

PHARMACEUTICAL & MEDICAL

# Packaging<sup>®</sup>

THE PACKAGING MAGAZINE FOR THE HEALTHCARE INDUSTRY

NEWS

MARCH 2007

VOLUME 15, ISSUE 3



**Stress-Free  
Trays**  
p. 94

**Efficient Contract  
Packagers**  
p. 100

**Materials and  
Supplies  
Buyers  
Guide** p. 32

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# Unique Identifiers for Medical Devices

*HIBCC standards allow for direct and literal encoding of product information.*

The Health Industry Business Communications Council (HIBCC; [www.hibcc.org](http://www.hibcc.org)) is a leading standards development organization for healthcare-related issues, including



Robert A. Hankin

medical device identification. Founded in 1983 by a task force composed of manufacturers, distributors, and providers of healthcare services, HIBCC develops and maintains accredited e-commerce and product identification standards. Through the efforts of HIBCC Technical Committees, HIBCC maintains standards that are approved by international standards bodies, including ANSI and ISO, and endorsed by FDA.

In this interview, Robert A. Hankin, PhD, HIBCC's president and CEO, answers questions that *PMP News* originally posed during its 2006 Medical

Packaging Roundtable. Hankin discusses FDA's interest in unique device identification (UDI) and current industry practices.

### Why is unique medical device identification necessary?

Automated processes, such as standardized product identification, have proven to be highly effective for reducing errors and improving efficiencies in many industries. In healthcare, the potential benefits have even greater significance. A standardized system for UDI such as that being considered by FDA has tremendous potential for cost containment and patient safety.

For suppliers, UDI will enable process consistency and efficiency, enhance full-cycle supply-chain management from manufacturing to end-user delivery, and improve track-and-trace protocols in the event of product recalls.

The benefits to providers include improved patient safety through secure product identification, efficient traceability, and greater ability to monitor expenditures and reimbursements.

### Are the current systems being used for medical device identification appropriate for unique identification?

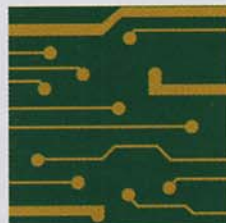
Absolutely. In the mid-1980s, the healthcare

industry recognized the need for developing standards that would address the unique security concerns of medical product identification. Existing retail standards were considered by some to be inadequate because they are based on all-numeric, point-of-sale-based transactions, and thus failed to allow millions of alphanumeric identifiers. This limitation required costly and risky translation processes. HIBCC standards were developed based upon an alphanumeric format that allows for direct and literal encoding of product information. For medical devices this is especially critical, as many product identifiers and serial numbers contain both alphabetic and numeric identifiers.

The healthcare industry was not unique in its concern. Many industries for which safety is essential, such as aviation, automotive, and blood banking, also rely upon alphanumeric-based standards.

### Is serialization necessary?

Serialization will require fundamental changes to current processes, so it should not be approached generically. Its relative need and potential benefit should be weighed for different product classes. For instance, a pace-maker, which is com-





posed of many different parts, creates a level of complexity that may warrant serialization for track-and-trace purposes. But serialization will provide little to no added benefit to batch-processed consumable products such as dressings and gloves.

### **What technologies are viable?**

There are many technologies that can accommodate serial numbers, including traditional linear bar codes, two-dimensional (2-D) symbols such as Data Matrix, and, of course, radio-frequency identification (RFID). Although serialization is often discussed as a driver for RFID, and space constraints on packaging may make 2-D and RFID applications more practical, it does not lead exclusively to any one technology.

Serialization, if necessary, can already be accomplished through existing HIBCC standards. This continuity allows labelers to maintain and preserve their established labeling processes—the benefits of which

are significant in terms of backward compatibility and associated costs.

### **Should the pharmaceutical industry serve as a model?**

The guidelines set forth by FDA regarding identification of pharmaceutical products are important for several reasons. First, they provide clear direction and guidance to the industry. Second, the requirements provide continuity by specifying existing and internationally recognized standards for product identification. And third, within this

framework, they allow for flexibility in the choice of identifiers. FDA recognized the importance of the alphanumeric HIBCC standards to the industry in its bar code rule.

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### **What challenges do medical device manufacturers face?**

There are no significant technical or practical barriers to implementation provided that existing international standards are required.

Regulations should be relatively straightforward and should not be made overly complex as a consequence of onerous requirements. Technology creep, as in any industry, can overly complicate what can be very simple processes. Any regulation should define current capabilities, consider what future needs are likely to be, and weigh the cost benefits of complex processes such as serialization.

### **Is this a global issue? Is one region or country ahead of the rest?**

Patient safety and cost containment are critical issues in any language, and product identification goes a long way toward reducing these risks. The efforts of international standards organizations such as ISO and ISBT have

*HIBCC standards were developed based upon an alphanumeric format that allows for direct and literal encoding of product information. For medical devices this is especially critical.*

### **Should the pharmaceutical and medical device industries share the same identification systems and standards?**

It is absolutely critical that government regulations support existing healthcare standards. These standards have been long established, are proven, and are in practical use by healthcare participants. What is important now is developing incen-

already addressed issues related to global harmonization for identification. FDA should be building upon these successful efforts.

### **What needs to be done?**

Implementation, implementation, implementation. This is where FDA can be of great benefit. The standards and systems exist and are effective when used.

## What is HIBCC proposing?

HIBCC was developed by the healthcare industry, and our efforts reflect the stated needs and interests of our constituents—the suppliers of medical goods and the providers of medical care. Our proposals are the products of

these efforts and have already been implemented on a global scale.

## How have these standards been received around the world?

The HIBCC standards have been implemented by thousands of compa-


nies from every region of the world, representing small manufacturers to multinationals. Many of the largest U.S. exporters that supply a vast percentage of total product worldwide have implemented HIBCC standards. The success of the HIBCC standards is based upon two critical factors: first, the preference by these companies for alphanumeric identifiers, and second, the global consistency of the HIBCC standards. The HIBCC data structure is standardized no matter in what region of the world it is applied.


*FDA recognized the importance of the alphanumeric HIBCC standards to the industry in its bar code rule.*

## What do you predict will happen in the next two years? Five years? Ten years?

There is no doubt that technology integration has been recognized by the industry as a powerful tool. The extent to which new technologies are integrated depends largely on how the marketplace learns to leverage them. Over the next two years, there will be an increasing use of 2-D symbols, particularly for small packages at the unit-of-use level.

These symbols will also be etched onto metal surfaces for some medical devices, such as surgical instruments. Within five years, there will likely be increased use of RFID within closed-loop or internal systems. And over a period of 10 years, bar coding and 2-D symbols will coexist as alternative technology options for healthcare participants to choose. Bar codes and 2-D will continue to represent a low-cost option that delivers significant ROI for many applications. ■


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