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**UDI Survey Reveals Medical Device Companies Still Scrambling to Meet**

**September 24th Deadline**

**Loftware and USDM Life Sciences Report Lack of Sustainable Labeling Processes For Medical Device Companies to Meet Evolving Regulatory Requirements**

**Portsmouth, NH — August 1, 2016** – [Loftware](http://www.loftware.com), Inc., the global leader in [Enterprise Labeling Solutions](http://www.loftware.com/topics/what-is-enterprise-labeling.cfm), and [USDM Life Sciences](http://www.usdm.com/), a leading global professional services firm for Life Science and Healthcare organizations, today announced availability of a report uncovering the status of [UDI](http://www.loftware.com/industries/unique-device-identification-UDI.cfm) (Unique Device Identification) readiness of [medical device](http://www.loftware.com/industries/medicaldevices.cfmhttp%3A//www.loftware.com/industries/medicaldevices.cfm) manufacturers nationwide. The report shows that only 15% of respondents are currently compliant with the next phase of regulation (labeling regulations are being phased through 2020) and are in need of a sustainable labeling solution, which would allow them to make the necessary adjustments to achieve compliance across their enterprise and be prepared for ensuing phases of the regulation.

The survey, which polled approximately 120 medical device industry professionals responsible for regulatory, IT and labeling, showed that 93% reported that UDI requirements have had a major or at least noticeable impact on their existing labeling processes. Also, only half felt that their current barcode labeling software solution would be able to scale to meet long-term UDI regulations and other evolving international requirements, as well as allow them to expand into new markets. This in part is due to the fact that many companies are not standardized on a single solution, with over 70% reporting that they currently maintain between two and four barcode labeling software solutions.

“With all of the evolving FDA and EU regulatory requirements, it’s important for medical device companies to be able to quickly implement and maintain a validated, compliant and sustainable labeling solution,” stated Josh Roffman, Loftware Vice President of Product Management. “To respond to our customer’s needs, Loftware and USDM have partnered to deliver a Validation Accelerator Pack (VAP), which provides a standardized and streamlined approach for ongoing validation and is designed to address the unique complexities and regulatory requirements of labeling in the medical device space,” he added.

Additional results from the survey showed data collection and output continue to be a struggle as respondents cite getting all of the necessary data on the label (50%) and pulling labeling data from enterprise applications (45%) as their top challenges. Maybe not surprisingly, the next biggest challenge is simply understanding and applying the regulation (36%).

“Many device manufacturers are struggling to meet the FDA UDI compliance timelines – however, the overriding issue to UDI compliance is in developing and implementing a sustainable, extendable UDI program and understanding that UDI is and will be a constantly growing and evolving process. As new products come on to the market and as new needs arise we need to continue to evolve how we identify medical device and document the metadata associated with them,” stated Jay Crowley, USDM Life Sciences Vice President of UDI Services and Solutions. “I can’t stress enough the need to have your approach to UDI compliance be well thought through, well documented, and well implemented - in a way that’s going to provide a path forward that can grow and evolve with your organization as new needs and new opportunities come along,” he added.

UDI labeling regulations are being phased in through 2020 in a concerted effort to provide a comprehensive methodology for medical practitioners, caregivers, and patients to identify and track and monitor the safety and efficacy of medical devices. The September 24 deadline stipulates that labels and packages of Class II medical devices bear UDI barcode labels with correctly formatted dates, and data for Class II devices must be submitted to FDA’s Global Unique Device Identification Database (GUDID). Also, Class II standalone software must include its UDI as required by the mandate. In addition, Class III devices that are intended for reuse must bear a UDI as a permanent marking on the device itself.

To get a copy of the full report or to offer the report to your readers, please go to [Taking the Pulse of UDI Compliance](http://resources.loftware.com/UDI-Label-Compliance-Survey-Report.html?utm_source=Website&utm_sourcedetail=Resources&utm_asset=Report&utm_assetdetail=Survey-Report-UDI) or check out the on-demand [webinar](http://resources.loftware.com/Taking-the-Pulse-UDI-Compliance-Crowley.html?utm_source=Website&utm_sourcedetail=Resources&utm_asset=OnDemand-Webinar&utm_assetdetail=Webinar-USDM-UDI-Results-2016&__hssc=231853056.1.1469820056883&__hstc=231853056.c488c1561ed6dcbe7b1cdef3b499a881.1441817053372.1469815490940.1469820056883.859&__hsfp=1440650216&hsCtaTracking=bac8b0c6-8d4c-4e78-82de-25db9ff7fc6b%7C8eccd769-7c4a-442c-810e-4404d9af5ba0) highlighting the report. Also, to find out more about how [Enterprise Labeling](http://www.loftware.com/topics/what-is-enterprise-labeling.cfm) can help medical device manufacturers meet complex regulatory labeling requirements go to Loftware’s [Medical Device Industry](http://www.loftware.com/industries/medicaldevices.cfm) page.

**About Loftware**

Loftware, Inc. is the global market leader in Enterprise Labeling Solutions with more than 5,000 customers in over 100 countries. Offering the industry’s most comprehensive labeling solution, Loftware’s enterprise software integrates SAP®, Oracle® and other enterprise applications to produce mission-critical barcode labels, documents, and RFID Smart tags across the supply chain. Loftware’s design, native print, and built-in business rules functionality drives topline revenue, increases customer satisfaction, and maximizes supply chain efficiency for customers. With over 30 years of industry leadership, Loftware’s Enterprise Labeling Solutions and best practices enable leading companies to meet their customer-specific and regulatory requirements with unprecedented speed and agility.

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