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# Unique Device Identification

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## What is HIBCC?

- The Health Industry Business Communications Council (HIBCC) was founded by major industry associations in '83/'84 to create identification standards for products in the health care supply chain. Twenty-fifth anniversary next month!
- HIBCC Standards 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).



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



- HIBCC Standards are globally deployed and are a predominate device standard.

## *How do we convey the UDI concept?*

- FDA needs to clearly define “UDI” to the industry.
- The most exacting UDI definition provides for a unique serial number for *each* medical device. In this scenario, each identical device would be assigned its own serial number.
- However, for many medical devices serialization is unnecessary. Supply chain costs would far exceed any benefits.
- Other UDI definitions would thus vary its meaning based upon broader classes of devices.
- HIBCC standards can accommodate all UDI definitions.
- UDI information should be shared among manufacturers and their trading partners/customers and the FDA should publish UDI information on its website.

## *Which standards should be utilized for the UDI?*

- HIBCC recommends that existing Universal Product Number (UPN) standards (HIBCC and GS1) be adopted. Both contain the same data elements and are widely used in the industry.
- Utilizing UPN in the UDI framework will allow the FDA to leverage the industry's existing standards and will both minimize costs and avoid inherent risks from cross-referencing or changing existing product identifiers.
- Utilizing UPN in the UDI framework accommodates both alphanumeric and numeric variants.
- Basing the UDI on UPN is consistent with FDA's prior rules regarding bar code labeling requirements 21 CFR Parts 201, 606, et al. Bar Code Label Requirements for Human Drug Products and Biological Products.

## *What else should be included in the UDI?*

- Serialization should be required only for medical devices that are comprised of numerous parts (such as pacemakers/defibrillators) and for devices that are reused and must be tracked.
- Consumables need not be serialized.
- “Kits” should have their own UDI.
- We do not see a need for “exceptions”.



## ***Are there issues regarding “reused” devices?***

- This issue requires close supervision by FDA
- Re-sterilization may not constitute “single use”

## ***Are devices controlled other than by lot or serial numbers?***

- HIBCC is not aware of any other relevant controls.

## *Can UDI replace other label information?*

- No! UDI codes will be too ambiguous to the average user.

## *If a device is changed, when is a new UDI necessary?*

- Always! A UDI should **NEVER** be reused. The number of available alphanumeric HIBC combinations is so large that the need for reuse will not be an issue.

## *How should we handle devices that are sold in both retail and health care settings?*

- Pharmaceutical/devices found in retail and health care must change their labeling under the current FDA proposal.
- “Price check” codes are not acceptable for UDI.



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**For more information:**



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