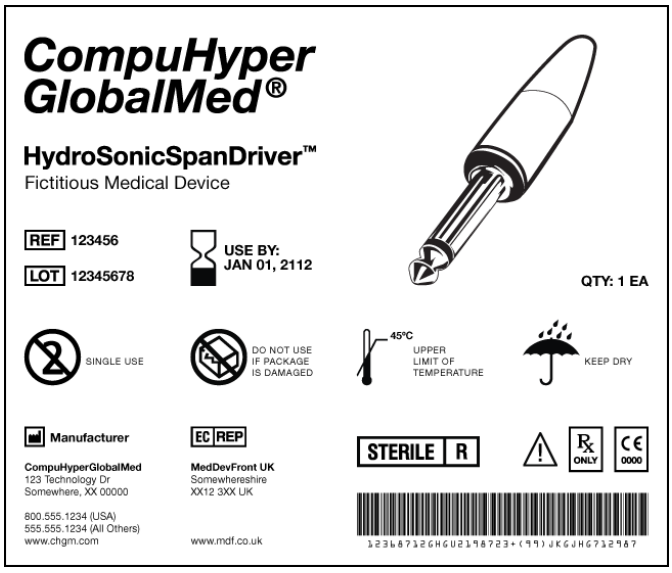
CLARKSTON CONSULTING

INSIGHTS

Unique Device Identification

A Top 10 on How and Why to Implement UDI

On September 27, 2007 the Food & Drug Administration Amendments Act (FDAAA) required the FDA to implement regulations establishing a Unique Device Identification (UDI) System. These regulations are expected to go in to effect around May 2013. As a result of this new requirement, several existing regulations will be changed and at least one new regulation introduced. The FDA has released the proposed final ruling with the comment period ending in November 2012. Have you read the proposed ruling yet? Do you know what is going to be required of your organization? The following tips will help you understand what steps you need to take, when and why.



Example of what a unique device identifier (UDI) would look like on a medical device label. The label contains information about the product name, its expiration date, reference and lot numbers, manufacturer information, bar code, details about the item, and an illustration of the item. Source: FDA

Number 10: What's the Plan?

One of the biggest struggles for the Medical Device industry is setting the parameters around how to implement UDI. Who will be responsible? What parts of the organization need to be involved? What product or products are affected? How will that product be identified and contained? What about training and logistics?

While it's tempting to get in the weeds with UDI, the plan needs to start at the strategic level. Many UDI projects have failed or are still trying to get started because there was no centralized strategy driving the initiative. When tasks are not identified or planned, resources not provided and milestones not mapped out, it can be difficult to take those first steps. Address these things from the start, and the implementation will go much smoother.

Within the plan, make sure to incorporate the technology side as well. Specifically, the engineering elements needed at the packaging line. It is critical to incorporate the accredited global standards and data to facilitate collaboration and information exchange with trading partners and the FDA, especially for incorporation into the UDI public database. For global medical device companies, it may be smarter to plan for a global approach as a first step to your implementation, followed by local or regional implementation plans as well.

Number 9: Education and Training

It is critical that the strategic team developing your UDI implementation plan be properly trained on the best practices of UDI. It is also important to bring the IT team in early so they understand the scope, technical standards and application of UDI. The FDA has established a global database that must be used to comply with the pending regulations.

Once the strategic team is trained and a plan developed, training needs to be incorporated throughout the plan. Your plan should include training in the specific areas of your sub-plans. The timing of your training is also critical. Implementing training before the team knows what questions to ask or what areas are affected, or the timelines may be a waste of time and money.

Number 8: Emphasize Documentation

The importance of documentation cannot be emphasized enough, and the most important documentation is around the implementation plan. Document and control the plan as if it were any other controlled document. When changes are made to the plan – and it is best to expect changes – make the changes in a controlled environment. If these changes are not documented, there is a huge risk for wasted time and money.

Not only it is important to document the plan, but the specific processes as well – both new and updated. Document the training and continually maintain and update accurate records. Some of the items and processes that will need documentation: marketing & sales, packaging & labeling, supplier requirements, warehouse & distribution, manufacturing operations, quality and inspection, monitoring and auditing, complaints and reporting, and regulatory. These are just some of the areas to consider, as they will differ within each company.

"Document and control the plan as if it were any other controlled document. When changes are made to the plan – and it is best to expect changes – make the changes in a controlled environment. If these changes are not documented, there is a huge risk for wasted time and money."

Number 7: Have you Selected an Accredited Issuing Agency?

An accredited issuing agency is an agency that is accredited by the FDA to issue UDIs that meet the standards required by the UDI ruling. At this time, there are two known agencies that meet these standards: GS1 and the Health Industry Business Communication Council (HIBCC).

There is the potential that other agencies may be developed as the regulation matures. There are concerns at the Federal level surrounding the costs incurred in working with these agencies, especially for small businesses. It is expected that if the agencies cannot be competitive enough to keep costs down, then the FDA will act as a no-cost accredited agency to make sure small businesses are not unfairly impacted by these regulations.

Number 6: What Product is Affected?

The easy answer is all medical devices are affected. But, in the regulatory industry, there are no easy answers. As you know, medical devices are broken down into three classes; Class III, Class II and Class I. Within these classes there are exceptions, and the same goes with UDI. The UDI proposed rule has broken down the timeline for implementation to align with the three classes of medical devices. Class III is one year after the final rule (with exceptions), Class II is three years after the final rule (with exceptions), and Class I is five years after the final rule (with exceptions). The reason for this phased approach is so the industry is not required to implement UDI all at once. Given this phased approach, implementation will vary from company to company depending on how the products are identified.

Number 5: Containment…How do we Maintain Control?

While this will be different for each company, there are several things to consider around containment and how to apply it within the company:

- Timelines and how they apply to production?
- What product goes through the UDI process and when?
- Who will have overall responsibilities?
- Who will do what, and will they have and understand their authority and responsibility?
- Who are the gatekeepers?
- Has validation or verification been completed and acceptable?
- Are the audits acceptable?
- Are all the in-process and final checks in place and functioning correctly?

And there are many more. What is important is to have complete control. Know what UDI is and what it isn't, and control the release into commerce in accordance with regulations.

Number 4: Process Change

As changes to process and product are made, make sure to follow the existing change control processes and procedures. It is key as the UDI implementation process is implemented, that existing company rules are not broken. Due to the time constraint on this process, many UDI implementations are plagued with limited time resources coupled with multiple and competing priorities. If a good process control is not followed, not only will problems related to UDI implementation occur, it may affect other processes and procedures as well, leading to costly issues. A well-planned UDI effort can be efficient, cost-effective and provide value to a company when implemented correctly.

Number 3: Verification/ Validation

To ver/val or not ver/val… It's not a choice. One or the other must be done, and preferably both. This is a key point in the implementation process.

Planning the verification and validation is important as well. At key points of the process, ver/val should be conducted to determine if the process is being implemented as expected and functioning as expected. It is important to plan where the ver/val will be done in the process in order to determine if everything is proceeding according to plan.

Also, remember the importance of timing. Too soon and the entire function many not measure correctly. Too late, and the implementation process may go down the wrong path. Ver/val should be included within the master planning as milestones. It is also important to have the person responsible for achieving a milestone signing off on the ver/val.

Number 2: Auditing

Auditing is another good measurement of the UDI implementation process. It is best to have the internal regulatory compliance auditing group and/or a third party auditor review the implementation process initially, as well as during key points throughout the process.

Not only is it important to assure the UDI implementation is following defined processes, but it is critical to ensure regulatory requirements are met. Audit is an important part of the planning as new regulations are being required as well as existing regulations changing. Regulatory (including compliance) has a big role in implementing UDI. Not only from the compliance/auditing point of view but through PMA and the 510K process as well.

As audits are conducted, make sure to place priority on taking action on the audit results. The results, along with ver/val, will indicate the implementation is going down the right path or whether it has deviated from the original plan. The sooner feedback is received through the audit, the least costly any mistakes will be. Another important point is to make sure to take actions on the feedback and findings, verifying that the corrections taken are effective.

> "Audit is an important part of the planning as new regulations are being required as well as existing regulations changing. Regulatory (including compliance) has a big role in implementing UDI."

Number 1: Implement Now, It's the Law!

Or at least it will be. Expected release of the regulations is May 2013, which is not far away, especially if UDI has not been initiated, or has been initiated, but is not getting the expected results.

As you see above, there is a lot of work involved with implementing UDI. There are also many resources to help implement UDI as well. The FDA has been very supportive in working with industry, not only in the United States, but throughout the world.

There is no doubt that FDA regulations surrounding UDI are coming. If you haven't already, it's critical to find answers to those key questions; Who will be responsible? What parts of the organization need to be involved? What product or products are affected? How will that product be identified and contained? What about training and logistics?

For more information on Clarkston's UDI Services, please visit:
www.clarkstonconsulting.com/UDI

About the Author

Philip Lamory is a senior consultant with Clarkston Consulting. He has over 30 years experience in Quality Assurance with over 10 years experience in medical device and pharmaceuticals and 17 years in management. Mr. Lamory has extensive experience in medical devices and pharmaceuticals in the development of quality systems and supplier management. Mr. Lamory is proficient in 21 CFR part 820, 210, 211, ICH Q7, ISO 13485, ISO 9001, ISO/TS 16949, AS 9100. He has experience in statistics, SPC, process control, and lean manufacturing.

CLARKSTON CONSULTING

Headquarters
Research Triangle Park
1007 Slater Road, Suite 400
Durham, NC 27703
Phone: 800-652-4274
Fax: 919-484-4450

www.clarkstonconsulting.com

707_0912

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 10-year average client satisfaction rating of 97%.