by manual recording of the information. The Global Data Synchronisation Network (GDSN) provides a single point of connection to manage medical device-related data.



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, and to view this paper please visit www.gs1.org/healthcare.

