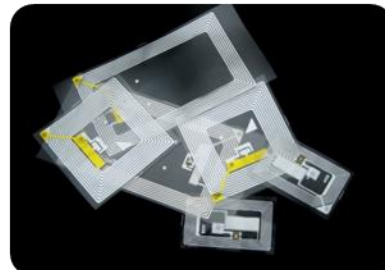




LEVERAGING HIBCC STANDARDS FOR UDI

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About HIBCC

HIBCC is an industry-sponsored, non-profit, Standards Development Organization (SDO). Founded by major industry associations in 1983 to develop auto-ID standards for the healthcare supply chain, we are endorsed and represented by groups such as:



We are accredited by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and are recognized by the International Organization for Standardization (ISO).

Our standards are globally deployed and are a predominate device standard.



European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung



International
Organization for
Standardization

Why Has the FDA Proposed UDI?

- FDA and industry partners have been studying the benefits associated with auto-ID technologies deployed in both healthcare and non-healthcare industries;
- FDA is reinforcing the importance of these technologies, developed by organizations like HIBCC, in support of enhanced safety and cost containment strategies;
- Implementation of UDIs and Automatic Identification Data Capture (AIDC) systems can help reduce the incidence of medical error, thereby enhancing patient safety efforts, and can also assist with streamlining supply chain processes, reducing costs to all parties.

Which AIDC Technologies Are Supported?

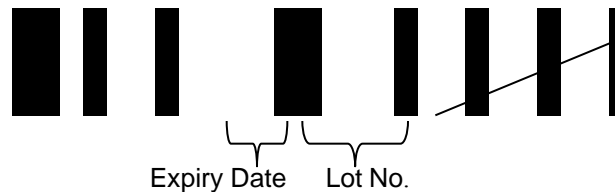
- The FDA did not specify, nor prohibit, a specific type of AIDC to be used, believing that the selection decision is best left to the issuing agency or labeler, so as not to hinder development of new and improved technologies, nor the broader adoption of them, with overly prescriptive rules.
- The HIBC Supplier Labeling Standard (SLS) supports linear barcodes, 2-D symbols, such as Data Matrix and PDF-417, as well as RFID tags.

Using HIBC As Your UDI Data Source

HIBC Primary:
(Linear Format)



HIBC Secondary:
(Linear Format)



Link character*

Data
Matrix
Option

**HIBC Primary & Secondary
Concatenated:**
(Linear Format)



* The HIBC Primary and Secondary data may also optionally be combined (concatenated) into a single line of code.

HHS/FDA, Federal Register, Vol. 77, #132

“A UDI may consist of two parts:

*A **device identifier** that identifies the specific version or model of a device and the labeler of that device; and*

*A **production identifier** that identifies one or more of the following, when present on the label of the device:*

- The lot or batch within which a device was manufactured;*
- The serial number of a specific device;*
- The expiration date of a specific device;*
- The date a specific device was manufactured.”*

Benefits of HIBC SLS

SAFETY

- The alphanumeric format allows for direct and literal encoding of identifiers, eliminating need for cross-referencing. Many industries for which safety is essential, such as aviation, automotive and blood banking also rely on alphanumeric-based standards.
- The variable length data structure allows the manufacturer to incorporate current product identifiers without having to truncate or pad digits.
- The 36 alphanumeric characters, combined with the flexibility of a 1-18 digit variable length format, provide an almost infinite set of identifiers so there is no risk of duplication.

Benefits of HIBC SLS

FLEXIBILITY

- They accommodate identification of multiple levels of packaging - from pallets down to individual units of measure - using a standardized code and consistent format. This allows for easier identification within various packaging configurations.
- They are globally compatible as they are the same everywhere in the world. There are no regional variances. This enables implementation of secure and efficient tracking processes in both domestic and international markets.

Benefits of HIBC SLS

COST

The FDA has stressed in its proposal that the cost of UDI should not cause an undue financial burden on manufacturers and other labelers.

- The HIBCC registration for a Labeler Identification Code (LIC) is modest and is based upon an organization's gross annual sales. It is a one-time fee. There are no reoccurring costs to maintain the registration.
- HIBC LIC is a global identifier so can be used throughout the world with no additional fees.

How Do I Comply with UDI?

- HIBC Labelers are already a long-way to complying with the proposed regulation. As noted, the HIBC SLS has been identified by FDA as an acceptable UDI format. As a consequence, HIBCC will apply to the FDA to become an issuing agency.
- Several tools to assist with the creation of UDIs are currently available, including:
 - The HIBCC Resource Desk @ **1.855.HIBC.UDI (1.855.442.2834)**;
 - The online data formatter; and
 - Participation with the AIDC Technical Committee.

How Do I Become a HIBCC Labeler?

- First, apply for a Labeler Identification Code (LIC) from HIBCC by submitting an application online, by mail or by fax. The application is available at www.hibcc.org.
- The assigned LIC identifies the *registered company*, not an individual product or device, and thus can be used across multiple product lines. The cost of an LIC is based upon a company's gross annual sales and is a one-time fee. There are no reoccurring costs to maintain the global LIC registration with HIBCC.
- Then, utilizing the HIBC SLS companies can begin to create UDIs at multiple packaging levels, depending upon the required granularity of identification necessary.

HIBCC'S UDI Resources

HIBCC provides a wealth of free resources on UDI and auto-ID technologies, including:

HIBCC UDI GUIDELINE
LIC REGISTRATION FORM
HIBCC ONLINE DATA FORMATTER
CURRENT HIBC REGISTRANTS BY COUNTRY
THIS SLIDE SET

To download these documents or to create a HIBC barcode online, please visit our website:



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