Medical device companies are striving to capitalize on market opportunities while simultaneously dealing with increasing regulatory compliance requirements. One of the newer mandates, the FDA ruling on Unique Device Identification (UDI), requires action in three main areas:

**Label & Packaging**
- UDI = Device and Production Identifier (Di) + (Pi)
- Inclusion of UDI and barcode on label
- Labels on lowest level of packaging

**Direct Marking (DM)**
- Directly marking the UDI as a permanent marking on multi-use devices intended to be reprocessed prior to each use.

**UDI Database**
- Publishing of DI and product attribute database via direct entry or HL7/SPL for bulk uploads

While working to comply with the rule, manufacturers have realized that the problem to be solved is multi-faceted and interconnected. It’s like the ancient Greek myth of Pandora opening the box releasing the not-so-pleasant things into the world. Although kinder to the industry than originally anticipated, the FDA’s UDI ruling is more complicated than just a labeling change, making implementation a challenge.

**Opening the Box: Common UDI Challenges**
- All supplier relationships are not the same; roles and responsibilities for labeling vary dramatically across the original equipment manufacturer (OEM) spectrum
• Label standards are not always enforced; label format, content and systems are often not consistent across product lines, business units and manufacturing sites
• Label data are often converted to artwork and retained in a document format (i.e. pdf) verses a structured database making them difficult to retrieve for Global UDI Database (GUDID) submissions
• When labels are managed as documents using a change control process, traceability of common data across product lines, business units and manufacturing sites becomes a challenge
• There is often no single source of truth; isolated labeling systems are not well integrated with overall product data and lifecycle management

Recommendations for Addressing Pandora’s Box of UDI Challenges

The Labeler

In addition to specifying the data required and its format, the UDI rule also defines which company is “the labeler.” This is a complicated area that needs to be interpreted by each manufacturer who must submit UDI records to the GUDID under their respective Dun and Bradstreet (D&B) number, refered to as a DUNS). The complexity comes from not having a one-to-one relationship between GS1 company prefix numbers and DUNS numbers.

The FDA identifies several entities associated with medical device registration, but is flexible on who is responsible for submitting the UDI record for the device to the FDA. To address this challenge, manufacturers need to look at the spirit of the ruling. Since the rule is intended to aid in patient safety, they should ask key questions such as:

• Who will the customer contact as their ultimate source of information for the device?
• Who will the FDA initiate an investigation with if an adverse event should occur?
• Who has overall regulatory responsibility?

The answers to these questions helps companies decide who should assume responsibility for submitting information on devices to the GUDID under their respective DUNS number.

Labeling Data

There is a broad range of information typically found on current product labels, most of which is required for submission to the GUDID, including catalogue numbers, brand name, description, quantity, size, sterility status, production identifiers, bar codes, etc. Many times, however, this information is not consistent on labels across product families.

We recommended that manufacturers assess their product portfolio and define the level of product groupings (i.e. product family) where there is a common denominator for mandatory labeling elements. Based on these groupings, a common template can be defined that includes standards for formats and uses database functionality to maintain data respective to individual product labels at the lowest level of packaging. Label data should be maintained as elements in a structured database by product code to facilitate federating to other systems such as label printing.

Recent learnings pertaining to attributes lead us to recommend limiting production identifiers to only those that define production control (e.g. lot/batch or serial number, expiration date, etc.). It is not recommended to use additional production identifiers (i.e. manufacturing date) on the primary label if there is no regulatory requirement to do so, as this complicates data to be encoded in the Automatic Identification and Data Capture
(AIDC) version of the UDI.

**Labeling Processes and Systems**

Traditional label development processes are inefficient and prone to costly errors. With no single source of truth, unstructured, disparate product data makes device labeling a manual and tedious process. Legacy systems and processes increase the risk of lost productivity, non-compliance, and cost overruns due to labeling errors caught later in the production stream. Companies can even face fines and legal action if misbranded inventory makes it to market.

To address this challenge, new requirements for labeling and packaging need to be taken into account at the design input stage of the development process to ensure that UDI compliant labels and GUDID submissions are timed with new product introduction.

When implementing systems that support a single source of truth for product data, companies see the best results when they utilize a product lifecycle management (PLM) platform complemented with a best-of breed labeling and artwork management system(s) (AMS) that allow all data to be stored and controlled in a central location. Having one source of truth for label data enables syndication of data to other locations such as printing labels on the plant floor; package artwork and Instructions for Use (IFUs); product registration; and the GUDID. Companies can act with confidence knowing that it is the same data being sent to multiple locations.

Integrating labeling and AMS with PLM ensures that all product, labeling, and UDI data is tightly controlled from the central core product record, enhancing product development processes with integrated change control and workflows across product development, labeling, and product registration. This approach not only meets the new UDI requirements, but also sets up the organization for a more streamlined and compliant product development and lifecycle management process.

**Steps to Conquering Pandora’s Chaos**

How will manufacturers meet the UDI compliance deadlines? Assuming a cross-functional, enterprise-wide team is in place and the program plan and corporate policy are defined, the first place to focus is labeling. It is
critical to align on the Device Identifier (DI) standard (i.e. GS1, HIBCC and ICCBBA/ISBT-128) and ensure all labels are compliant with the ruling, making appropriate changes as necessary.

The next focus area is UDI data, with strategies for both currently marketed and future new products. For current products, failure to comply is not an option; heavy lifting will need to be done to locate and map data in existing systems and on current labels. Manufacturers then need to prepare to submit via one of the three methods the FDA describes.

For new products, there is a chance to build a cohesive data, processes and system architecture with an implementation plan for the future. The key steps for this are:

- Define a strategy to author, maintain and submit to the GUDID the data and attributes for new products that detail roles, responsibilities and governance
- Unify separate data silos with a PLM system and plug-in artwork management, label management and printing systems to complement PLM
- Develop a UDI governance process to create and maintain UDI data in a single, controlled location as part of a change management processes (defined by quality systems)

Avoiding Competitive Disadvantage

The UDI mandate is happening now and the challenges may be greater than expected. Labeling is a key component of the ruling, but not the only component. UDI compliance may not be a competitive advantage, but if manufacturers are not prepared, it could be a formidable disadvantage. Detailed interpretation can be confusing and there is a tendency to overcomplicate the effort when a new challenge arises. To avoid this, manufacturers should thoughtfully define their approach and plans in the spirit of the regulation. All policies, procedures and approaches to UDI should be logical, rational and defensible. Most importantly, as the implementation rolls out and more guidance is given, companies must be prepared to learn, adjust and evolve.

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