UDI: COMMANDING THE COMPLEXITIES

The good news for medical device manufacturers: UDI is nearly here. Thanks to the FDA rule, problems stemming from product misidentification in the marketplace should soon decline. The bad news: UDI is nearly here. Complying manually will drain company resources – and can in-house IT or outside consultants keep up with evolving UDI needs? No need to panic, though: An expert-built, out-of-the-box solution is ready to roll.

So much to do...in so little time

By now the UDI reality for medical device manufacturers should be firmly setting in.

The U.S. Food and Drug Administration will soon require Unique Device Identification of all classes of medical devices distributed within the 50 states. The FDA's first UDI compliance deadline – for high-risk Class III devices – hits September 24, 2014.

See the previous article in this two-part series – "Complexities of Compliance" – for details on device categories, compliance deadlines, and the costs of non-compliance.

Medical device manufacturers have no choice but to put in place a complete UDI compliance solution in time. This is true whether they produce something as complicated as a pacemaker or a pulse generator... as variable in specifications as a contact lens or an orthodontic wire... or as simple in design as a tongue depressor or a sample collection bottle. The right compliance solution will enable the manufacturer to:

- **Gather, submit, and track UDI data**. The manufacturer must collect and properly format data for submissions. They must monitor FDA responses and quickly resubmit corrected data, when needed. Accurate data must be stored for recalls and audits.
- **Govern the UDI submission process.** A compliance solution using software must support 21 CFR Part 11 requirements for secure electronic records, technology validation, and fully documented training. Reporting will help to track compliance status. The software should also be scalable to meet emerging global UDI needs.
- **Manage and synchronize UDI changes.** All UDI submissions must be current with product line updates. Change and configuration management capabilities are critical.

That's the UDI challenge in brief; more on specific requirements and best practices follows below. But as manufacturers should already see, the UDI rule presents them with a tall order – not one that's easy to fulfill with the resources immediately at hand.

Regulatory requirements for UDI compliance

There may be many ways for medical device manufacturers to proverbially skin the UDI cat. But certain requirements must always be met. For complete compliance with UDI regulations, any approach used by the manufacturer will need to properly:

- **Gather, format, and transmit the 62 requested pieces of information for every submission to the FDA's Global Unique Device Identifier Database (GUDID).** That's a big task by itself. Now keep in mind that it must be repeated for every new product, including all versions and variants. A change to a product's color, material, dimensions, or packaging will necessitate a new UDI submission. So will changes to many of the other product specifications requested. Consider that the typical medical device manufacturer has from 50 to 200 variations of each product in their line. The sheer task of gathering, creating, and transmitting UDI submissions for all of these products and their variations grows exponentially.
- **Receive FDA responses – and respond quickly to rejections.** As UDI submissions are delivered electronically, a "successful" response from the FDA must be received at three key gateways. If an unsuccessful response comes from any one of the gateways, it will demand immediate action. The FDA requires the device manufacturer to correct an imperfect submission within seven days.
- **Comply with 21 CFR Part 11 standards for data management and software validation.** Any software used to meet the FDA's quality and compliance standards must be validated to ensure that its development process has delivered all of the capabilities required by the agency. Software validation is a complex process involving documentation of design inputs, use cases, and test cases. As software development proceeds, test cases must be run repeatedly at key milestones. This is required to further document how the software has fulfilled the FDA's requirements.

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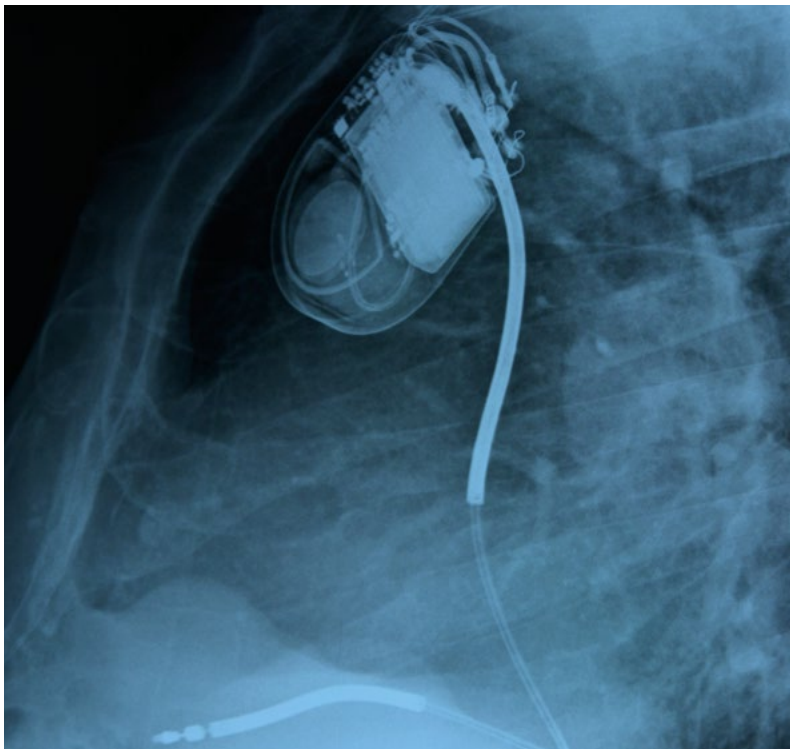

- **Develop and deliver a fully documented training program.** Training, as required by 21 CFR Part 11, must cover UDI compliance processes and technologies. It must be fully executed before the software is actually used to make UDI submissions. This adds time and complexity to the compliance challenge.
- **Plan for possible FDA audits.** In another 21 CFR Part 11 requirement, the manufacturer must document and store UDI submission data in a human-readable format that can be easily reviewed for FDA audits. Physical paper trails showing all submissions, resubmissions, and approvals must be easily accessible for three or more years after the device goes off the market. This helps protect the manufacturer when challenged on compliance.

Requirements beyond the regulation

The regulatory requirements are only part of the UDI story for your organization. They tell what's absolutely needed, at a minimum, for any solution to meet the FDA's requirements. But to ensure that the approach and solution you choose can meet internal operational excellence standards, there are additional considerations:

- **Executive Reporting.** The software should allow reporting on UDI compliance across the product line. This is to help ensure that compliance is on track, enterprise-wide, with management's goals to meet all UDI deadlines. Reporting metrics should be available to multiple stakeholders throughout the organization – upper management, in particular – for tracking compliance progress from end to end. Reporting will help the company reduce the risk of falling out of compliance – and suffering the severe consequences.
- **Global Adaptability.** The FDA's UDI rule will continue to evolve. As it changes, any compliance approach used by a manufacturer – including the associated validation and training processes – must be updated to maintain compliance. Plus, as more countries bring their own flavors of UDI to bear upon the marketplace (at least 12 are now considering it), the software must be flexible enough to accommodate these additional submission requirements in robust, yet efficient ways. Otherwise, the whole process of managing and submitting product data will need to begin again each time a new regulation comes online.

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> "Continuing compliance will require a practical solution **that's fully capable of meeting current UDI regulations, and fully scalable for the future."**

- **Future Flexibility.** Through all of this ongoing effort to comply with UDI regulations, manufacturers' product lines are sure to expand – significantly, in most cases. Success will bring not just new products, but also new worldwide markets, many wanting adapted products to meet regional needs. The most successful manufacturers may also acquire other medical device makers, adding entirely new lines to their product mix. New products – products that are continually developing and improving, and custom products for new markets – all will add continually to the complexity of UDI compliance.

The only real certainty in all of this is change. Continual compliance will require a practical solution that's fully capable of meeting all current UDI regulations, and fully scalable to support the many more global regulations anticipated for the future.

Why in-house and outsourced solutions may fall short

Yes, the medical device manufacturer can try to comply manually with the UDI rule. They can collect data, key in submissions, track responses, and handle changes one by one by one. But this will be prone to errors and schedule slips. And it will seriously sap the company's people, time, and budgets. So, for even the largest manufacturers, a manual approach to UDI compliance will likely be an impractical drain on resources.

How about developing an automated UDI compliance solution internally? Conceivably this is an option. But as manufacturers who have considered it are increasingly coming to conclude: The do-it-yourself approach may bring many more risks than rewards.

The FDA rule's demands are numerous and complicated. Manufacturers must assess their in-house ability to meet them. How many have IT departments with enough expertise in the regulation – and its industry-related standards for technology, training, and validation – to successfully handle the many fine points of UDI-compliant data collection, formatting, submissions, monitoring, corrections, resubmissions, and reporting?

Developing a complete and forward-looking UDI compliance solution may simply be too much to take on internally. It's the rare in-house IT staff – focused as they are on other development priorities and distracted by day-to-day fire-fighting demands – that can truly be prepared to deliver on such a large and growing regulatory compliance challenge.

> "Manufacturers are increasingly coming to conclude: **In-house development of UDI compliance software may bring many more risks than rewards."**

Outsourcing custom software development to consultants may be another option – though certainly costly. And here too the truth remains: The software can't be a one-off project. How many consulting firms are equipped to design, develop, support, and maintain compliance software for a rule as complicated and continually changing as UDI?

A solution out of the box

Medical device manufacturers seeking an alternative to manual submission processes and in-house or outsourced software development approaches can take heart: A pre-configured, out-of-the-box solution for UDI compliance is available now for deployment.

PTC, a leader in product lifecycle management solutions, has partnered with the FDA and major medical device manufacturers to develop the first complete UDI compliance system. The software – which began development concurrently with the FDA's UDI announcement in 2011 – is built tightly to the regulation's requirements, yet designed for flexibility to fit a manufacturer's evolving products and processes. Users will also find it scalable to keep pace with new global UDI regulations as they emerge.

Here are some functional highlights of the PTC UDI Solution:

- **All FDA submission requirements for industry-compliant technology, training, and validation are met.** The software enables the manufacturer to automatically collect, organize, and control data from across the organization. The software then automatically generates and transmits UDI submissions – but not before running pre-validation data checks that leverage the FDA's own internal data-checking algorithms.
- **Key submission workflows – including data verification, submission edits, reviews, and approvals – are also automated.** Data templates help manage previously unmanaged regulatory data. They also help efficiently handle high-volume data loads and approvals for product lines with many versions and variants.
- **UDI data can be managed and traced at every stage of the compliance process.** FDA response tracking and reporting is greatly simplified. Dashboard-level reports, accessible enterprise-wide, keep stakeholders abreast of full product-line compliance at the highest level. With each submission, an easily readable PDF is automatically generated to meet the stringent records management and data storage requirements of 21 CFR Part 11. This minimizes the effort required in audits and recalls.

The Basic Why, How, and When of UDI

The FDA's UDI rule aims to dramatically reduce the instances of patient injury and death that result from the misidentification of medical devices in the field due to device renumbering. To continue selling across state lines, medical device manufacturers will need to:

- **Label each product, version, and variant** – as well as the device's packaging and bar code information – with a Unique Device Identification (UDI) number.
- **Register each device's UDI number** and key product attributes for storage and reference in the FDA's Global Unique Device Identifier Database (GUDID).

The FDA will require complete UDI compliance for the most complex, life-sustaining Class III medical devices by September 24, 2014. Compliance deadlines for lower-risk Class II and Class I devices will follow on the same date in subsequent years

Learn more at www.fda.gov/udi.

> How many manufacturers have IT staffs with enough expertise in the **UDI regulation and its industry-related standards to successfully handle the fine points?"**

> A pre-configured solution – the first complete system for UDI compliance – **is available now for implementation within a four-month timeline."**

- **A historical record – or "snapshot" – of the UDI data is automatically stored and change-controlled with every submission.** As a result, the manufacturer can deal more efficiently with future product versions and variants, regional needs, and new and revised regulations.
- **To handle the needs of constantly developing and changing products, dynamic connectivity to upstream source data is maintained.** The software automatically initiates a new or revised submission for every new product, version, variant, and configuration. Change management is easier. So is keeping track of a product's submission history, which is stored side by side with its version history. The manufacturer can leverage a single source of UDI regulatory data, continually updated for accuracy. This will help ensure ongoing compliance as the FDA's ruling changes and new worldwide UDI regulations emerge.

The PTC UDI Solution is built upon PTC's industry-leading, enterprise-class PLM platform, PTC Windchill, for managing business processes and product data efficiently. The software's web-based workflow, automation, and electronic gateway capabilities have been proven in mission-critical applications by thousands of innovation-driven manufacturers.

Rapid compliance to reduce risk

Medical device manufacturers utilizing the PTC UDI Solution can quickly comply with the UDI regulation. Experience to date indicates that the system can be fully implemented, in a phased approach based on business priorities, within a four-month timeline.

Compliance is complicated. The risks are high. Time to prepare is ticking away.

Yet companies don't need to hit the panic button. A total UDI compliance solution is within easy reach. Medical device manufacturers will be wise to weigh this existing offering from PTC against in-house or outsourced alternatives that have yet to be imagined.

More about the PTC UDI Solution can be found at PTC.com/solutions/udi-solution/. If you'd like to speak directly with PTC about the UDI solution, please let us know.

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