WHITE PAPER

UNIQUE DEVICE IDENTIFICATION (UDI)

The Current Landscape and the Benefit of Early Compliance

May 2016

MAETRICS+
Compliance Agility + Global Acumen

WHITE PAPER PRODUCED BY MAETRICS

For more information, please contact:

USA Office: +1 317 706 1493
globalsales@maetrics.com
www.maetrics.com

UK Office: +44 115 921 6200
uksales@maetrics.com
www.maetrics.co.uk

Introduction

The U.S. Food and Drug Administration (FDA) imposed a series of compliance dates for Unique Device Identification (UDI) requirements, a system finalized in 2013 to precisely identify medical devices through distribution and use. The next compliance date arrives on September 24, 2016. Will you be ready?

The UDI Final Rule, published September 24, 2013, has raised, and continues to raise, considerable technical, operational, and administrative challenges in virtually every facet of the medical device and healthcare industries.

Despite the effort required to implement UDI, medical device manufacturers stand to gain significant long-term benefits from early compliance. Business advantages include improved inventory control, potential increased sales, and more time to identify and troubleshoot product issues. UDI also aims to improve medical billing accuracy and reduce fraud, both of which influence manufacturers' bottom line. Noncompliance or delayed compliance may result in fines, lost revenue, and a damaged reputation.

To reap the most benefits from UDI and to ensure that they meet the remaining deadlines, it's imperative that manufacturers begin planning for UDI without delay.

Overview

In late 2006, the American Hospital Association (AHA) and the Association for Healthcare Resource & Materials Management (AHRMM) urged the FDA to develop a mandatory unique device identification system for medical devices.

Although the medical device industry already tracked and identified its products, it did not have a global unified system to track device name, model, and other production information. A single identification system for medical devices, the AHA and its membership group wrote, would increase the quality, safety, and efficiency of hospital care.[1]

Congress agreed. It recognized that a standardized medical device tracking system would allow for more accurate and timely detection of medical device adverse events, facilitate product recalls, and enable "robust post-market surveillance." This surveillance would help medical device manufacturers and end users track product safety and performance—key elements to public health and safety.[2]

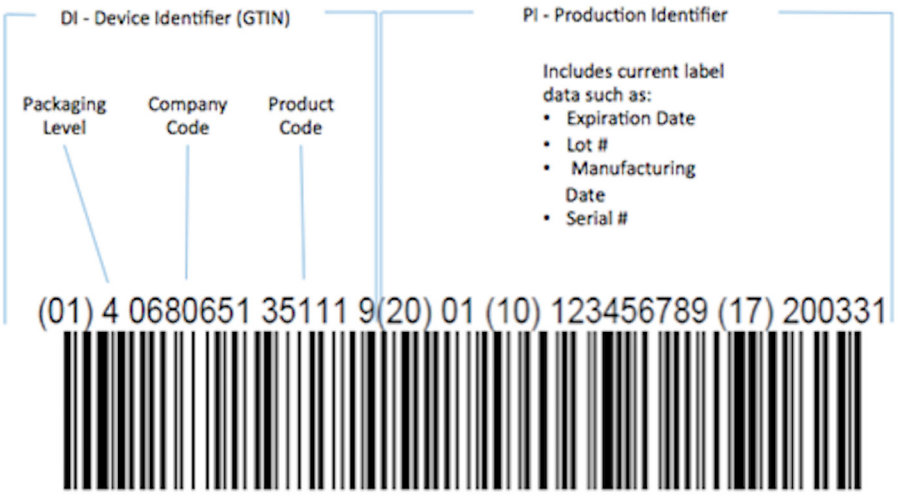
On September 27, 2007, President George W. Bush signed the UDI System into law as part of the FDA Amendments Act of 2007. In 2012, Congress required that the Sentinel Initiative, an insurance claims database used to evaluate the safety of drugs and biologics, expand to include medical devices.[2] In between, stakeholder negotiations and rule changes ensued. The FDA published the Final Rule the following year.

Original Expectations of UDI

The FDA, medical device manufacturers, healthcare providers, and other UDI stakeholders (consumer advocates, industry groups, other governmental agencies, electronic health records vendors, and third-party solutions) all had different views about UDI. The FDA required a globally adaptable solution. The healthcare industry wanted a method to accurately identify products to improve procurement and inventory management, improve patient safety and enhance billing accuracy to reduce fraud. The medical device industry ultimately saw benefits in improved inventory control, both outbound and for returns.

The Federal Perspective

The FDA intended to replace manufacturer-specific barcoding with a global identification system—UDI. The UDI has two components: a device identifier (DI), which is a mandatory, fixed portion of the UDI that identifies the labeler and the version or model of device; and a production identifier (PI), which is a variable portion that identifies lot or batch number, serial number, expiration date, manufacture date, or an identification code required under Section 1271.290(c) (21 CFR 1271.290(c)) for a human cell, tissue, or cellular and tissue-based product regulated as a device.



To assign the UDI codes, the FDA brought in third parties: GS1, a global barcoding organization, the Health Industry Business Communications Council (HIBCC), used in many domestic hospitals, and ICCBBA, for medical products of human origin. The FDA then developed a process through which an applicant would obtain FDA accreditation. It determined the information the applicant must provide for accreditation and the criteria it would apply when evaluating applications.

The FDA developed a seven-year rolling timeline for the UDI system to take effect so that device manufacturers could implement the program in stages. With a phased rollout, which includes five deadlines for Class III, II, and I devices, the FDA intended to lower the financial impact for manufacturers.

The FDA also administers the Global Unique Device Identification Database (GUDID), which it created to collect and house the device identification (DI) attributes in a single system. Medical device manufacturers must submit information to GUDID by specified compliance dates, primarily based on risk class. By developing the database, the FDA intended to make information (with the exception of data protected under FOI or HIPAA) publicly available.

Individuals can search AccessGUDID, currently in beta, for device information. The database currently includes descriptive information such as brand, version or model number, characteristics, and device status, among other fields. The database does not include PI information such as lot number, serial number, or UDIs of devices contained within a kit. GUDID does contain production identifier "flags" to indicate which PI attributes the label includes.

Manufacturers' Interpretation

Although UDI offers many advantages, medical device manufacturers initially held mixed opinions about the FDA's then-new regulation, according to Maetrics President Steve Cottrell. Cottrell is a hands-on leader with deep life sciences experience in regulatory, quality, and compliance.

Not long before the FDA issued the UDI Final Rule, the IRS issued final regulations on a 2 to 3 percent medical excise tax on certain medical device sales, which prompted its fair share of opposition. (President Barack Obama later issued a two-year moratorium on the tax from January 1, 2016, through December 31, 2017.)

Cottrell believes that some device manufacturers objected to the FDA's new level of oversight. Others assumed the FDA launched UDI so that the medical device industry would "catch up" with the pharmaceutical industry's anti-counterfeit and serialization measures. Manufacturers attributed any confusion with the existing system to the fact that there was no consistent coding system shared by wholesalers, distributors, and other organizations downstream.

Most of the disfavor toward UDI, Cottrell notes, stemmed from the major labeling and operational overhaul required to implement UDI. Eastern Research Group, Inc. (ERG), under contract with the FDA, estimated that, in total, domestic labelers (manufacturers, reprocessors, specification developers, repackagers, and relabelers) would incur up to $82.6 million annually over a 10-year period to implement the Final Rule.[3]

Yet, for all of the resistance from manufacturers regarding UDI, the program did have champions and adopters.

One global device manufacturer reported that early adoption of standard labeling, when considered as part of a focus program, saw duplicate items/SKUs reduced by 15 percent. The number of SKUs with a variance between physical count and inventory was reduced by 50 percent, which resulted in dramatically improved inventory accuracy.

Labeling content management firm Kallik reported that a U.S.-based life sciences company—which specializes in medical devices and implants for use in orthopedics, neurosurgery, and spinal, reconstructive, and general surgery—needed to make 10,000 labeling design changes to comply with UDI's September 2014 compliance date.

It used the UDI rule as the impetus to invest in centralized content management and an integrated artwork system. As a result, the company reduced its labeling time from 90 weeks to 10 days—saving millions in costs.[4]

Medical device manufacturers that understand UDI is more than just a regulatory compliance process with deadlines, but rather, an expansive measure toward global regulatory harmonization, with benefits to companies and patients alike, will benefit most from implementing the requirements.

Healthcare Perspective

Many healthcare providers initially argued that implementing UDI would be cost-prohibitive and technically difficult. Once healthcare providers started to see their first UDI labels, evidence surfaced to show that their early suspicions had merit. However, implementation had the potential to offset much of the initial costs.

Mercy Health conducted a demonstration project for the FDA where it implemented prototype UDIs for cardiac stents in its electronic data systems for safety surveillance and research purposes. Mercy Health reported that its inventory tracking system requires serial numbers. Manufacturers use lot numbers, which created confusion. The study also found that device descriptions were not standardized, so Mercy Health had to use multiple device descriptions for each UDI.[5]

Conversely, the study reported that an inventory check at one Mercy Health facility indicated an $800,000 value. After it implemented the UDI system for six months, it found an inventory value of about $1.5 million. This resulted in significant cost savings from curbing excess inventory. [5]

The FDA's phased rollout means that healthcare providers need multiple barcode-reading devices to accommodate both UDI- and non-UDI-labeled products. Products with a UDI that include both HIBCC and GS1 barcodes create additional technical challenges and confusion, as personnel and database programs can't readily determine which barcodes are valid for a particular healthcare system.

To further complicate matters, Madris Tomes, CEO of Device Events, former FDA contractor, and manager for medical device post-market surveillance and UDI projects, reports that healthcare providers received little guidance from electronic health records (EHR) companies on whether those companies would uniformly implement UDI in their product. Healthcare companies could not determine if they would have to make software modifications in-house to incorporate UDI in their EHR applications.

Current State of UDI & Serialization

The FDA required labels and packages of Class III devices and Class III stand-alone software to bear a UDI label by September 24, 2014, with data submitted to GUDID by the same date.

The labels and packages of implantable, life-supporting, and life-sustaining devices and life-supporting or life-sustaining stand-alone software were required to have a UDI label, with data submitted to GUDID, by September 24, 2015.

The next compliance date, September 24, 2016, applies to Class II medical devices and stand-alone software. The remaining compliance dates, September 24, 2018 and 2020, apply to Class I devices and devices not classified as Class I, II, or III.

Convenience kits must bear a UDI, but devices packaged within the container of the kit are exempt from UDI. The FDA defines convenience kits as "two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user." [6]

"The next compliance date, September 24, 2016, applies to Class II medical devices and stand-alone software. The remaining compliance dates, September 24, 2018 and 2020, apply to Class I devices and devices not classified into Class I, II, or III.]"

Convenience kit examples include first aid kits (contain two or more devices, packaged together, not intended to be replaced, repackaged, or sterilized before being used) and an anterior cruciate ligament (ACL) disposable kit (the contents are used for a single procedure, and the remainder of the contents are disposed).[6] Kits that contain both Class I and II devices, such as some orthodontic kits, pose complex labeling challenges, especially when the manufacturer must disclose materials.

UDI requires direct marking on a device if the device is intended to be used more than once and reprocessed before each use. The requirement generally applies to Class I, II, and III devices. Because the device will be separated from the device label and packaging, direct marking helps ensure identification of the device. Implantables do not need to be directly marked with a UDI.[7]

For all devices except "implantable, life-sustaining, and life-supporting" devices, direct marking requirements go into effect two years after the device's direct labeling requirement. [7]

The FDA does not specify a direct marking method, though it does expect the UDI to last throughout a device's life cycle. Manufacturers may decide the safest and most sustainable method to use.[7]

Diagnostic Challenges

Use of UDI labels on diagnostic instrument systems will allow the FDA and in vitro diagnostics (IVD) manufacturers to identify and fix potential problems with devices used for clinical purposes. The challenges come in how to label.

For example, blood diagnostic equipment may include the machine, a blood sample container, and software used to analyze the blood. One manufacturer may register the machine as a complete unit, while another may register the machine, container, and software separately. The FDA has yet to clarify which process is correct.

Existing Inventory and Exemptions

After it published the Final Rule, the FDA clarified that devices manufactured and labeled before their compliance dates are exempt from UDI labeling requirements for three years. However, the data must be filed with GUDID. A device in commercial distribution before its compliance date is exempt from UDI requirements.

A labeler may also request an exemption from UDI labeling requirements if the requirements are "not technically feasible" or if an alternative would provide more accurate identification. The FDA may also exempt devices intended for research and educational purposes, as well as custom and investigational devices.[8] If the FDA determines an alternative label is in the best interest of public health, it may exempt that product from UDI requirements.

Although some manufacturers may see the inventory and labeling exemptions as a way to postpone UDI or bypass the rule altogether, companies should consider the competitive disadvantages. Healthcare companies and hospital systems that have restructured their inventory management to accommodate UDI may stop accepting products without a UDI label because they no longer comply with their systems.

Exempted products also risk noncompliance with health systems' push toward industry-wide collaboration. Healthcare Transformation Group, a collaboration composed of Geisinger Health System, Intermountain Healthcare, Kaiser Permanente, Mayo Clinic, and Mercy Health, has already implemented GS1 standards that identify trade items at all levels of packaging.

Cottrell suggests that it's also possible that the FDA, overwhelmed with requests, will delay its response. If the FDA later denies the exemption request, that labeler will have to act fast to comply with UDI compliance deadlines—and UDI compliance is not a process that companies can rush through.

"The idea of requesting an exemption should not be taken lightly. It should only be considered if you really strongly believe that your product is not covered by the regulation."

-Steve Cottrell

Serialization

High-risk devices that previously required a serial number must retain a serial number with UDI. The healthcare and medical device industries have also strongly stressed the need for more detailed identification of reused devices due to recent high-profile safety concerns.

In response to a series of antibiotic-resistant infections in patients that used contaminated closed-channel duodenoscopes, the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP) recommended, among other measures, that Congress require UDIs in insurance claims. "The widespread inclusion of UDIs in medical data including claims data, electronic health records, and registries, is an absolutely essential piece of any fully functional, high-quality device surveillance system," the report concluded.[9]

Submissions

A device manufacturer's labeler must enter a range of device data for GUDID submission. Required device information includes company name and contact information, device count, model and/or catalog number, device description, commercial distribution status, quantity per package (if applicable), device status (human cell or tissue, kit, or combination product), FDA listing number, and more.

GUDID does not contain serial numbers due to privacy issues under HIPAA. When registering the DI information with GUDID, PI attributes would not yet be known. The FDA requires that manufacturers maintain those PI fields internally.

The FDA is currently not collecting information for some fields required for GUDID submission under the UDI Final Rule. Data such as previous DI, which tracks the ownership lineage of a device, will be collected in the future, however. Therefore, device manufacturers should collect all data required under the UDI Final Rule in the event of a change in GUDID submission fields, an audit, or an investigation.

Device Classes

The FDA classifies medical devices based on patient safety risk. It deems Class I devices, such as elastic bandages, low risk and subjects these devices to less regulatory control. The FDA subjects Class III devices, such as an implantable pacemaker, to the highest level of scrutiny. These devices require premarket approval.

The Centers for Medicare and Medicaid Services (CMS) defines risk based on fraudulent claims, billing of counterfeit products, and related infractions.

If the Senate HELP Committee succeeds in its push to include UDI in claims payment systems, the FDA could potentially change the PI flags contained in GUDID to coincide with claims form requirements, Tomes says. Requiring a UDI with serial number for high-risk devices (as defined by CMS), prior to claims payment, could potentially reduce healthcare fraud and eliminate CMS's current "pay and chase" model of pay first, investigate later.

Healthcare fraud is serious business. In 2012, Donald Berwick, a former CMS administrator, and Andrew Hackbarth of the RAND Corporation, estimated that fraud (and the extra rules and inspections required to fight it) added as much as $98 billion (roughly 10 percent) to annual Medicare and Medicaid spending—and up to $272 billion across the entire health system.[10]

$98 billion

Medicare and Medicaid spending, due to FRAUD, in 2012.

Healthcare fraud perpetrators range from large corporations to individuals to small businesses. In January 2016, the Department of Justice found that the former owner and operator of Long Beach, California-based JC Medical Supply engaged in a $1.5 million Medicare fraud scheme. [11]

The owners and operators, Amalya Cherniavsky and Vladislav Tcherniavsky, paid illegal kickbacks to patient recruiters in exchange for patient referrals. They also paid kickbacks to physicians for fraudulent prescriptions—mainly for expensive, medically unnecessary power wheelchairs. Cherniavsky and Tcherniavsky used these prescriptions to send fraudulent bills to Medicare.[11]

Considering the weight of the issue, any effort to reduce healthcare fraud would benefit the healthcare industry, the medical device industry, and the public at large.

Redactions

As part of a UDI implementation plan, medical device manufacturers should incorporate UDI into procedures for complaints, Medical Device Reporting (MDR), corrections, recalls, and service reports.[8]

MDR regulation informs the FDA that a device poses a potential safety problem. Incorporating UDI allows the FDA to improve its post-market surveillance and recall process.

The MDR initiative links to the public Manufacturer and User Facility Device Experience (MAUDE) MDR database; however, UDI information in that database is either redacted or not included. According to Tomes, the FDA has not disclosed the reason for the omission.

Benefits of Prompt Compliance

If UDI is implemented promptly, medical device manufacturers have the potential to realize long-term benefits from it. When viewed as an opportunity to restructure operations to adopt more thorough tracking and inventory systems, device manufacturers may achieve significant cost savings from improved inventory control and other business measures.

Traceability

An updated platform for tracking, cataloging, and entering information for UDI compliance may yield benefits beyond meeting FDA regulations. Residual benefits may include a reduction in counterfeit products and better management of "trunk" inventory and consignment product as a result of a more efficient tracking process.

Cottrell reports that one major manufacturer implemented GS1-compliant labels over a three-year period—two years before the FDA published the UDI Final Rule. The company documented savings of 15 percent, which covered the IT costs incurred to comply with GUDID. He says that this company's experience closely paralleled pharmaceutical companies that adopted more aggressive track-and-trace systems to comply with planned serialization requirements.

UDI also allows device manufacturers to more closely evaluate product portfolios. With a database of every manufactured device, down to the unit, a business can determine whether it should remove outdated products from its catalog.

As UDI moves through its compliance benchmarks, the potential exists for a system-wide reduction in counterfeit and grey-channel product.

Counterfeiting occurs when non-genuine product enters the supply chain. Grey market occurs when product is sold in a lower-cost market but is re-exported from the low-cost market to a higher-cost market and sold at the higher price. The combination of part-marking and UDI-compliant labels makes it much easier to detect anomalies with products and quantities by location within the supply chain.

> "Take the extra steps to prepare now, because there will only be more devices in the future. You will have tactical advantages if you implement the UDI system correctly from the outset."
>
> *-Madris Tomes*

As U.S. Senators Elizabeth Warren and Charles Grassley note in their March 8, 2016, letter to CMS[2], UDI has the potential to reduce fraud, improve post-market surveillance, and curb waste if implemented in health insurance claim forms. Active medical device post-market surveillance helps track product safety and performance, the senators wrote.

Improved medical device traceability improves patient safety in many ways. In cases that involve contaminated devices, hospitals could track which devices hospital staff used on patients based on UDI information provided in the EHR and/or claim form. Hospitals could more quickly identify and treat affected patients.

Improved tracking of recalls also benefits patient health. A study conducted by the Office of Inspector General (OIG) suggests that recalls of defective products have resulted in millions of claims for monitoring, replacement, and follow-up care.[2]

The OIG cited a case where Medtronic's Sprint Fidelis defibrillator wire was recalled in October 2007 after surgeons implanted 268,000 devices. "For months, Medtronic and the FDA lacked the data to gauge the extent of the danger to recipients; subsequent research studies done by two independent groups estimate that Medicare incurred costs exceeding $1 billion due to this recall alone."

The OIG further identified about $10 million in over-payments to hospitals for device manufacturer credits that hospitals received but did not report to Medicare or for credits available under manufacturer warranties not obtained by hospitals.

UDI would allow for faster and more accurate identification of recalled devices. Hospitals, device manufacturers, and CMS would also receive proper reimbursement.

The Sunshine Act, which requires manufacturers of drugs, medical devices, and biologicals to publicly report certain payments given to physicians and teaching hospitals, as well as Open Payments data, will incorporate UDI once the system is fully implemented.

Complaint Handling

Form FDA 3500A—used for mandatory reporting to FDA of adverse events, product use errors, product quality problems, and therapeutic failures of drugs, biologics, medical devices, and other products—now requires UDI if available.

Medical device manufacturers should also incorporate UDI into procedures for MDR as soon as it is required on device labels. The addition of this information is necessary for transparency and public safety. Device manufacturers should make sure to expand their database so that complaints, corrections or removals, and service records incorporate UDI.

Mergers and Acquisitions

Following the initial announcement of a proposed merger or acquisition, one or both companies must conduct due diligence before committing to the arrangement. UDI can help ensure a more seamless transition.

The complete identification of products, volume manufactured and in use, expired products, and equivalent or identical products becomes simpler and more accurate with UDI. A definitive list of all products manufactured, plus the annual sales of those products, would allow the acquiring company to more accurately evaluate the transaction and perform a comprehensive risk assessment. The incorporation of UDI would allow for greater insight into the number of units in distribution, complaint profiles, frequency of returns, service records, and other data.

Consequences of Noncompliance

Failure to comply with the UDI Final Rule, a federal regulation, poses serious legal consequences, and delayed compliance poses serious business ramifications.

In addition to potential fines, the FDA may prohibit non-compliant manufacturers from selling their products across state lines and from importing devices into the U.S.[12] This sanction would cause the infringing manufacturer to lose sales to competitors and damage its reputation.

In less extreme cases, certain customers may not accept products without UDIs. This would also result in lower market share. In some situations, the manufacturer may have to abandon the product.

Next Steps

Preparing your company for the complex UDI compliance process involves multiple departments and functions and requires considerable time, money, and resources. Thorough planning will help reduce unnecessary expense.

Before making any operational or IT changes, medical device manufacturers should conduct a thorough readiness assessment to determine whether all products are compliant, or will be, by the applicable deadline. Plan gap analysis and data management ahead of time to ensure proper UDI compliance.[12]

The list to the right only scratches the surface of preparation and action steps necessary for UDI compliance. To avoid errors and other pitfalls that might arise during the UDI process, choose a capable project manager and a strong team. That team may include both internal staff and outside consultants. The guidance of a professional experienced in UDI regulations can help a company avoid fines, recalls, rejections, and unnecessary project delays. Understanding the intent of the UDI Final Rule can help device manufacturers understand how UDI decisions made today affect various systems downstream.

Maetrics, a global life sciences consulting firm, has more than 30 years of experience guiding life sciences companies through quality, regulatory, and compliance challenges. Our consultants have in-depth knowledge of UDI requirements and will work with medical device manufacturers through each phase of the UDI compliance process. We also have experience in foreign market compliance, risk management, regulatory applications, and complaints and recalls. Contact us at info@maetrics.com or 1-877-MAETRICS to find out how we can help you develop a comprehensive plan to navigate UDI regulations.

Develop a company-wide UDI strategy that includes the following:

- Assign labelers and individuals responsible for the GUDID account. Determine how to handle submissions across multiple divisions.
- Contact an issuing agency (either GS1 or HIBCC for most companies) to obtain a company prefix.
- Obtain appropriate Dun and Bradstreet (DUNS) numbers or verify that your current information in the D&B database is correct. Know that it may take up to 30 days to obtain a DUNS number.
- Create, transmit, and track GUDID submission data to meet UDI requirements.
- Determine a GUDID submission option, either GUDID Web Interface or HL7 SPL (for large volume) submission.

Conclusion

Although medical device manufacturers face considerable upfront costs to implement UDI requirements, they have the potential to see short- and long-term benefits. Aside from the global data harmonization that the FDA envisioned, medical device manufacturers stand to achieve significant cost savings from improved inventory tracking and management of recalls. The healthcare industry and public at large relatedly benefit from improved billing accuracy and a reduction in adverse events and Medicare fraud.

Medical device manufacturers that launch a comprehensive UDI implementation plan as soon as possible—if not already—stand to reap the greatest rewards. The risk of lost sales and a damaged reputation isn't worth the risk of delayed compliance.

Sources

1. "AHA Calls for Medical Device Identification System." AHA News, American Hospital Association, November 13, 2006.

2. Letter from United States Senators Elizabeth Warren and Charles E. Grassley to Sylvia Matthews Burwell, Secretary, U.S. Department of Health and Human Services; Andy Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services; Robert Califf, MD, MACC, Commissioner, Food and Drug Administration. March 8, 2016.

3. Unique Device Identification System; Final Rule: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis; 78 FR 58817.

4. "Delivering ROI for UDI," Ashley Goldie, Kallik.com. April 14, 2014.

5. "Advancement of innovative methodologies and medical device specific infrastructure for evidence-based regulatory science and public health surveillance: implementation of unique device identification demonstration projects," final report. Drozda, JP, et al. December 2013.

6. Unique Device Identification: Convenience Kits: Draft Guidance for Industry and Food and Drug Association Staff. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research. January 4, 2016.

7. Unique Device Identification: Direct Marking of Devices: Draft Guidance for Industry and Food and Drug Association Staff. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research. June 26, 2015.

8. "FDA's New UDI Rule: What Device Makers Need To Know." Jim Pomager, Med Device Online, October 2, 2013.

9. "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients." The United States Senate Health, Education, Labor, and Pensions Committee, Minority Staff Report, January 13, 2016.

10. "The $272 Billion Swindle: Why thieves love America's health-care system." The Economist, May 31, 2014.

11. "Former Owner and Operator of California Medical Equipment Supply Company Sentenced for Their Roles in $1.5 Million Medicare Fraud Scheme." Press release, Department of Justice, Office of Public Affairs, January 29, 2016.

12. "UDI: What You Need to Know About Timelines, Compliance and Submissions." Yasser Mohammed, MedTech Intelligence. December 3, 2014.

MAETRICS+
Compliance Agility + Global Acumen

USA Office: +1 317 706 1493
globalsales@maetrics.com
www.maetrics.com

UK Office: +44 115 921 6200
uksales@maetrics.com
www.maetrics.co.uk

Co-authored by Maetrics and Madris Tomes, Founder and CEO of Device Events.

Founded in 1984, Maetrics is a global consulting firm dedicated to guiding life sciences companies through the challenges related to quality, regulatory, and compliance. Our comprehensive solutions allow clients to reach new efficiencies and achieve compliance objectives.