

## Global Data Standards for Medical Devices: Is Your Organization Prepared?

by Barry Blake

For the past year, the healthcare reform effort in Washington has consumed most of the attention of the healthcare and life sciences industry. One regulation that has seemingly slipped under the radar is the impending Food and Drug Administration's (FDA) Unique Device Identifier (UDI).

Since supply chain and operations functions will bear most responsibility for implementing this regulation, medical device companies must not only be prepared with a regulatory and quality affairs response strategy, but with a UDI implementation roadmap as well. Inevitably, a company that delays mobilizing resources to address this regulation will face higher implementation costs than one that has already completed a thorough assessment of the organizational and operational barriers to adoption.

The Medical Device Supply Chain Council, an informal network of supply chain and operations thought leaders from the medical device industry, recently created a network chartered to raise awareness and increase adoption of UDI and associated data standards. The Council will act as a source of information and forum for manufacturers to stay current on the state of global standardization efforts, providing easier access to the information that medical device companies need to implement standards and stay compliant. Furthermore, part of the Council's goal is to help global device manufacturers identify and articulate the business value of track-and-trace standards like UDI and their associated data models. Benefits identified so far include streamlined internal distribution and logistics processes, more compliant and efficient management of recalls, and a fact-based understanding of customer service measurements.

While the UDI regulation pertains solely to the U.S. healthcare environment, the Council is very much focused on the global regulatory environment. The FDA regulation allows manufacturers to choose between a few FDA-qualified data standards. Around the world, however, most regulators aren't allowing manufacturers a choice in the standards used. All indications suggest that GS1 is the global standard of choice for regulatory bodies outside the United States. Therefore, the Council's focus will be centered on global GS1 Standards.

The Medical Device Supply Chain Council's UDI/Standards Adoption Network provides a much needed and timely service for global device manufacturers. After all, a majority of organizations are just beginning to understand the level of effort required to respond to legislation like UDI in a compliant and efficient manner. Since the UDI regulations will affect a company's entire product and customer data management processes as well as associated information systems capabilities, a "slap-and-ship" application won't suffice—a well-planned and executed voyage is required.

In many ways, these are uncharted waters for device manufacturers, but with the help of the Council, the coordinates to adoption and implementation will become clearer.