TAKING THE PULSE OF UDI COMPLIANCE

A SURVEY OF THE MEDICAL DEVICE INDUSTRY

ON COMPLIANCE AND LABELING

LOFTWARE™
ENTERPRISE LABELING SOLUTIONS

USDM
Life Sciences

TAKING THE PULSE OF UDI COMPLIANCE

2016 MEDICAL DEVICE SURVEY REPORT

Loftware, the global leader in Enterprise Labeling Solutions, and **USDM Life Sciences**, the leading global professional services firm focused on increasing the capacity of Life Science and Healthcare organizations to accelerate innovation and maximize productivity, recently polled Medical Device Industry professionals* to see where their companies are with UDI compliance—as well as to gain insight into the labeling solutions they're using to help meet FDA requirements.

As you may know, the U.S. Food and Drug Administration (FDA) created the Unique Device Identification system in 2012 in response to growing calls for the development of a standardized medical device identification system. The UDI system offers a number of benefits to the health care delivery system, including more precise tracking and tracing of medical devices, faster response to product recalls, and overall improved patient outcomes.

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. When fully implemented, most devices will include a Unique Device Identifier (UDI)—which will be both human readable and encoded in a barcode typically. Device labelers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID).

At the time of this survey, medical device manufacturers were gearing up for the next FDA deadline of September 24, 2016, when the labels and packages of Class II devices must bear a UDI with correctly formatted dates on the labels, and data for Class II devices must be submitted to the 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.

WHAT DID WE LEARN?

Based on the results of the survey, we came away with these key conclusions:

Compliance is still deadline driven – Despite adequate lead time, just 15% of respondents indicate that they are already compliant with the next phase of the regulation, and of those who are currently working towards compliance, nearly 40% will be taking it right to the due date of Sept. 24th. For regulations that they've been aware of for three years now, it's surprising that so many companies are cutting it this close with impending deadlines.

**All respondents included in this data were verified as qualified participants of this survey based on title, function, and relevant knowledge of their organization's labeling processes.*

Internal programs are a work in progress – The data suggests that a good number of companies have additional needs before their UDI programs are operating at optimal efficiency. With almost half of respondents indicating that they haven't conducted nor even planned internal audits—and more than half (53%) requiring ongoing support for their UDI processes and regulatory requirements—we can surmise that many companies' programs are far from complete.

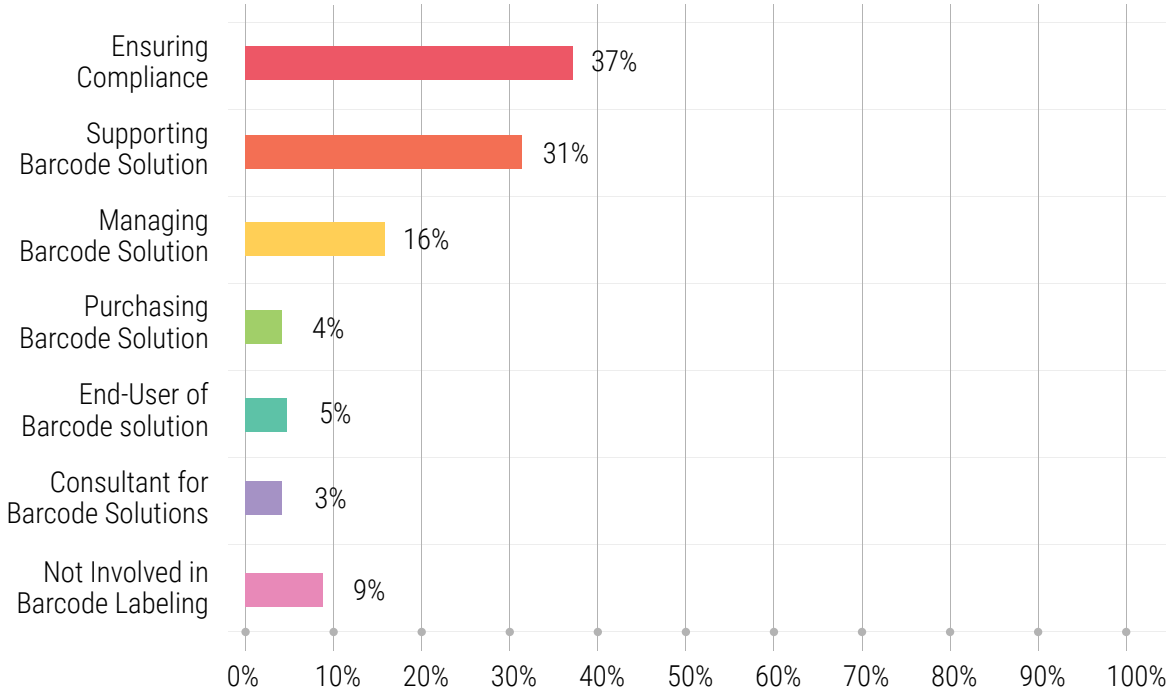
Significant need for more sustainable solutions – Even though a great majority of respondents indicate that they will be compliant by the next deadline, there are still challenges ahead. Nearly half (47%) aren't sure their labeling solution will scale to meet international UDI requirements. And about the same number (45%) struggle with integrating labeling into existing enterprise applications as well as fitting all the data on the device label (50%). Such remaining hurdles point to the need for a scalable, flexible approach to UDI labeling and compliance.

Where do you stand with UDI compliance? We invite you to take a look at the full results of the survey and see how you compare with other professionals in the Medical Device Industry. At the end of the report, you'll learn about a new approach to reduce the time and cost of implementing a validated Enterprise Labeling Solution that will help meet your long-term UDI requirements.

Quickly you can see the breakdown of participants in our survey with the majority either responsible for regulatory compliance of barcode labeling (37%), supporting barcode labeling solutions (31%) or managing barcode labeling solutions (16%).

CHART 1

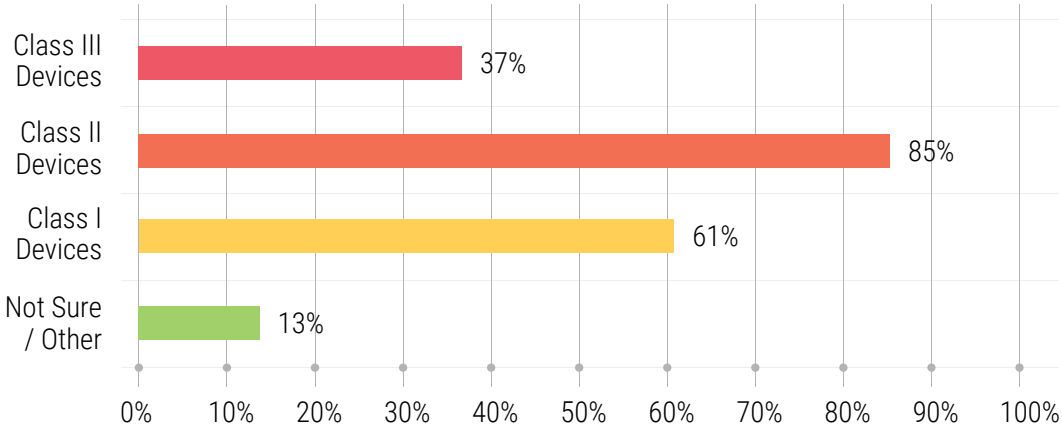
QUESTION: WHAT IS YOUR INVOLVEMENT IN BARCODE LABELING IN YOUR ORGANIZATION?



With respondents' organizations manufacturing or supporting mostly Class II devices (85%)—and these same devices a key focus of the Sept. 24th deadline—we can assume that the majority of survey participants have recently been involved in UDI compliance.

CHART 2

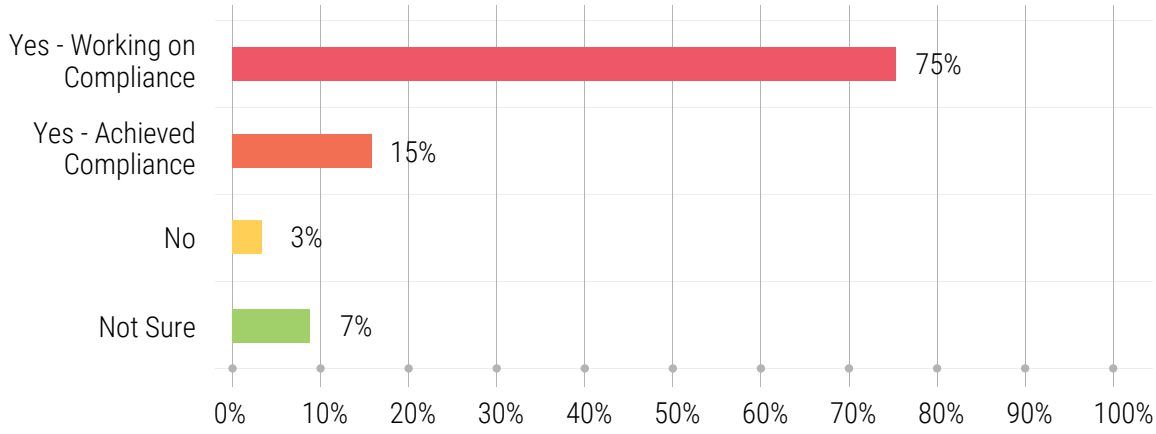
QUESTION: WHICH OF THE FOLLOWING CLASSES OF MEDICAL DEVICES - AS DEFINED BY THE FDA - DOES YOUR ORGANIZATION MANUFACTURE OR SUPPORT? (CHECK ALL THAT APPLY)



The good news here is that the great majority of respondents—90% to be exact—expect to be compliant by the next UDI deadline. Just 3% are willing to admit that they are not working toward, nor have they met, compliance requirements.

CHART 3

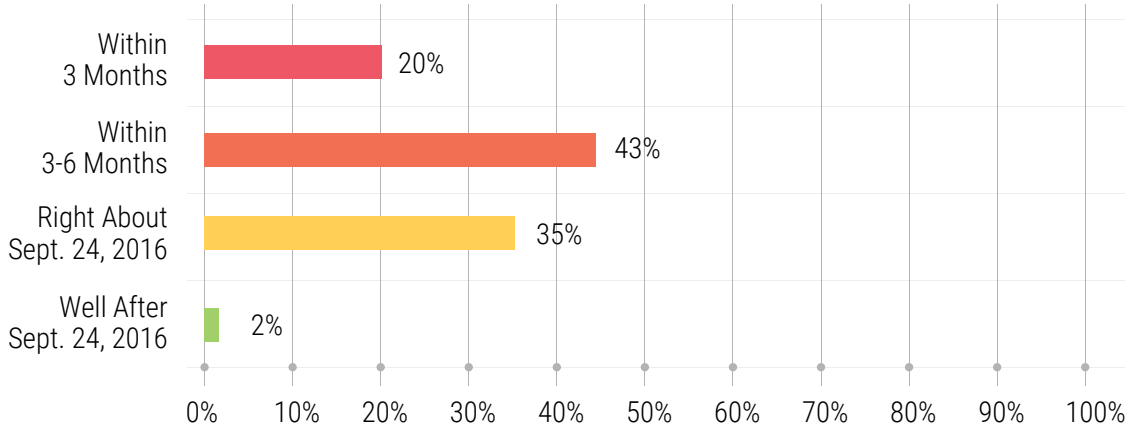
QUESTION: ARE YOU CURRENTLY WORKING TOWARDS OR HAVE YOU ALREADY MET ALL OF THE COMPLIANCE REQUIREMENTS FOR UDI FOR THE CLASS II AND CLASS III DEVICE DEADLINE OF SEPTEMBER 24, 2016?



Of those respondents who are still currently working toward compliance, close to half (43%) expect to meet requirements within 3-6 months, and just behind them at 35% is the group that expects to take it right down to the deadline date of September 24th. Then there's the unfortunate small minority (2%) that won't be ready until well after the due date.

CHART 4

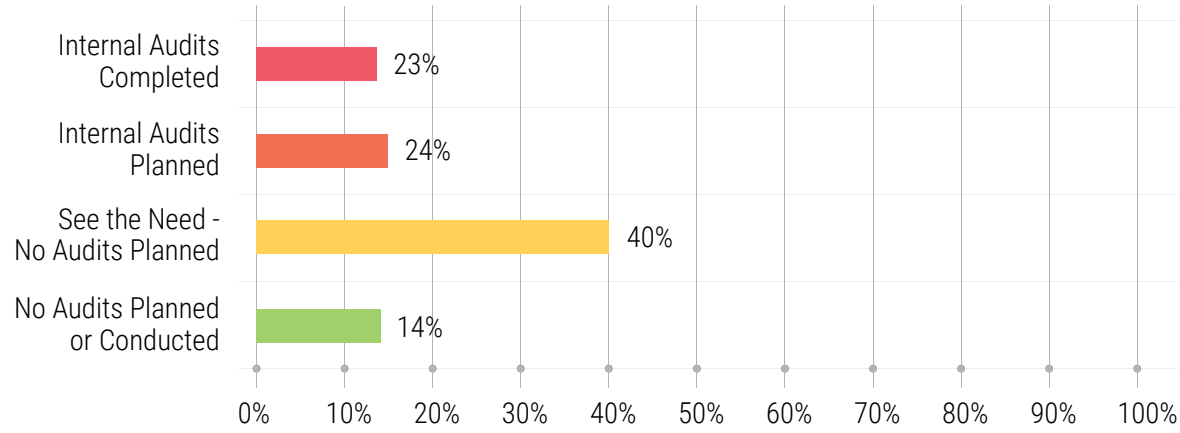
QUESTION: WHEN DO YOU EXPECT TO BE ABLE TO MEET ALL OF THE CLASS II AND III UDI REQUIREMENTS?



Given the importance of UDI compliance industry wide, the results here may be most alarming in that 54% of respondents indicate that audits have not been made nor are they even planned. One could surmise that this is due to the impending deadlines and that more companies will have audit processes in place before the next phase of compliance.

CHART 5

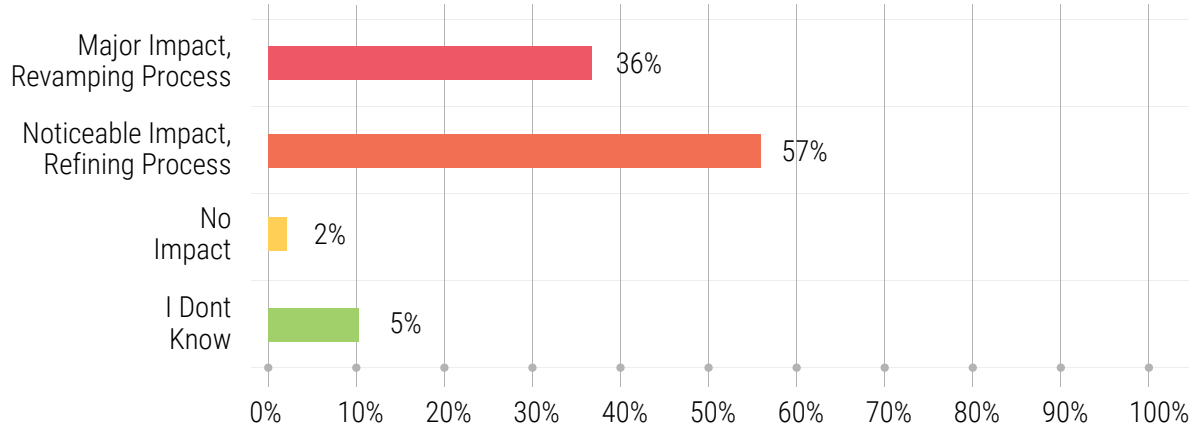
QUESTION: WHAT AUDIT PROCESSES HAVE YOU INSTITUTED ON YOUR UDI PROGRAM?



Respondents readily admit that UDI has had an effect on labeling with a whopping 93% citing a noticeable or major impact to their labeling process. Just 2% say the regulation had no impact at all, which may point to smaller companies or respondents who are not directly involved with labeling.

CHART 6

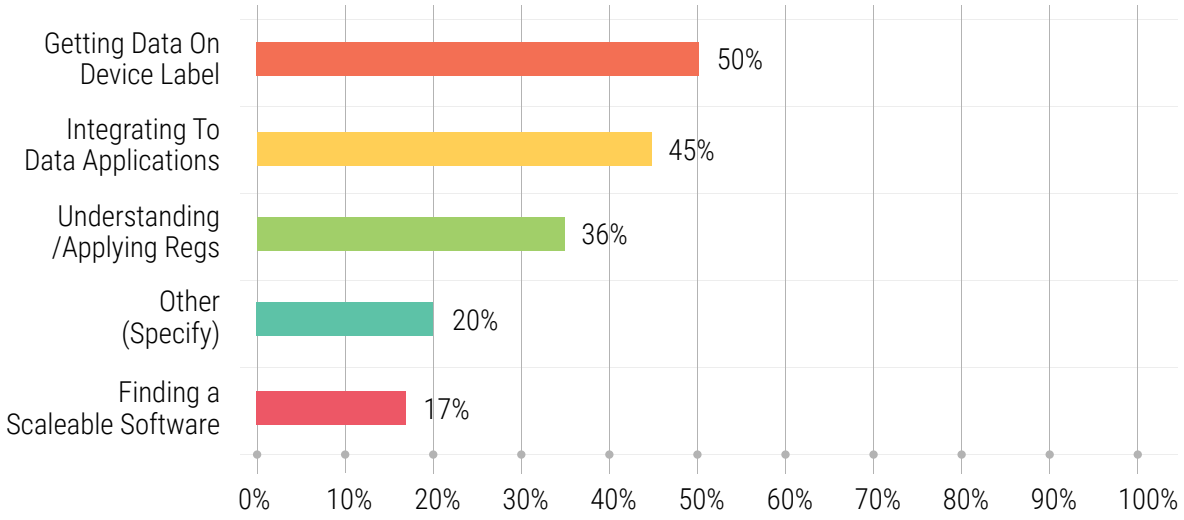
QUESTION: HOW MUCH OF AN IMPACT HAS UDI HAD ON YOUR LABELING?



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%).

CHART 7

QUESTION: WHAT ARE YOUR REMAINING CHALLENGES IN MEETING UDI LABEL REQUIREMENTS? (PLEASE CHECK ALL THAT APPLY)



Scalability appears to be another challenge as nearly half of the respondents (47%) are not sure their solution will adapt to meet international UDI requirements. This should be a priority as companies move forward with global UDI demands.

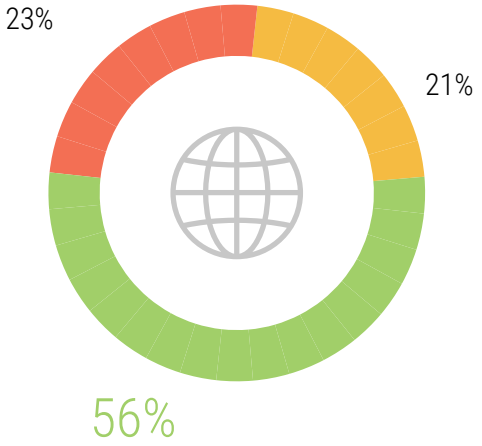
CHART 8

QUESTION: WILL YOUR CURRENT BARCODE LABELING SOFTWARE SOLUTION BE ABLE TO SCALE AND ADAPT TO MEET INTERNATIONAL REQUIREMENTS OR EXPAND INTO NEW MARKETS?

While most respondents (56%) indicated they were standardized on a single barcode labeling solution, that still leaves nearly half (44%) either not standardized or not sure. It's encouraging that companies recognize the need for a standardized solution—but we would expect that number to be higher.

CHART 9

QUESTION: ARE YOU STANDARDIZED ON A SINGLE BARCODE LABELING SOFTWARE SOLUTION TO MEET YOUR UDI REQUIREMENTS?

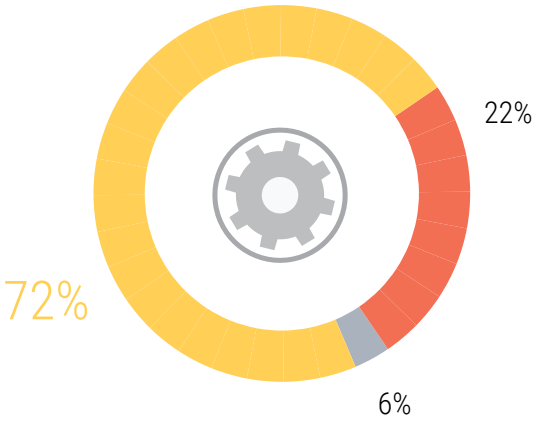


Yes	56%
Not Sure	23%
No	21%

And of those who are not standardized on a single barcode labeling software solution, the great majority (72%) say they have between 2-4 solutions. Not ideal but better than the 22% who have 4 or more labeling solutions.

CHART 10

QUESTION: HOW MANY DIFFERENT BARCODE LABELING SOFTWARE SOLUTIONS IS YOUR ORGANIZATION USING COMPANY-WIDE?

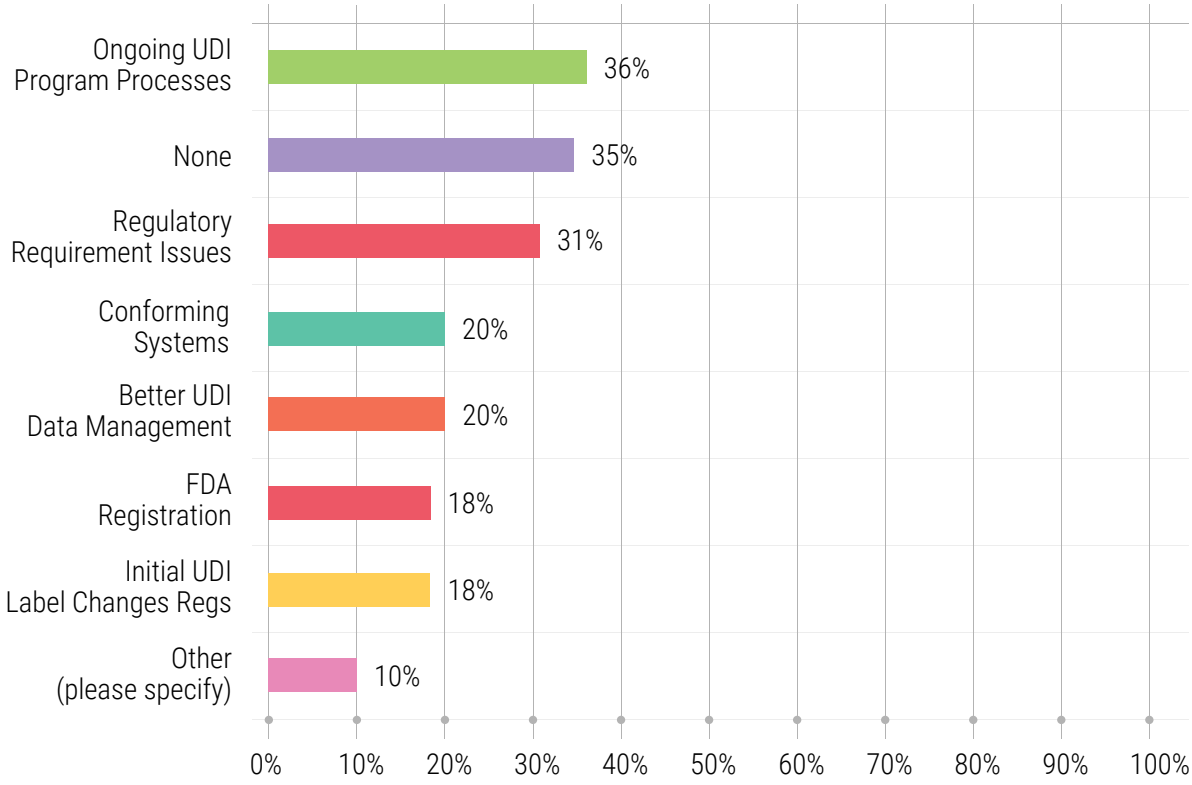


2 to 4	72%
4 or more	22%
Not Sure	6%

In a question that allowed multiple replies, respondents chose “ongoing UDI program processes” (36%) as the area that needed most support besides labeling and printing. Interestingly, “none” (35%) was the second highest response, but the other options did garner enough of a response to indicate that companies will continue to need support across multiple areas of their UDI program.

CHART 11

QUESTION: IN ADDITION TO LABELING AND PRINTING, ARE THERE OTHER AREAS OF SUPPORT NEEDED ON YOUR UDI PROGRAM? (PLEASE CHECK ALL THAT APPLY)



In summary Medical Device companies appear to be taking the necessary steps to meet UDI compliance in time for the September 24, 2016 deadline. However, some results of the survey indicate that there is still work to be done in achieving a sustainable, long-term UDI program with respondents indicating the need for additional technology solutions as well as improvements to their internal processes.

How Medical Device companies meet this next phase of compliance could be dramatically different from where they are in future phases—and probably should be. International standards in particular may require them to evaluate more robust and comprehensive labeling solutions. And the fact that nearly 40% of the respondents either have or may soon be looking for consultative help shows that this is a significant endeavor for many companies; outside regulatory expertise could go a long way to keeping their UDI program on track and implementing a proven, validated labeling solution.

Given the results of this survey and what we've been hearing from customers, it's clear that today's medical device companies continue to be challenged to manage compliance standards and accelerate performance to maintain a competitive edge. The pursuit is ongoing to find new ways to decrease costs, shorten time to market and increase productivity—all while achieving and sustaining compliance with US and international regulatory requirements.

To that end, USDM Life Sciences and Loftware have partnered to develop a Validation Accelerator Pack (VAP) to simplify compliance, increase productivity and minimize costs. The Loftware VAP enables medical device companies to quickly and cost-effectively implement and maintain a validated, compliant labeling solution. In some cases, they have reduced validation time and costs by up to 50%.

Beyond UDI compliance, these same companies require an Enterprise Labeling Solution that's standardized and centralized when necessary, and that taps into the data and business rules of existing enterprise systems. Such a solution enables organizations to become more operationally efficient—saving on costs, avoiding expensive mistakes, and ensuring that even the most remote facility is in compliance with governmental and industry regulations, while also meeting overall internal branding standards.

See how Loftware can provide you a competitive edge to stay UDI compliant while improving the bottom line.
Visit our Medical Device Industry page and keep up with the latest industry news by subscribing to our Blog.