For more information, please contact:
media@maetrics.com
1-877-623-8742
Or download the paper at:
http://maetrics.com/whitepaper/unique-device-identification/

June 2016

Are you ready for the fast approaching compliance date for UDI?

Maetrics unveils the current landscape of UDI in the USA and the substantial benefits of early compliance in latest free whitepaper

The next imposed compliance date for Unique Device Identification (UDI) in the USA is 24th September 2016 – it could not be more critical, than it is now, for medical device manufacturers to make sure they are prepared.

Since 2013, the U.S. Food and Drug Administration have been imposing a series of compliance dates for UDI requirements to help precisely identify medical devices through distribution and use. In fact, manufacturers who are on top of launching an all-encompassing UDI implementation plan will garner the best rewards for their business.

The medical device manufacturers who have started to implement UDI into their processes will already be seeing the significant long-term benefits from complying early, such as inventory control, potential increased sales and more time to identify and troubleshoot product issues. Manufacturers must not delay further and ensure they are on target to meet the next big deadline in order to reap the benefits.

If manufactures have not addressed taking extra steps to prepare for UDI, now is the time; there will only be more devices in the future. In order to help manufacturers to stay compliant and make sure they are set up to meet the remaining deadlines, Maetrics, a leading international consulting firm focusing on providing life science companies with deep quality, compliance and regulatory solutions, has published a free whitepaper that is available to download here:
http://maetrics.com/whitepaper/unique-device-identification/

The free must read guide, co-authored by Steve Cottrell, President at Maetrics and Madris Tomes, Founder and CEO of Device Events, focuses on the current landscape of UDI and the benefit of early compliance. The guide looks in particular at:

- A detailed overview of UDI
- The varying expectations of UDI (Federal perspective, manufacturers interpretation and a healthcare perspective)
- Current state of UDI and Serialization including diagnostic challenges, existing inventory and exemptions, submissions, device classes and redactions
- The benefits of prompt compliance
- The consequences of non-compliance
- Next steps for preparing for the complex UDI compliance process

Mr. Cottrell comments: “If UDI is implemented promptly, manufacturers are well positioned to realize long-term benefits from it. UDI needs to be viewed as an opportunity to restructure operations to adopt more thorough tracking and inventory systems.”

Ms. Tomes remarks: “Preparing your company for the complex UDI compliance process, really involves multiple departments and functions and does require a substantial amount of time, money and resources – thorough planning will help you to avoid any unnecessary expense. Manufacturers that launch a comprehensive UDI implementation plan as soon as soon as possible are the ones who will garner the biggest rewards.”

--- end ---

About Maetrics

Maetrics, a global leader in life sciences consulting, develops comprehensive regulatory, quality, and compliance strategies that drive results for our clients. With offices throughout Europe and North America, Maetrics can assist with local, regional, or global compliance needs in the medical device, pharmaceutical, diagnostics, and biotech industries.