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# TOP MAETRICS EXECUTIVE OUTLINES COMMON PITFALLS OF NEW FDA UDI IMPLEMENTATION AND HOW TO AVOID THEM, AT BIOMED BOSTON

(Boston, Massachusetts USA) About six months ago, the United States Food and Drug Administration (FDA) released new rules which require most medical devices distributed in the United States to bear a Unique Device Identification, or a UDI. Debara Reese, Vice President, Quality and Compliance, for global life sciences compliance consulting firm, Maetrics, recently spoke at the BioMed Conference in Boston where she explained, "The most common pitfall I've seen regarding UDI implementation is underestimating the complexity of the project. This is not just a labeling issue; it involves multiple departments and functions, including suppliers and distributors. It requires time, money and resources."

The UDI system is intended to help identify medical devices quickly and efficiently when recalled, improve adverse event reports, and help companies secure their distribution chains, according to the FDA. "Implementation of a UDI system is a costly and challenging endeavor. It is a major change in the industry, but it is the law," said Reese. The three main parts of the UDI implementation process are: 1) to develop UDIs for all devices; 2) to place the UDI on labels in both human-readable and machine-readable format; and 3) to submit this data to the FDA's Global Unique Device Identification Database (GUDID).

Reese went on to describe some of the tactics Maetrics practices, as a consultant to medical device manufacturers, in order to avoid any issues that might surface with the UDI process. She stressed the fact that choosing a project manager and a

strong team is essential for these projects.  It is important to understand that not all requirements apply to all medical devices. After conducting an inventory of impacted hardware, software and processes, one must assess the capability of the systems, develop a project plan, and execute.  Said Reese, "without the help of an experienced expert, a company can risk a warning letter, fines, recalls and other forms of punishment."

Now in its thirtieth year, Maetrics is a leading global consulting firm specializing in compliance strategy and solutions - regulatory and compliance, performance improvement, risk management, organizational change management, and information technology for top-tier pharmaceutical, biotech and medical device companies, and reflecting the highest levels of quality, value and business acumen. Maetrics supports its global client base through worldwide offices, with headquarters in Indianapolis, Indiana, USA:

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