UDI: COMPLEXITIES OF COMPLIANCE

The stakes can literally be life or death if medical device manufacturers fail to adhere to the Food and Drug Administration's (FDA) new Unique Device Identification (UDI) rule. Compliance is complicated, and the costs of non-compliance are severe. With deadlines for many devices less than a year away, manufacturers must implement compliance processes and technology now.

The Patient's Health at Risk

Few products depend more on accurate identification than medical devices.

Take, for example, an implanted pacemaker. If it malfunctions, it's critical for the information in the adverse event report to match the manufacturer's product identification system; otherwise the adverse event may go unreported.

The same need holds just as urgently for a product recall sent from the pacemaker's manufacturer to the doctor, hospital, or patient. An inability to identify the device affected by the recall could have potentially disastrous results for patient health.

In a five-year period, the U.S. Food and Drug Administration (FDA) received an average of just less than half a million adverse event reports involving medical devices. More than 280,000 of these reports noted injury to the patient. In nearly 18,000 reports, the patient's outcome was death.

This harsh reality raises the stakes for consistency and accuracy in product identification. When misidentification occurs, it's most often due to a distribution company, hospital, or clinic renumbering the product. The need to correctly identify the medical device—both when conveying vital product information from the manufacturer to the field and when reporting problems back to the manufacturer—could hardly be more urgent.

Every minute lost to product misidentification can put a patient's life on the line.

Time Is Tight

Problems with correctly identifying medical devices have not escaped government notice. Recently issued (and soon to be enforced) is the FDA's new rule requiring Unique Device Identification (UDI) of medical devices distributed within the United States.

Over the next few years, all classes of U.S. medical devices—ranging from the most complex life-sustaining machines (pulse generators, defibrillators, pacemakers,

etc.) to the simplest healthcare aids (e.g., elastic bandages, arm slings, and examination gloves)—must become UDI compliant.

Time to comply is tight. For manufacturers of Class III medical devices (i.e., those involving the highest risk,) the UDI compliance deadline is less than a year away.

The FDA announced the requirements of the UDI regulation on September 24, 2013. The new standards also include updates to other regulations, including 21 CFR Parts 16, 801, 803, 806, and 810. See www.fda.gov/udi to learn more.

By September 24, 2014, Class III medical devices will need to be fully UDI-compliant. Compliance deadlines for Class II and Class I devices will then roll out each year in succession until all classes are covered by September 2018.

More Than a Label

The UDI regulation is broad in scope. It asserts that for a manufacturer to be allowed to continue shipping medical devices across U.S. state lines, they must identify each device and its packaging with UDI-compliant labeling. This may look like a mere string of numerals on a sticker, but there's a lot more to it. UDI requires the manufacturer to:

- Create a unique, 14-digit product identification number based on 65 specific points of product data for each device version and variant
- Submit specific information about the device, including the UDI number, for review and approval to the FDA's Global Unique Device Identifier Database (GUDID), where it will permanently reside for reference
- Ensure that any software systems used are 21 CFR Part 11 compliant, meaning they must meet specific technology requirements for secure electronic data management and review.
- Conduct and fully document 21 CFR Part 11 compliant training on UDI submission processes and technologies before the compliance deadlines hit
- Submit updated product information, including a new UDI number where needed, for review and approval each and every time a product, version, or variant changes

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> "Getting the UDI compliance solution right **is essential for simply staying in the game."**

Soon to Go Global

Non-compliance, of course, is not an option, but neither is a "wait and see" approach.

As UDI enforcement begins, the FDA can bar noncompliant companies from cross-state selling. Manufacturers who procrastinate or delay implementing their UDI compliance solutions will sacrifice sales to compliant competitors. Also, as word gets out, there may be serious damage to the noncompliant manufacturer's reputation and brand.

This is more than a competitive threat—it's a potential disaster. Manufacturers will find that getting the UDI compliance solution right is essential for simply staying in the game.

These consequences don't even begin to address the looming global compliance challenge. More than a dozen other countries, in addition to the U.S., are expected to follow the FDA's lead and will soon introduce UDI-like regulations for identifying medical devices distributed within their own national boundaries.

See the website of the International Medical Device Regulators Forum (www.imdrf.org) to learn more. Members of IMDRF currently include Australia, Brazil, Canada, the European Union, and Japan, as well as the U.S.

Many more emerging global markets will be lost to the manufacturers who are slow or unable to comply with these anticipated new product identification rules worldwide.

Demand for Data Management

Training, submissions, and labeling are only parts of the UDI challenge. The rule also adds significantly to the medical device maker's product data management demands.

Most manufacturers will find they need to mine vast stores of product information—for anything from a common tongue depressor to an individually customized endosseous jaw implant—to compile the particular 62 points of data needed to create the UDI-compliant product identification number for each particular device. They must then correctly format the data for submission, review, and approval, and closely track the FDA's response.

Precision is paramount. The FDA will allow only seven days to correct an imperfect submission before it is labeled noncompliant, giving the manufacturer every reason to get the submission right the first time.

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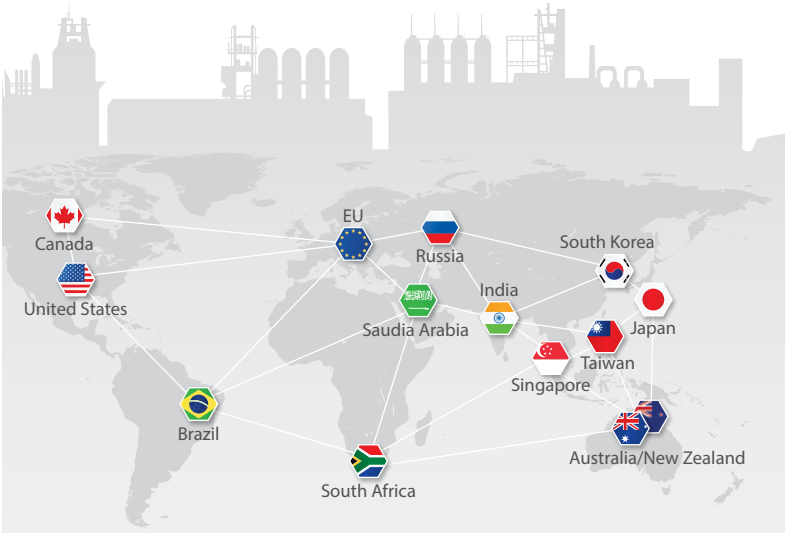
>
> **"As manufacturers continually refine their product designs, they will have to repeat the UDI submission cycle again and again and again.**

Looming global compliance challenge



Regulators	Countries/Stakeholders
TGA	Australia/New Zealand
ANVISA	Brazil
HC	Canada
EC DG SANCO	European Union
CDSCO	India
MHLW	Japan
COFEPRIS	Mexico

Regulators	Countries /Stakeholder
Roszdravnadzor	Russia
SFDA	Saudi Arabia
DOH	South Africa
KFDA	South Korea
	Taiwan
FDA	United States
HSA	Singapore

Product data management needs can seem overwhelming for even the smallest of medical devices. Consider a contact lens: It's a tiny sliver of plastic, yet it's incredibly complex in design. One size does not fit all, or even very many. Every optometric prescription for every lens wearer's eyes calls for a custom configuration drawn from literally thousands of design variables. There are a multitude of lens versions and variants to keep track of.

It's precisely this kind of design diversity, which is very typical of medical devices, that compounds the complexities of UDI compliance for even the most data-minded manufacturer.

A Challenge Times a Thousand

It's not uncommon for a medical device manufacturer's line to have hundreds, thousands, or even tens of thousands of products. Most products have design variations, often many more than a few, and packaging can also vary. An electronic blood glucose tester, for example, is almost sure to be packaged differently for hospitals than for retail shelves.

Manufacturers will need to conduct the FDA's complete submission and labeling process to ensure UDI compliance for each of these product versions, variants, and packaging configurations. Think of stents in many lengths and diameters, new lines of stents made from new materials, and packaging variations for an electronic defibrillator's varying cord lengths. An accurate UDI submission will be required for every single one of them.

Repeat: Every. Single. One.

Then, as manufacturers continually refine their product designs (while also developing and introducing entirely new products), they'll have to repeat the UDI submission cycle again and again and again…and again. If not quite ad infinitum, almost.

Few Clear Paths to Compliance

Something else to keep in mind is that, in time, the FDA could adapt or add to their current UDI rule. Also, as global agencies unveil UDI-like regulations of their own, they may require different—and continuously evolving—data components for compliant submissions. This means medical device manufacturers must take care to approach compliance with an eye to the future.

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>
> "The manufacturer must ask: **'Do we really want to be in the business of building and maintaining a UDI regulatory compliance system ourselves?'"**

Put it all together, and the enormity of the UDI challenge becomes clear. Manufacturers have little choice but to implement a comprehensive compliance solution that is not just fully tested and proven, but also flexible and scalable to handle their increasingly complex product data management needs both at home and around the globe.

What's even more difficult? They have precious little time to accomplish this.

Many manufacturers are acting quickly to implement solutions for the most complex UDI requirements. Some are attempting to develop compliance solutions internally. But this, as even the most IT-intensive manufacturers are finding, is fraught with hazards.

Ultimately, manufacturers must face the vexing realization that there are very few clear paths that will put them in position for full UDI compliance on September 24, 2014.

A Solution Ready to Roll

In 2011, when the UDI regulation was initially conceived, PTC began partnering with the FDA and leading medical device manufacturers to specify and develop software to support UDI compliance. The solution's aim: to fulfill the FDA's new regulatory requirements while reducing the complexity of complying with such a far-reaching rule.

The PTC UDI solution is the first preconfigured, out-of-the-box enterprise software solution to help medical device manufacturers meet the end-to-end needs of UDI submissions as quickly and effectively as possible. The solution is fully validated in accordance with 21 CFR Part 11 requirements and includes a fully documented. It also ensures scalability to meet future FDA or worldwide requirements for Unique Device Identification.

The PTC UDI solution is backed by a world-class support organization with decades of experience in helping major manufacturers transform their business processes.

The medical device manufacturer must now ask: "Do we really want to be in the business of building and maintaining a UDI regulatory compliance system ourselves? Why not rely instead on a tested and proven compliance solution from an industry specialist?"

Why not indeed? **To learn more, visit** PTC.com/go/udi-solution.

Why UDI?

At the end of the day, the FDA's main purpose with the new Unique Device Identification rule is to improve patient safety. To get there, UDI specifically aims to:

- Allow more accurate reporting, reviewing, and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly
- Reduce medical errors by enabling healthcare professionals and others to rapidly and precisely identify a device and obtain important information about it
- Enhance analysis with a clear, standard way to document devices' use in electronic health records, clinical information systems, claims databases, and registries
- Provide a standardized product identifier to allow manufacturers, distributors, and healthcare facilities to more effectively manage medical device recalls
- Provide a foundation for the global distribution chain to help address device counterfeiting and diversion and prepare for medical emergencies.
- Lead to the development of a medical device ID system recognized worldwide.

Get the details at www.fda.gov/udi.

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