Merit SOLUTIONS

# UDI: Staying Ahead of the Curve

By Merit Solutions
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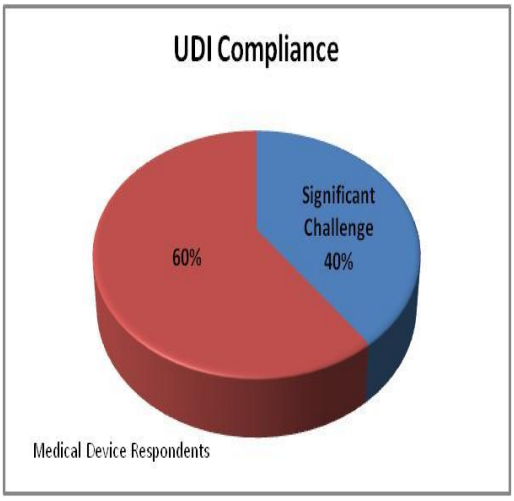
## EXECUTIVE OVERVIEW

It has been difficult to track safety issues associated with medical devices as there is no single universal means to identify these products. Gathering the appropriate surveillance data in order to make safety decisions is a challenge.

The FDA's Unique Device Identifier directive was developed to provide a means to track medical devices to facilitate post market surveillance for adverse event and recall activities that will lead to improved device safety.




The first deadline for UDI implementation has come and gone. A recent survey conducted by a labeling solutions provider for medical device manufacturers indicated that 40% of respondents were already experiencing challenges with the UDI regulations. Subsequent deadlines over the next few years will increase these challenges. The survey went on to indicate that another 40% do not have a plan in place to overcome these obstacles and successfully implement UDI.

These companies may have already implemented GS1 and thought they were most of the way there. They may have underestimated the complexity of the project or its impact on the entire enterprise. It is not just a labeling issue. The entire supply chain is impacted. Not fully understanding the scope of the project may have led to underestimating the overall cost.

Whatever the cause of the challenges, it is clear that manufacturers need to create a multidisciplinary collaborative team to step through the process of data gathering, formatting and storage to facilitate implementation and future lifecycle management. This is the opportunity to create a single product definition label profile using a software solution with the flexibility to interface with multiple users throughout the enterprise.

## Challenge #1 – Understand the Product Portfolio

| Date | Class of Device |
|---|---|
| **09-24-14** | Class III including standalone software |
| **09-24-15** | Implantable, life-supporting and life sustaining including standalone software |
| **09-24-16** | Class II, Direct Marking for Class III |
| **09-24-18** | Class I, Direct marking of Class II |
| **09-24-20** | Direct Marking of Class I |

Most companies have a rough idea how many SKUs will be affected by the UDI regulation, but few begin their journey with a clear analysis of the portfolio broken down by device class, manufacturing location, OEM etc… Each manufacturer needs to understand the product portfolio and how it fits into the timeline. The vendors used within the supply chain may have different responsibilities. Some products might come in as finished goods and then distributed by the parent company.

Over time, companies may have acquired other manufacturers or product lines leading to inconsistent methods for managing labels including differences in the format of the labels based on line of business or manufacturing site.

Be aware of the multiple packaging levels and the relevance to the UDI labeling requirements. The base package, the lowest level of device packaging with a unit of 1 may be contained in a box with 100 per box and may be shipped with 50 boxes per case. Each level is part of the device identifier.

## Challenge #2 – Find the Product Data

Product information and labeling data may reside in silo systems. Different departments in a company or vendors have various responsibilities when it comes to the product information and lifecycle management. Data may need to be gathered from:

- OEM Vendors
- Label Vendors
- ERP System
- Product Lifecycle Management System
- DMR

Packaging layers may be defined in the individual SOPs or work instructions specific for the put-up. Outer shipping container labeling, if considered a package layer, may reside in warehouse procedures or in the order fulfillment system. This may be complicated if warehousing or distribution functions are outsourced.

Define how many unique labeling situations there are as this will impact implementation. The data must be collated in a single secure tool and administered by individuals trained to identify the critical elements.

## Challenge #3 – Technology and Equipment

Companies will need to determine if current equipment technologies are capable of producing the necessary AIDC and human readable format. Obtaining this equipment or capability on current equipment in time to meet the required deadlines is a huge undertaking. These upgrades cannot negatively impact manufacturing functions or impede the flow of the supply chain.

Critical questions to answer may be:

- Is the data transmitted directly from an ERP system to the printers?
- Can the equipment produce the barcode and the human readable data?
- Where will the UDI data be stored internally?

*Data is spread throughout the organization without a single source of truth. The lack of an overarching lifecycle management solution and aging equipment may pose significant obstacles to meeting the directive.*

The new criteria will need to be tested and any new equipment validated. This is where companies may incur significant costs.

All the pertinent product data must be collated from the disparate locations and bundled in a single place in preparation for the transfer to the GUDID. The method to transfer the Device Identifier data to the GUDID must be determined and must meet the formatting requirements. A third party may submit to the GUDID on behalf of the labeler.

## PRESENT SITUATION

Current equipment and systems may not have the capability to control and produce the requirements necessary to satisfy the directive. Companies still using a paper based process and outdated labeling systems will be challenged to accommodate the additional labeling standards. In other areas of the supply chain, vendors may face the same capability challenges. The IT system may not be integrated into all areas that need to touch the label or product data. Lack of a comprehensive label lifecycle management system will exasperate the problem.

Labels contain a broad range of information and the content may not be consistent across products. Companies or manufacturing sites may execute different procedures to make labeling changes. These disparate processes are inefficient and tend to be costly. Manual methods can cause labeling errors which can lead to market withdrawals or recalls.


To address poorly managed data or processes, companies often employ manual methods to collate divergent data into a makeshift tool. This doesn't alleviate redundancies and allows it to continue. The current labeling lifecycle process may not be adequate to meet the demands of the additional labeling requirements. A one and done philosophy will not address the potential need for a new DI as products change overtime. A long term solution is needed to develop a robust, secure labeling process.

## THE SOLUTION

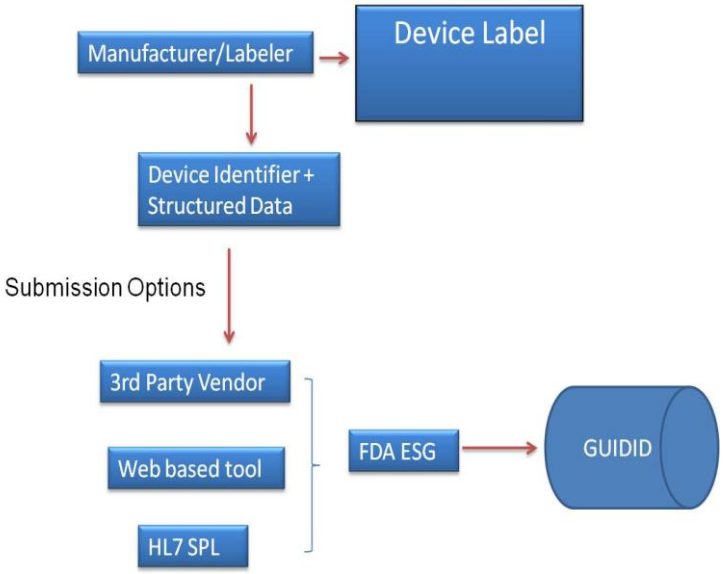
Many medical device manufacturers are pursuing integrated data management tools which are supported by master data management solutions that minimize the need for manual processes and diverse data reservoirs throughout the organization. Their objective is to drive toward a single source of truth for

product data. This database stores the critical data elements necessary to populate the GUDID in a secure location.

Ideally the PI elements should be generated in an ERP system and interfaced to the critical equipment. This data is converted into barcodes when printing begins.

Finally, there are 3 options for submitting to the GUDID.

- HL7 SPL XML file format-sends a file to the FDA Electronic Submission Gateway (ESG)
- Web based interface –a manual data entry method
- 3rd party submission-a separate vendor transfers the data on the labeler's behalf




Some testing is required for the XML file to ensure it is formatted correctly for the ESG.

Organizations can take the opportunity to improve on the overall label lifecycle management process. Using master data solutions and flexible data sharing options that can change with the product and be a single source of truth leads to efficiencies and less errors.

## CHECKLIST

- ✓ Develop an enterprise-wide plan
- ✓ Review product portfolio and apply the implementation timeline
- ✓ Understand the packaging levels
- ✓ Gain agreement on supplier responsibilities
- ✓ Update label and packaging files
- ✓ Select an Issuing Agency
- ✓ Review equipment capabilities
- ✓ Determine software solution for master data management
- ✓ Collate product data and populate the tool
- ✓ Determine the submission option
- ✓ Obtain GUDID account
- ✓ Transfer data

*Regardless of the timeframe, a comprehensive plan is required for UDI implementation.*

*Start now.*

## CONCLUSION

The UDI requirements are happening now regardless of the product portfolio. Manufacturers are encountering challenges. Many labeling systems really amount to several disjointed processes cobbled together over time. There is no better time to seize the opportunity to improve to a streamlined cohesive enterprise strategy. With a well thought out approach and a unified data solution, companies can meet the challenge of the new regulation and reap the benefits of improved product life cycle management.

## About Merit Solutions

Merit Solutions is a global business process consultant and systems integrator with offices in North America and Europe. We are a focused-strategy company with the goal of being the very best at helping clients automate, grow, and transform their business through process mapping and optimization, change management, and innovative IT consulting and development services.

Merit Solutions works with clients to understand and triangulate their exact business needs in terms of people, workstreams, and enabling systems. From future state business process mapping to systems analysis, fit-gap process definition and scoping, sourcing, design and deployment, integration with other systems, and on-going support - we provide end-to-end global services that help clients successfully transform their business and build a foundation that continuously flows value to their customers.

Our clients are typically medium to large, global enterprises who are challenged by inefficient workstreams that cost money, waste time, and reduce quality; information flows and systems that no longer support the goals of the company; and lack of visibility into business data which impedes effective decision making.

## Additional Resources

Related resources to this white paper include:

- ERP in Life Sciences
- Understanding CAPA
- CAPA, Customer Satisfaction, and the FDA

Information on Merit Solutions or other publications can be found on www.meritsolutions.com

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